Implications of the Patentability Requirements and Other Policy Considerations to the Pharmaceutical Industry - The Japanese and Philippine Experience

By Ronil Emmavi J. Remoquillo

Supervised by Prof. Yoshitoshi Tanaka
Graduate School, Tokyo Institute of Technology

 Intellectual Property Philippines
WIPO/JPO Long-Term Research Fellowship
April 1 –September 30, 2009

§It should be noted that the views and opinions expressed in this research paper are those of the author and do not necessarily reflect the position of the organization she is affiliated to and the organizers of the research fellowship§
Acknowledgements

First of all, I would like to express my deepest gratitude to the following institutions that made this fellowship program possible:

The World Intellectual Property Organization and the Japan Patent Office (JPO);
The Intellectual Property Office of the Philippines (IP Philippines);
The Asia Pacific Industrial Property Center (APIC) of the Japan Institute of Invention and Innovation (JIII); and
The Graduate School of Tokyo Institute of Technology (TIT)

I would also like to acknowledge the support of the following:

Mr. Adrian S. Cristobal, Director General, IP Philippines;
Mr. Koichi Minami, Deputy Commissioner, JPO; and
Mr. Shin-ichiro Suzuki, Director General, APIC-JIII;

My deepest and sincerest thank you for the guidance and assistance to the following Officials in Japan:

My research adviser-
Prof. Yoshitoshi Tanaka, Associate Professor, Department of Management of Technology, The Graduate School of Tokyo Institute of Technology

The JPO Officials-
Mr. Masashi Nemoto, Deputy Director, Developing Country Cooperation Section, International Affairs Division;
Ms. Mari Mori, Administrative Official of METI, Developing Country Cooperation Section, International Affairs Division

The APIC officials and staff-
Mr. Masakazu Yokoyama, Manager, International Training Team, Asia-Pacific Training Group, APIC
Ms. Yukiko Koyanagi, International Training Team, Asia-Pacific Training Group, APIC
And
Mr. Toshiyasu Matsutani, formerly from APIC-JIII;

The IP Practitioners from the Industry and Agencies-
Mr. Yoshifumi Saeki, Senior Vice President, SHIGA International Patent Office
Mr. Toru Watanabe, Associate Manager, IP Department, Daiichi Sankyo Co., Ltd.
Mr. Mitsuo Fujii, Director, Intellectual Property, Astellas Pharma Inc.
Mr. Shozo Nagai, Director, Intellectual Property, Japan Pharmaceutical Manufacturers Association
I would also like to extend my deepest gratitude to the people in the Philippines whose support went beyond country border and time zone:

The IP Philippines Officials and Industry representatives-
**Mr. Epifanio M. Evasco**, Director, Bureau of Patents  
**Ms. Leny B. Raz**, Director, Bureau of Trademarks  
**Ms. Marilou B. Encarnacion**, Division Chief, Organic Chemistry Division, Bureau of Patents  
**Mr. Jose Maria Ochave**, Vice-President Business Development, United Laboratories, Inc.  
**Mr. Noel Laman**, Senior Partner, Castillo Laman Tan Pantaleon & San Jose Law Offices  
And my fellow **Patent Examiners**;

And my sincerest thank you to my fellow researchers-

**Mr. Babu Nediyamparambathu**, Senior Examiner of Trademarks, Govt. of India, Ministry of Commerce & Industry, Trademarks Registry and  
**Mr. Juldin Bahriansyah**, Directorate General of Intellectual Property, Department of Justice and Human Rights, Indonesia

for the support and encouragement, for sharing their culture and knowledge, and for being not just colleagues but my “big brothers” here.

Lastly, I would like to give my heartfelt thanks and love to my *family and friends* back home for the understanding, encouragement, support and love that they extended overseas.

~ o0o ~
ABSTRACT

Modern medicine is substantially dependent on the pharmaceutical manufacturing industry. While the mass production of effective medications provides a tremendous benefit to the human community, in developing societies, access to even basic medications by large segments of the population is severely limited, primarily because of cost. Intellectual property (IP) rights are an essential part of modern industry; within the pharmaceutical industry, they are absolutely essential to ensure that long-term investment of time, money, and other resources can be recouped by the entities whose research and development efforts are necessary to bring new beneficial drugs to the market. On the other hand, excessively restrictive patent protection may preclude pricing that is affordable to many within developing societies by promoting long-term monopolies on commercial rights associated with proprietary pharmaceutical products. Several nations have already dealt with this dilemma with mixed results. Japan in particular, provides a potential model for continued evolution of patent law in the Philippines, but optimal results depend on the degree to which Philippine authorities can differentiate beneficial aspects of the modern Japanese approach from detrimental elements that may undermine the overall objective. By combining certain aspects and principles of patent law already in effect abroad, the Philippine government has implemented specific legislative changes designed to best balance the competing concerns of increasing the availability of beneficial drugs in the community, lowering their price to make them more affordable, without inappropriately restricting exclusive proprietary rights of companies responsible for their development by jeopardizing the substantial investment necessary to continue developing modern pharmaceutical products.
# Table of Contents

## Chapter 1
**Introduction**
- 1.1 Statement of the Problem
- 1.2 Objectives
- 1.3 Theoretical Background
- 1.4 Significance of the Study
- 1.5 Scope and Limitations
- 1.6 Methodology
- 1.7 Review of Related Literature
- 1.8 Definition of Terms

## Chapter 2
**Background**
- 2.1 Pharmaceutical Industry
  - 2.1.1 The Global Pharmaceutical Industry
  - 2.1.2 The Japanese Pharmaceutical Industry
  - 2.1.3 The Philippine Pharmaceutical Industry
- 2.2 Patent System
  - 2.2.1 Japan Patent System
  - 2.2.2 Philippine Patent System

## Chapter 3
**Patent System and Pharmaceutical Industry**
- 3.1 Role and Importance of Patent System to the Pharmaceutical Industry
  - 3.1.1 Patent as Product Protection
  - 3.1.2 Patent for Research and Development
  - 3.1.3 Patent for Profits
  - 3.1.4 Patents and Generics
- 3.2 Amendments of IP Code in the Philippines
  - 3.2.1 Patentability and Patent Scope
  - 3.2.2 Bolar Provision
  - 3.2.3 Parallel Importation
  - 3.2.4 Compulsory Licensing
- 3.3 Role of Japan Patent System to its Competitive Pharmaceutical Industry

## Chapter 4
**Impacts of the Revised Patent Rules to the Pharmaceutical Industry**
- 4.1 Research and Development
- 4.2 Business
  - 4.2.1 Entry of Generic Drugs
  - 4.2.2 Foreign Investment
  - 4.2.3 Multinationals
- 4.3 Patenting Activity
- 4.4 Society and Healthcare System
Chapter 5  Conclusion and Recommendation ............................. 41

References .................................................................................. 44
CHAPTER I

1. Introduction

Intellectual property rights revolve around the concept of ownership to one’s work from designs to inventions in which no one can copy, sell or use your work without the holder’s permission. From designers to inventors, intellectual property rights is an issue and in a bigger scope big companies and even industries need the protection of IP rights to safeguard their interests.

Patent is one major branch of intellectual property rights used to protect a scientist’s invention. This is generally defined as a set of exclusive rights granted by a state or national government to an inventor or his/her assignee for a limited period of time in exchange for a public disclosure of an invention. The invention must be novel (meaning that it has not been previously disclosed anywhere in the world) and because it cannot be obvious to one ordinarily skilled in the art, the grant of the property right cannot interfere with the public’s access to what already exists.

There are generally five important substantive requirements that should be complied with for a patent to be granted to an invention: patentable subject matter, novelty, inventive step, industrial applicability and description of the Invention. Collectively, these requirements are known as the patentability requirements.

Patentability requirements are defined and applied differently in the IP system of each country. And this is a crucial determinant of the pool of knowledge that is taken out of the public domain.

---

One of the industries that rely heavily on patent and its laws are the pharmaceutical industry. After all, the procedures and activities of this industry are not only limited to promoting, distributing and selling drugs and medicines but researching, creating and developing drugs. Many pharmaceutical companies label themselves as “research-based” companies wherein they have their own research and development division to create and discover breakthrough products. With all the hard work and large amount of investment to create and develop a certain product, it is not surprising why these pharmaceutical companies rely on patent laws and patents per se.

With branded drugs and medicines that took some time and money to create and develop, these are more expensive compared to generic drugs. Many sectors specifically governments accuse these companies of placing high prices on their medicines; this has been a long-term struggle in the Philippines wherein majority of its citizens are not capable of buying medicines. Hence, the latest move of the Philippine government to cut the prices of medicines is to create the “Universally Accessible Cheaper and Quality Medicines Act of 2008” and in effect amendments were made to its Intellectual Property Code.

With these amendments, the pharmaceutical industry is reacting negatively specifically from the multinational companies. The pharmaceutical companies have many patents for their different drugs and with these amendments; their patented drugs and their whole business are at stake.

Hence, this study will identify and discuss the amendments to the Intellectual Code of the Philippines. Likewise, it will dig into the effects and further impacts of these amendments to the pharmaceutical industry in the Philippines.
1.1 Statement of the Problem

This study will look into the effects of patentability requirements and other policies in the pharmaceutical industry specifically the amended Intellectual Property Code to the pharmaceutical industry in the Philippines.

1.2 Objectives

1. To discuss the patent system and the pharmaceutical industry in the Philippines.
2. To show the role and importance of the patent system to the pharmaceutical company.
3. To identify and discuss the effects of the amendments in the Intellectual Property (IP) Code to the pharmaceutical industry in the Philippines.
4. To show how the Japanese patent system can be used as a model to help the local pharmaceutical industry in the Philippines.

1.3 Theoretical Background

The patent system acts as a safety-net for many pharmaceutical companies and the whole industry as well. With patents awarded to their drugs, they can have longer time to market and distribute them thus making profit and earning from their investment. With a strong patent system, a pharmaceutical company will feel assured to devote big amount of capital in research and development. But in the current state of Philippine pharmaceutical industry, there is a drift with regards to its patent system.

The best example for this is the Japanese pharmaceutical industry; in her report entitled “Japan Second Medical Use for Developed Countries”, Viviane Kunisawa said that “Japan is an example that the introduction of an effective patent protection leads to increased R&D activities and thus, economic growth becoming one of the largest trading economy in the world”. 
John Gibson et al (1980) in their report entitled “Patent –Term Extension and the Pharma Industry” reveals that pharmaceutical companies that researches, develops and create their own drugs “consider patent protection as a pre-requisite for innovation” and its big role is “restricting the entry of competitors”. However, patents according to Reiko Aoki, hinders “local firms to manufacture copies of new drugs” which in effect result to less competition in the market and high cost of medicines.

Chapter 2 of the Universally Accessible Cheaper and Quality Medicine Act of 2008 clearly focused on amending the Intellectual Property Code of the Philippines. Though intellectual property rights and patents are enshrined by the World Trade Organization (WTO) particularly with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), member-states can have their own domestic patent laws. The amendment of the IP Code was urged to change the patent rights of many pharmaceutical companies in which the government alleged is the main reason why medicines in the Philippines is expensive and thus inaccessible to the public. The Act is targeting to “strengthen competition” with the amendment of the Intellectual Property Code of the Philippines.

The said amendments received different reactions from different sectors. In his article, “The Mighty Pharmaceutical Industry” Oliveros believes that “necessary first step, there is a need to reconstruct the patent system”. But on the other hand the Pharmaceutical and Healthcare Association of the Philippines (PHAP) emphasizes that “the proposed amendments to the aforementioned laws will not automatically translate to improvements in healthcare in the Philippines”. Multinational companies are anxious of its effects on their business but the said move of the Philippine government can foster more generic drugs and medicine in the markets. While some local pharmaceutical companies feel that it can protect them from “harassment from MNCs”.

1.4 Significance of the Study
This study will greatly contribute to the advancement of knowledge about how patent requirements and other guidelines can affect the pharmaceutical industry. Specifically, this study:

1. Promotes the patent system of Japan as a good model in helping and aiding the pharmaceutical industry.
2. Serves as base-line information on how research and development, healthcare and business are affected by the amendments in the Intellectual Property Code.
3. Proposes strategies for improving access to drugs and promoting domestic or local innovation in the pharmaceutical industry.
4. Encourages a spring board for another study related to the subject matter.

1.5 Scope and Limitation

This study is limited to the effects and likely effects of the amendments of the Intellectual Property Codes as of August 2009 in accordance to the Universally Accessible Quality and Cheaper Medicine Act of 2008 to the pharmaceutical industry in the Philippines. The amendments covered in this study are policies of compulsory licensing, parallel importation and Bolar provision; this study will also include the exemption of 2\textsuperscript{nd} medical uses of known drug as patentable.

There are many sectors that compose the pharmaceutical industry from manufacturers to distributors; for this study, pharmaceutical industry refers to the different pharmaceutical companies in the Philippines both local and foreign.

1.6 Methodology
This study is a desk-based research utilizing written reports and other data from different agencies as well as from literature like books, case studies articles, etc. To confirm and verify some information gathered from written sources, the researcher conducted selected interviews using some guide questions. Individuals and groups that were interviewed for this research include representatives from some pharmaceutical companies in the Philippines and in Japan, patent examiners and patent law experts.

1.7 Review of Related Literature

La Croix and Kawaura (1992) introduce patent rights associated with the pharmaceutical industry in the context of competing interests between the need to ensure affordable medicines in developing countries and the role of intellectual property rights in making pharmaceutical innovation economically viable for private sector research. In Japan, stricter patent legislation was resisted initially but eventually increased the profitability of the domestic pharmaceutical industry. In general, government legislators are reluctant to impose new patent laws that threaten short-term profits in major industry notwithstanding their positive effect in the much longer term.

Oliveros (2009) compares multinational pharmaceutical companies and distributors to oil cartels that arbitrarily dictate the price of their goods. According to The Mighty Pharmaceutical Industry (Oliveros, 2009), the local pharmaceutical industry is monopolized by multinational companies and “the control of multinational companies over the production and sale of medicines is ensured by the patent system.” Meanwhile, Anderson (2006) explains in Working Paper 1052, Global Pharmaceutical Patent Law in Developing Countries: Amending TRIPS to Promote Access for All” that stringent patent protections are absolutely necessary to creating incentives for continued pharmaceutical research in the private sector. The author regards the issue of small domestic companies’ market position as a short-sighted concern because over the longer term, stringent patent protections benefit them as well. Indeed, Aoki and Saiki (2005) draw similar conclusions in Implications of Product Patents: Lessons from Japan
detailing the extent to which legislative changes to Japanese patent law in the 1970s have actually increased the quality and affordability of Japanese pharmaceutical companies over the long term and are at least partially responsible for that nation’s having “caught up” with much larger nations in the pharmaceutical field.

The Business Monitor International (2008) further details the relationship between patent protection legislation and the availability of affordable drugs in the Philippines. According to the *Philippine Pharmaceutical and Healthcare Report Q4 2008*, generic medicines will be promoted by virtue of the IP Code amendments, but it suggests that the weak patent system in the Philippines is a continuing threat to the Philippine pharmaceutical industry. The PHAPS’s position paper (2009) *PHAP Advocacy Position on House Bill No. 2844* includes a special section regarding the proposed amendments to the IP Code. The 2008 PPHP Q4 report strongly implies that the strength of the Philippine pharmaceutical market could be significantly enhanced and the availability of affordable drugs increased, notwithstanding any legislative changes affecting patent protection, by more effective promotion and marketing of existing compounds no longer subject to exclusive patent rights. Dr. Kenneth Hartigan-Go (2008) echoes that view in *Why the RP Pharma Industry is Not Competitive*, in which he explains the reasons that the high price of medicines in the Philippines is not necessarily attributable to competition from multinational pharmaceutical company dominance over the market at the expense of smaller domestic players in the market.

Similarly, Cruz (2008) downplays the role of stringent patent protection in weakening the domestic pharmaceutical company’s position, instead focusing on the detrimental impact of excessively lax approaches including “frivolous” secondary use patents whose actual purpose is to extend expiring patent protections. In *The Patent System and the Quest for Affordable Medicines* (Cruz, 2008), the author explains this concept of “evergreening” expiring protections and suggests the need for IP Code changes to prevent such deliberate circumvention of existing patent law principles that contribute to the comparative weakness of the domestic pharmaceutical industries, particularly in developing nations. With regard to recent legislative changes of this nature, Villanueva
(2009) explains that compulsory licensing was merely one small component of necessary IP Code changes and explains why that particular mechanism is weakened by the delays associated with litigation, often resulting in the fiscal obsolescence of pharmaceutical compounds by the time compulsory licensing can be enforced.

Umbach (2001) introduces the issues arising in connection with inappropriately narrow legislative and judicial focus on claims and embodiments of patent applications, suggesting that the more general and logically relevant focus on equivalence of patentable concepts is the key to effective protection of intellectual property rights in the pharmaceutical industry. Gross (1998) specifically argues that this element of the Japanese patent system (i.e. the excessive focus on claims and specifications largely irrespective of equivalence) undermines some of the usefulness of that nation’s patent regulation. Yumy and Kunisawa (2008) provide a comprehensive analysis arguing that a balanced approach to the competing concerns (i.e. affordable medications vs. exclusive intellectual property rights) is essential to patent legislation, especially in developing countries where the commercial viability of domestic pharmaceutical companies lies on delicate ground, particularly during the short term after the initial imposition of more stringent patent protections.

1.8 Definition of Terms

In this study, the following words are defined operationally:

**Intellectual Property Code** – protects the copyright laws of the Philippines that likewise safeguard trademarks, patents and other creations and inventions that are considered as intellectual properties

**Generics** – another drug version of off-patent products.
**Patent** – absolute rights and ownership to an invention and creation that is recognized by the state within a specific time period.

**Patent system** – method and practice on how patents are given and protected to a specific invention and creation. Patent system differs from one country to the other.

**Patentability requirements** – prerequisites or conditions before a patent is given to any invention and creation that is given application for a patent. These requirements include novelty, inventive step and industrial applicability.

**Pharmaceutical Industry** – companies that promote and later sells drugs and medicines. Bigger pharmaceutical companies also research and develop their own medicine and drugs before introducing them to the market. These companies can be local operating in their home countries or big multinational companies covering different companies and continents.
2. Background

2.1 Pharmaceutical Industry

2.1.1 The Global Pharmaceutical Industry

The use of medicines and drugs was set forth by the need to save lives as well as improve every human being’s wellbeing. Discoveries of medicines like penicillin and insulin lead to the use of medicated drugs and led to the formation of many pharmaceutical companies. At present, many leading pharmaceutical companies can trace back their origins in the 19th century. This industry has become one of the most profitable businesses in the world with billions of revenues and profits reaped by pharmaceutical companies. The pharmaceutical industry is #27 among the fastest growing industries in the world with 4.9% growth in profits in 2008\(^5\).

These companies are not just limited to marketing and selling medicines but developing new substances and later discovering new medicines. Investing billions for research and development, these companies rely on the patent system to safeguard their intentions on how they can utilize their new discoveries and inventions. The role of patent system to the pharmaceutical companies will be further discussed in Chapter III.

The special report of Forbes magazine\(^6\) shows that more than 30 pharmaceutical companies were able to make it to the top 2000 companies across the globe. Out of 30, 6 of them made it to the top 100 spots with profits of more than $8 billions.

Table 1 shows the six pharmaceutical companies that made it to the top100 companies. It also shows that most of the companies are from developed countries like the United States, United Kingdom and Japan.

| Table 1 |

---

\(^6\) Top 2000 Companies (as of 2008)
## Multinational Companies that belong to the Top 100 list of Forbes Magazine’s Top 2000 Companies

<table>
<thead>
<tr>
<th>Company</th>
<th>Rank</th>
<th>Country</th>
<th>Sales ($B)</th>
<th>Profits ($B)</th>
<th>Assets ($B)</th>
<th>Market Value ($B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>57</td>
<td>United States</td>
<td>48.42</td>
<td>8.14</td>
<td>115.27</td>
<td>152.17</td>
</tr>
<tr>
<td>Johnson and Johnson</td>
<td>58</td>
<td>United States</td>
<td>61.10</td>
<td>10.58</td>
<td>80.95</td>
<td>175.51</td>
</tr>
<tr>
<td>Sanofi-Aventis</td>
<td>67</td>
<td>France</td>
<td>40.95</td>
<td>7.68</td>
<td>104.98</td>
<td>101.17</td>
</tr>
<tr>
<td>Novartis</td>
<td>72</td>
<td>Switzerland</td>
<td>40.22</td>
<td>12.62</td>
<td>71.89</td>
<td>111.62</td>
</tr>
<tr>
<td>Roche Holdings</td>
<td>74</td>
<td>Switzerland</td>
<td>40.65</td>
<td>8.60</td>
<td>67.72</td>
<td>169.32</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>79</td>
<td>United Kingdom</td>
<td>45.07</td>
<td>10.35</td>
<td>57.16</td>
<td>120.05</td>
</tr>
</tbody>
</table>

* sales, profits and assets are in billions

### 2.1.2 Japanese Pharmaceutical Industry

Japan is one of the most attractive markets for pharmaceutical companies; in fact according to the Japan Pharmaceutical and Healthcare Report Q3 2008, it is the second largest pharmaceutical market in the world with an estimated value of $76B in 2008. With their good healthcare system along with its effective National Insurance, the Japanese population mainly composed of elderly citizens that have high demand for medicines. Combined with their high demand and accessibility to medicines, Japan is a very a good market for pharmaceuticals local or multinational.

Like other markets, Japan’s pharmaceutical industry is composed of both foreign and local pharmaceutical companies. Leading pharmaceutical companies in Japan are local companies like Takeda, Daiichi Sankyo and Astella Pharma and even made it to the top 2000 companies of Forbes magazine going side by side with other American and European pharmaceutical companies.
Like other countries, multinational companies are also competing with local companies which reach up to 1500 manufacturers. However, majority of these companies are small and medium-sized enterprises. These small local Japanese pharmaceutical companies refrain from merging and acquiring other companies to double profits and strengthen their respective market shares.

In the words of Amy Gross in her report entitled “Reorganizing the Japanese Pharmaceutical Industry”, there are many reasons why Japanese companies are hesitant of merging and acquiring:

“Japanese executives tend not to take risk just to increase profitability because the pressure on executives to increase stock dividends is usually minimal. Second, corporate organizational procedure for discussion making are usually very slow. Lifetime employment is still a fixture of Japanese labor and employment practice. This makes it difficult for a company to reduce its workforce and build up economies.”

Japan’s pharmaceutical industry also deals in research and development which also helped itself to become globally competitive. Japanese companies have laboratories and other research facilities not just in Japan but in other countries as well. With the growth of its pharmaceutical companies, many of them are in fact multinational companies like Takeda which is the leading Japanese pharmaceutical company in Japan.

2.1.3 Philippine Pharmaceutical Industry

Like the rest of the world, Philippine pharmaceutical industry is a lucrative business. As of 2007, the Philippine pharmaceutical industry is valued at P101 billions. The value for this industry might be high but according to the Philippine Pharmaceuticals and Healthcare Report⁷, Philippines is one of the “less attractive markets in the Asia Pacific”.

---

In the case of the Philippines, local companies compete with multinational companies that operate in the country. PHAP Factbook for 2008 reveals that there are 471 pharmaceutical companies in the Philippines and the number continues as new companies specifically the local ones register as legitimate companies. However, it is not a secret that the Philippine pharmaceutical industry is dominated by multinational companies with 80% of the medicines sold in the country coming from multinational companies\(^8\).

Table 2 shows the top 20 pharmaceutical companies\(^9\) in the Philippines with only two local companies namely, United Laboratories and Pascual Laboratories. Local companies are also small companies that are usually managed by families; obviously, local companies cannot at par with the giant multinational pharmaceutical companies.

<table>
<thead>
<tr>
<th></th>
<th>MAT Aug 2006</th>
<th>MAT Aug 2007</th>
<th>Growth</th>
<th>Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL MARKET</td>
<td>92,885,882,166</td>
<td>102,892,062,012</td>
<td>11%</td>
<td>100.00%</td>
</tr>
<tr>
<td>1 UNITED LAB</td>
<td>19,034,201,069</td>
<td>21,340,371,291</td>
<td>12%</td>
<td>20.74%</td>
</tr>
<tr>
<td>2 GLAXO SMITHKLINE</td>
<td>8,543,867,266</td>
<td>8,764,783,647</td>
<td>3%</td>
<td>8.52%</td>
</tr>
<tr>
<td>3 PFIZER INC</td>
<td>6,145,728,812</td>
<td>6,937,710,638</td>
<td>13%</td>
<td>6.74%</td>
</tr>
<tr>
<td>4 WYETH PHILIPPINES</td>
<td>5,836,145,207</td>
<td>6,367,694,864</td>
<td>9%</td>
<td>6.19%</td>
</tr>
<tr>
<td>5 SANOFI-AVENTIS</td>
<td>4,202,109,133</td>
<td>4,458,352,254</td>
<td>6%</td>
<td>4.33%</td>
</tr>
<tr>
<td>6 ASTRAZENECA</td>
<td>4,033,147,280</td>
<td>3,857,958,669</td>
<td>-4%</td>
<td>3.75%</td>
</tr>
<tr>
<td>7 ABBOTT LAB</td>
<td>3,106,255,279</td>
<td>3,781,479,968</td>
<td>22%</td>
<td>3.68%</td>
</tr>
<tr>
<td>8 NOVARTIS</td>
<td>3,351,197,241</td>
<td>3,406,871,792</td>
<td>2%</td>
<td>3.31%</td>
</tr>
<tr>
<td>9 ROCHE PHILIPPINES</td>
<td>2,695,489,288</td>
<td>3,250,050,495</td>
<td>21%</td>
<td>3.16%</td>
</tr>
<tr>
<td>10 JOHNSON</td>
<td>2,936,337,055</td>
<td>3,217,156,084</td>
<td>10%</td>
<td>3.13%</td>
</tr>
<tr>
<td>11 BOE. INGELHEIM</td>
<td>2,764,714,285</td>
<td>2,983,665,652</td>
<td>8%</td>
<td>2.90%</td>
</tr>
<tr>
<td>12 BRISTOL-MYERS SQB</td>
<td>2,940,439,895</td>
<td>2,885,443,947</td>
<td>-2%</td>
<td>2.80%</td>
</tr>
<tr>
<td>13 BAYER PHARM</td>
<td>2,193,442,530</td>
<td>2,333,639,382</td>
<td>6%</td>
<td>2.27%</td>
</tr>
<tr>
<td>14 PASCUAL LABS</td>
<td>1,847,106,515</td>
<td>2,233,335,226</td>
<td>21%</td>
<td>2.17%</td>
</tr>
<tr>
<td>15 SCHERING PLOUGH</td>
<td>1,543,215,799</td>
<td>1,658,449,759</td>
<td>7%</td>
<td>1.61%</td>
</tr>
<tr>
<td>16 MERCK SHARP&amp;DOHME</td>
<td>1,578,695,824</td>
<td>1,613,525,693</td>
<td>2%</td>
<td>1.57%</td>
</tr>
<tr>
<td>17 SERVIER PHILS</td>
<td>1,386,312,437</td>
<td>1,546,608,332</td>
<td>12%</td>
<td>1.50%</td>
</tr>
<tr>
<td>18 NATRAPHARM</td>
<td>1,118,177,168</td>
<td>1,508,954,461</td>
<td>35%</td>
<td>1.47%</td>
</tr>
<tr>
<td>19 MERCK INC</td>
<td>1,139,948,191</td>
<td>1,153,087,258</td>
<td>1%</td>
<td>1.12%</td>
</tr>
<tr>
<td>20 GX INTERNATIONAL</td>
<td>869,120,456</td>
<td>1,058,297,390</td>
<td>22%</td>
<td>1.03%</td>
</tr>
</tbody>
</table>


\(^9\) As of August 2007
Unlike other countries and Asian counterparts like Japan, Philippine pharmaceutical industry lags behind and even considered as “not competitive”\textsuperscript{10}. In his article, “Why the RP Pharma Industry is Not Competitive”, Dr. Kenneth Hartigan-Go cites that “inaccessible and poor-quality drugs” along with poor research and development, insufficient quantity and quality pharmacists, and threats of inappropriate use as indications why the industry is incompetent. Likewise, regulatory problems weakens the industry like “lack of enforcement and poor patent and data protection”\textsuperscript{11}.

2.2 Patent System

As countries embrace globalization and the rise of patents and issues surrounding it; international organizations specifically the United Nations made steps to deal with patent issues between member states. To have a “global” patent system where member states can refer to was prompted when international trade has been vulnerable and inevitable affected.

Globally, patent system is administered by many international organizations between member states as part of international relations. There are three major agencies that have their respective functions in terms of patents- the World Intellectual Property Office (WIPO), the World Trade Organization (WTO) and the respective National Patent Offices of each member states.

The WIPO, a United Nation agency functions as a secretariat for the administration of most of the intellectual property treaties among its 184 member-states while the WTO intervenes in regards to trade rules between nations that deals with patents. Lastly, National Patent Offices of the member states interprets these rules and regulations locally and can have their own patent system where local patent filing are accepted, examined and later granted.

\textsuperscript{10} Kenneth Hartigan-Go, MD. “Why the RP Pharma Industry is Not Competitive”, Medicine, Policy Science Journal 2008.
\textsuperscript{11} PHAP. Philippines Pharmaceuticals and Healthcare Report Q4 2008.
Likewise, many international treaties were made to strengthen and improve the “global” patent system. The most important is the Agreement on Trade Related Aspects of Intellectual Rights or TRIPS that paved the way for the establishment of the WTO in 1994. TRIPs basically offer standardization with regards to patent protection like patent requirements among member states. However, each member state was given the privilege and freedom on how they define those set standards of patentability requirements.

Member countries apply these standards in a strict or flexible way that relatively depends on the country’s level of development as long as they abide by the essential definition of the said requirements as set forth in the agreement.

2.2.1 Japan Patent System

As the second largest pharmaceutical market in the world, with an estimated value of approximately US$76B in 2008\(^\text{12}\), its patent system played a major role in its very competitive pharmaceutical industry. Japanese pharmaceutical industry is made of local and foreign companies as well as foreign-affiliated local companies.

Demand for medicine soared after the Universal Health Insurance took effect in 1961 but its pharmaceutical industry experienced great improvement in the 80s with the introduction of product patent in 1975. It is not a surprise that Japan is one of the strictest countries when it comes to patent laws.

When Japan transitioned into a modern society from its feudal stage during the Meiji Era and continued during the Meiji Restoration in early 19\(^\text{th}\) century, patents are one of the daring changes in its bureaucracy. Using patent laws from countries like France and the United States as its models, Japan formed its Patent Monopoly Act in 1885. From then on, Japanese patent laws also changed and developed; factors that paved the way for these

---

amendments is to have good foreign relations with other members of international organizations in which Japan is also a member.

Japan’s patent laws were changed in accordance to many treaties like the Paris Convention and the TRIPS Agreement. Throughout its history, its patent system was amended in 1921, 1959, 1970 and 1975. In each amendment, changes in patent policies occurred like its “first-to-file” rule from “first-to-invent” rule in 1921 and patent extensions in 1959. As expected, attempts in amending Japan’s patent laws caused intense discussions among different sectors of Japanese government and society as well.

**Japanese Patentability Requirements and Policies**

As a member of the United Nations, Japan adheres to international treaties like the TRIPS Agreement. Hence, Japan has the same patent requirements as those of other countries like novelty and inventive step requirements as well have provisions like compulsory licensing and parallel importation. However, as stated in the TRIPS Agreement; member countries have the choice to apply such provisions. In the case of Japanese patent system, although they have provisions like compulsory licensing and parallel importation, Japan is not executing it.

Parallel importation is practiced in Japan individually as its citizens order and purchase drugs online and “drugs are not distributed through recognized distributor”\(^{13}\). With regards to compulsory licensing, it is acceptable for emergency cases only\(^{14}\). Japan also differs in terms of patent protection for 2\(^{nd}\) medical use or new crystal forms of known compounds. Under Japanese patent law, substance and crystal claim must be in different patent applications unlike the case of the Philippines and India wherein, microorganism, substances and crystal forms can be covered under one patent. Japan also practices the Bolar Provision in which different companies use patents from other companies for R&D purposes.

\(^{13}\) Based on the interview conducted with a representative from the Japan Pharmaceutical Manufacturing Association

\(^{14}\) Ibid.
2.2.2 Philippine Patent System

As a member of the United Nations, the Philippines comply with international treaties like TRIPs and acts in accordance to the rules of international organizations like WTO and UN itself. So when TRIPs was enacted in 1994, the country conformed to such treaty by amending its own patent system at that time.

The Philippine agency that oversees the patent system in the country is the Philippine Patent Office which was established in 1947, a few years after the Second World War ended. With TRIPS, the agency ratified the Republic Act 8293 in 1998, otherwise known as the Intellectual Property Code.

The Patent Office conforms to the basic patent requirement – novelty, inventive step and industrial applicability. Although TRIPS gives standard requirements in terms of granting patents members like the Philippines are free to define and interpret the criteria and other requirements based on national interests. Prior to TRIPS, Philippine patent system already had its own requirements and rules with regards to patents and when TRIPS was enacted the IP Code was amended with some changes in terms of requirements, terms, publications, examination and patentability.

The most recent amendment was in June 6, 2008 in accordance to the Universally Accessible Cheaper and Quality Medicine Act of 2008. This topic will be discussed further in Chapter III.
Chapter III

3. Patent System and the Pharmaceutical Industry

Many industries rely on patents to protect their products in terms of profit and further studies; one of the industries that are greatly connected with patent system is the pharmaceutical industry. Patent is very important for the pharmaceutical industry particularly that of the pharmaceutical companies who develop and promote drugs to the market. Some pharmaceutical companies have their specific Intellectual Property division to foresee any patent changes and the possible impacts on their business. Patent policies and other guidelines that are related to medicines and drugs surely affect pharmaceutical products.

The recent amendments of the Philippine Intellectual Code caused a stir within the pharmaceutical industry and with the execution of the Universally Accessible Cheaper and Quality Medicines Act, the pharmaceutical industry is affected.

Why is this so? How important is patent for the pharmaceutical industry? What are the effects of the recently amendments to the Philippine IP Code to the local pharmaceutical industry? These issues will be discussed in this chapter.

3.1 Role of Importance of Patent System to the Pharmaceutical Industry

Many pharmaceutical companies are not just centered in marketing and distributing drugs and medicines to the market. Many of these companies also have their own research and development division to study substances, processed and other compositions to develop and later create new drugs. With this, research and development takes a lot of investment in terms of cost and time; drugs would take at least 10 years to develop and millions of dollars in investment. Any inventor or creator would do everything to protect their hard work and this case is not different for the pharmaceutical industry.
The pharmaceutical industry is motivated with different reasons to apply for a patent – patents market monopoly period are crucial to recover their research and development costs; patents prevent others from commercially utilizing their invention; patents encourage financial risks and long-term research and patents guarantee the dissemination of information.\(^\text{15}\)

3.1.1 Patent as Product Protection.

Like other forms of patents, patents for the pharmaceutical companies are for their product’s protection and acts as their safety net. If they own the patent for a certain drug or substance, no other than the patent owner has the right to use it for profit-making or further studies without their consent. As a result of a long and expensive research, it is automatically considerable that it is the sole property of the patent owner and no one else.

A pharmaceutical company who owns the patent of a certain drug can feel safe and assured that only them can market and distribute such drug with its corresponding substances to the market. Patent gives the exclusive right to launch the new drug to the market to protect the product 100\(^\text{\%}\).\(^\text{16}\) With this, its product will be free from threats of competition from other pharmaceutical companies; if another company wants to market and distribute such products, such company must ask for a license from the patent owner.

3.1.2 Patent for Research and Development.

Pharmaceutical companies always argue that they need the protection of patents for their research and development. With strong patent protection, pharmaceutical industry can invest in research and development to come up with new drugs to introduce them to the global market.\(^\text{17}\) As stated earlier in this paper, coming up with a new drug involves huge investment and time. It goes to say that these pharmaceutical companies would seek the protection of patent for them to reap profits that can cover the investment they spent to

\(^\text{16}\) Japan Pharmaceutical Manufacturing Association
\(^\text{17}\) Ibid.
come up with new drugs. Without the protection of patents, pharmaceutical companies will not take the risk of investing huge amount and time.

3.1.3 Patents for Profits.

It is undeniable that patents help pharmaceutical companies assure their market share among its competitors. Patents give pharmaceutical exclusive commercialization of a new drug\textsuperscript{18}. Patent owners of drugs have monopoly of the drug in the market, deleting competitors and in the long run utilizing their opportunity to make profits out of their new drug. According to Atty. Jose Maria Ochave, Vice President for Business Development for United Laboratories\textsuperscript{19} “patent owners can set the price”. High prices of branded drugs are one of the attacks and criticism towards pharmaceutical companies.

Aside from covering the cost of investment for R and D, patent protection that can last for up to 20 years can assure that patent owners will also gain profits. For that long patent term, R&D costs will not just be covered but as well generate revenues and profits.

3.1.4 Patents and Generics

The patent system still affects the industry when patents expire. Expiration of patents may be troublesome or difficult for patent owners but in the other side, it is advantageous for companies who manufacture generic medicines; generic companies can only launch their own version after the patent expires. And in Philippine scenario where most local companies don’t have the capability to manufacture their own “branded” medicines and focuses on manufacturing generic medicines, expiration of patents will give them competition.

According to Ma. Elisa P. Osorio in her article, “Local Pharmaceutical Firms Set to Expand”, “as more patents are set to expire, local pharma will grow faster”. As more

\textsuperscript{18} Ibid.
\textsuperscript{19} Unilab is the leading local pharmaceutical company and one of the top pharmaceutical companies in the Philippines.
patents will expire in the coming years, the local pharma industry is expected to experience growth of up to 12%. Osorio added that, “more entry of generics as patent expires and led to competition from local pharma companies.”

### 3.2 Amendments to the IP Code

Since the establishment of the Philippine Patent Office in 1947, Intellectual Property Law was amended many times in 1951, 1965, 1977 and 1998 to cope up with the changing world particularly with that of economy and technology without sacrificing the country’s national interest. With each amendment, changes in patent requirements and guidelines are inevitable from patent term to patent subject.

The Intellectual Property Code or Republic Act 8293 was again amended to give way for the Universally Accessible Quality and Cheaper Medicines Act of 2008 or Republic Act 9502. House Bill 1758 of Congressman Joseph Emilio Abaya seeks to amend the IP Code of the Philippines to make patent laws “more responsive to the Filipino healthcare needs by legitimizing much flexibility under the TRIPS Agreement”\(^\text{20}\). The main goal of this law is to make medicines cheaper and more affordable for the public; “right to health of the people” by providing to them “safe and cheaper medicines”\(^\text{21}\). The Philippine government feels the urgency to amend the IP Code to review the patents owned by pharmaceutical companies in which for the government is the reason why such companies have the luxury to set high prices on certain drugs. Moreover, the government believes that high prices imposed by pharmaceutical companies particularly those of the MNCs is one of the hindrances why Filipinos cannot buy medicines and later have cure for their illnesses and diseases. It is a conclusion that cheaper medicines can improve the national healthcare among Filipinos.

---

\(^\text{20}\) From “Creating a Level Playing Field” as part of the discussion “Improving Accessibility to Cheaper Medicines”\(^\text{2007}\).

\(^\text{21}\) PHAP Advocacy Position on House Bill No.2844
The amendments made in the IP Code of the Philippine have similarities with that of India; Philippine government believes that India is a good model for a country who was able to lower the prices of its medicines by amending its own Intellectual Property Code in 2005. Indian government’s move to amend its own IP Code specifically with regards to patents led to the decrease of its medicines’ prices and entry of its generics to the market.

As expected, not all are seeing the amendments are great news particularly that of the pharmaceutical industries. PHAP believes that “amending the IP code will not automatically improve the healthcare in the Philippines”. Effects on these amendments will be discussed in the next chapter.

Amendments to the IP Code changed some of the patentability requirements as well as patent policies. In general, the following are the major amendments to the IP Code:

- Allow parallel importation of patented medicines from other countries where these are more affordable.

- Prohibit the grant of new patents based only on newly-discovered uses of a known drug substance;

- Allow local generics firms to test, produce and register their generic versions of patented drugs; and

- Allow the government to use patented drugs when the public interest is at stake.

- Allow compulsory license for the importation of patented drugs

These amendments received both praise and criticisms particularly from big pharmaceutical companies. As an unbiased research, let us discuss each amendment fairly.
3.2.1 Patentability and Patent Scope

The standards enumerated under the TRIPS Agreement namely novel, inventive step and industrial applicability are not accurately defined. Such flexibilities were intentional to give way for different member countries to adjust and interpret on their own in regards to national interest. One of the amendments for the Philippine IP Code to make patent scope narrow, that is to exempt 2nd medical use of patented products and process from patent.

Most drugs have 2nd medical uses or have continued research for its salts and crystals. The reason for this according to pharmaceutical companies is for self-life of these medicines and adaptability. With different environments where drugs and medicines are marketed and supplied, some of these drugs have different reactions when distribute in other countries like those humid areas like discoloration. Salts for a specific drug are discovered to affect penetration of such drug to the body system and as a result affects its over-all effectiveness. Discovering and developing these new substances also means big investment and with the large amount of investment for this additional research, companies want to seek patent protection.

However, many sectors of society have different perception about 2nd medical uses, discoveries along with salts and crystals. They believe that companies particularly the MNCs will only use this for their own interest. Granting patents for “second medical use” gives companies a chance to extend their patents and in the long run, monopoly.

Section 22 excludes some discoveries from patent protection:

“Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.”
“For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combination and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regards to efficacy.”

Likewise, let us recall that inventive step is one of the standard requirements for granting patents. With the amendment of the IP Code, Section 26 of R 8293:

“……there is no inventive step if the invention results from the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.”

In simpler terms, narrow patent scope is exempting patent for 2nd medical use or new crystal forms of known compounds and it goes to say that “pharmaceutical companies cannot apply for patents based on newly discovered uses of a known drug”\(^\text{22}\). The idea behind this provision is to stop an prevent the so-called “evergreening”\(^\text{23}\).

The provision of excluding 2nd medical use from patent protection is likeable among countries who want to promote their generic companies like India but for developed country, like Japan; patent protection for 2nd medical use is very important. As expressed by the Japan Pharmaceutical Manufacturing Association, “it takes almost the same investment as that of developing he 2nd drug to discover the 2nd medical use..hence, patent protection is still important”.

\(^\text{22}\) Ibid.
\(^\text{23}\) Evergreening happens when a company owns multiple patents which only pertains to one product. This is caused by granting patents to certain process, substance, etc for a single product.
3.2.2 Bolar Provision.

Before the implementation of Bolar Provision, generic companies have to wait for the patent to expire before they can conduct some tests and experiments on the drug that they want to manufacture a generic version. After the patent expires, only then can these generic companies can develop their generic drug and later launch it to the market. In effect, patents are actually extended since it would take 3 years or so before a generic drug is introduced in the market.

The Bolar Provision is legalized with Section 72 of RA 8293 stating that:

“...the owner of the patent has no right to prevent third parties from performing, without his authorization the acts referred to in Section 71…”

“making or exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or experimental use.”

“the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonable related to the development and submission of information and issuance of approvals by government regulatory agencies…”

Also known as “early working doctrine”, this provision will permit generic firms to perform tests as a preparation for their own manufacturing. Pro-patents view that this provision is the exact opposite of patent. This provision gives companies to use other company’s patents for their R&D to develop their own products. This is practiced in

---

24 This provision was named after the case of Roche Products vs. Bolar Pharmaceuticals. Bolar Pharmaceuticals is a generic company and was sued by Roche when they did some experiments of Roche’s product, Valium even before its patent expired.

developing countries like the United States and in Japan as well as applicable for both
generic and branded companies.\(^{26}\)

In the case of the Philippines, this provision is beneficial for local companies for they can
freely test, manufacture and then register their own generic versions of a patented
medicine. They will no longer wait for the patent to expire or secure license or even pay
royalty to the patent owner.

3.2.3 Parallel Importation

Policy of parallel importation is one of the flexibilities included in the TRIPS agreement.
This provision gives permission for a country to import off-patent or generic drugs from
other country even though patent for that drug in the importing country still exists. The
generic drugs from other countries are obviously cheaper compared to the patented drug.

The amendment of the IP Code will give way for the parallel important. Section 93-A
states that:

\[ \text{``The Director General of the Intellectual Property Office, upon written recommendation of the Secretary of the Department of Health, shall upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines...this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines...''} \]

The case of Pfizer for its patented drug, Norvasc (amlodipine besylate) is very related to
this policy of parallel importation. Prior to the amendment of the IP code, the
government through the Bureau of Food and Drug (BFAD) and Philippine International
Trading Corporation attempted to supply cheaper and generic version of Norvasc from
India. In India, patent for Norvasc already expired as a generic version, Amlogard which

\(^{26}\) Ibid.
was imported in the Philippines. Norvasc then costs almost 80 pesos while the Indian
generic version only costs less than 9 pesos. Since policy of parallel importation was not
implementation or made legal under our IP Code, Pfizer filed a lawsuit against the said
government agency and company.

With the provision of parallel importation legal, the Philippines can freely import
patented medicines from other countries where there are more affordable like India and
China. Medicines that Philippines can import from other countries are those that have
expired patents; hence, the imported off-patented medicine will “compete” with the
patented medicine in the country.

Though this provision is very promising, some groups are in doubt of the effects of this
policy. Some concerns raised about this policy is the dependence of the country with
imported medicines and the possible threats of hoarding and price manipulation27. With
parallel importation, some fear that counterfeit and fake drugs which are harmful might
be able to pass as imports to Philippine market.

3.2.4 Compulsory Licensing

Compulsory licensing is a policy that is allowed by the TRIPS Agreement. Though the
Agreement didn’t specifically identify the grounds for compulsory licensing, conditions
were stated. These conditions include that before filing or petitions; there must be efforts
for voluntary license between parties and remuneration to the patent holder in relevance
to the value of the license.

The policy of compulsory licensing will let the government “produce patented product or
process without the consent of the patent owner for public and non-commercial
purposes”28. Furthermore, Section 93 of RA 8293 states the Grounds for Compulsory
Licensing

28 http://www.drugterm.com/country/world.htm
The Director General of the Intellectual Property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances…”

Under this amendment, patented invention can be exploited either by manufacturing or through parallel importation. Those who want to minimize or shred products from patent are advocates of this policy. This policy is very useful when public health is at stake during emergencies or pandemic. This policy is applicable to countries like Rwanda and Canada, who can’t manufacture their own medicines and this provision acceptable is for emergency cases. Likewise, compulsory licensing is also enforced by countries like Thailand and Africa for drugs as treatments for HIV-AIDS.

As mentioned, these amendments particularly those in reference to the patent requirements and policies affected the pharmaceutical industry. These implications will be thoroughly discussed in the next chapter.

3.3 Role of Japanese Patent System to its Competitive Pharmaceutical Industry

With the introduction of product patent in 1975, the Japanese pharmaceutical industry boomed in terms of patent activities as well as its shift as mere imitators to innovations. Japan is aware of the big impact of patents to its industries particularly that of the pharmaceutical industry. According to La Croix and Akahiro Kawaura, “patent policy is an integral part of the industrial policy in Japan”. Japanese government believes that implementing pro-patent policies can attract innovations and R&D. Such policy of the Japanese patent system let the pharmaceutical industry experience the highest effect in terms of R and D and even patent activities.

29 Japan Pharmaceutical Manufacturing Association
In general, patent system of Japan offers a very strong patent protection to patent owners. With this, R&D flourished as investors are more secured to do business in the country even with billions-worth of investments. Japanese patent system offers broad patent scope which in effects, gives the utmost patent protection for patent owners. Japan Pharmaceutical and Manufacturing Association believes that narrow patent scope is not allowable in Japan for it takes almost the same investment as that of developing to discover the 2\textsuperscript{nd} medical use; with this, patent protection is still very essential. They further added that if patent protection for the 2\textsuperscript{nd} medical use is weak, there is no reason for Japanese companies to do business. The same is true for their policy of patent term extension; such extension is very important so pharmaceutical companies can extend their exploitation of the drug that took them at least 10 years to develop.

It is also worth mentioning that Japanese patent law is not pro-“branded companies”. In fact, like other national agencies, it seeks to introduce and promote generic drugs into the Japanese markets. As a whole, Japan’s patent system is one of the strictest but offers the strongest patent protection. The main goal of its patent office is to help usher research and development that can lead to manufacturing their own medicines that are of highest quality for its healthcare system. Likewise, as patent policies in Japan secures patent owners many Japanese pharmaceutical companies like Takeda are now multinational companies investing in other countries. In effect, Japanese pharmaceutical companies where able to compete globally and even made it to Forge’s Top 2000 Companies.
4. Impacts of the Revised Patent Rules to the Pharmaceutical Industry

When legislators decided to make a law that would lead to more affordable medicines in the Philippines, the first move was to amend the Philippine Intellectual Property Code. The mere suggestion of amending the IP Code already stirred the pharmaceutical community particularly the pharmaceutical companies who rely much on patent. Any change in patents can affect their products and their business as well. On the other hand, reproachful towards many pharmaceutical companies particularly the multinationals of monopolizing the industry with the power to dictate price; the government believes that doing something with patents will ease the burden. As established, patent is the ace among many pharmaceutical companies to be in control of price and monopoly; with this, the government made move to review and later amend the IP Code.

As the IP Code of the Philippines was formally amended with the Universally Accessible Quality and Cheaper Medicine Act of 2008 imposed in August of this year, the pharmaceutical industries are now experiencing the effects. Even before the Universally Accessible Quality and Cheaper Medicine Act of 2008 was enacted and took effect, implications of the IP amendment were already inevitable.

In this chapter, effects brought by the amendment of the IP Code will be discussed. Since, it was just recently that the Universally Accessible Quality and Cheaper Medicine Act of 2008 was implemented, likely effects will also be discussed based on the experiences of other countries. Providing fair report, this paper will both tackle the negative and positive impacts of the IP Code amendment.


4.1 Research and Development

As seen in many developed countries like Japan with high standards in their patent system along with a globally competitive pharmaceutical industry; patent system is an integral factor in the industry. Among the sectors within the pharmaceutical industry, research and development is also very essential since through R&D, medicines that they ought to promote and sell are being developed. Pharmaceutical companies get their respective breakthrough and block blaster products through R&D and when patented, they definitely reap big rewards.

With regimes in patent policies taking place like the changes in patent scope and the Bolar provision, R&D is affected. After all, these changes targets and pertains to R&D. Under the amended IP Code, 2nd medical uses and discoveries of known drugs as well as discoveries of salts and crystals will no longer be given patent protection. Likewise, based on the Bolar provision, a pharmaceutical company can now administer tests and experiments for a patent medicine as part of their manufacturing preparations.

Going back to the issue, how did the recent amendment affect R&D in the Philippines? To give clearly view of this, let us have comprehensible discussion on R&D in the Philippines. Dr. Kenneth Hartigan-Go in his article, “Why the RP Pharma Industry is not Competitive”, gave a very compelling scenario about Philippine R&D:

“The Philippine pharmaceutical industry, in general falls short of generating, research to extract and produce raw materials and chemicals from local sources. Some reports assert that there is research that is happening. However the problem is that it remains at the academic level and is not translated to commercial development. The research fails to reach the industry and thus is not utilized into marketable innovative products or processes..”

The Philippines simply lacks the right infrastructures and technology for R&D; local pharmaceutical industry is more inclined to manufacturing generic medicines. Hence, the amendment of the IP Code has no substantial impact pharmaceutical industry in the
Philippines in terms of R&D. However, United Laboratories, the leading local pharmaceutical company in the Philippines fears that the patentability requirement “could limit the free flow of information among scientists and R&D could be curtailed by too much emphasis on patents”.

R&D will be affected in terms of promoting R&D in the Philippines. As mentioned in the previous chapter, patent system plays a crucial role in influencing pharmaceutical companies to invest in R&D. Firms will not be that interested to invest in R&D simply because they will think that the medicines that will develop are not as marketable as those with strong patent protection. Urge to do further research on second uses as well finding the right salt and crystal for a known drug will no longer appeal to companies who are into R&D. In fact, according to the PHAP Report investors are reluctant to establish local manufacturing R&D facilities due to inadequate data security.

4.2 Business

Given all the advantages of owning a patent for a particular product, it is a setback when the patent either expires or discontinues. Therefore, when the changes in patent requirements and policies occur with the amendment of the IP Code, business or the financial part of the pharmaceutical companies may be affected.

Among the amendments of the IP Code, policies like compulsory licensing and parallel importation affects the business sector of the pharmaceutical industry the most. Particularly in regards to parallel importation where international trading is involve, its effects and impacts to the business world must taken into consideration.

Compulsory Licensing and parallel importation go hand in hand in the sense that compulsory licensing can result to the implementation of parallel importation. Satisfying the grounds for Compulsory Licensing as stipulated in the amendment, the government

---

30 Based on the interview of a medical representative from a multinational company. Upon request to conform with company regulations of data confidentiality, names and other information are not disclosed.
can exercise and intervene in making actions to make medicines available especially during emergencies or when the health of the Filipino nation is at stake. One of the result of compulsory licensing and parallel importation is the easy entry of generic drugs to Philippine market.

4.2.1 Entry of Generic Drugs.

Entry of generic medicines can be good for local Filipino pharmaceutical companies since majority of them are producing and manufacturing generic drugs. For United Laboratories, the Universally Accessible Quality and Cheaper Medicine Act of 2009 will “protect small generic companies from harassment by some multinational companies”. Furthermore, the said leading local pharmaceutical company believes that the new patent policy of parallel importation poses no effect on them as the aid policy is “commercially viable”. As generic drugs are made more accessible, local pharmaceutical companies can have more competition in the market. With new patent policies and requirement, local pharmaceuticals can now have the opportunity to launch more products in the market. With this, expansion of the local pharmaceutical companies is inevitable.

Likewise, patent policy of permitting companies to test and experiment on patented drugs will benefit the local companies or those companies who are into manufacturing generic medicines. With this provision, generic drugs can enter the market faster since while patent is still there, they can already start their tests and experiments. One the patent expires, these generic versions can immediately be launched in the market.

On the other side, it should be stressed out that entry of generic drugs in the market as the IP Code is amended is not limited to generic drugs from the Philippines. With the new patent policies like parallel importation, generic drugs from other countries are expected to come to Philippine market specifically that from India. Based on this, local companies will also have to face another competition from foreign companies.
4.2.2 Foreign Investment

In terms of investments from foreign companies, the new patent requirements and patent policies can pose both encouragement and discouragement. Foreign companies specifically those that develop their own “branded” medicines, will not be as compelled to introduce medicines in countries they think have weak patent protection as before. With the new policies, there is no reason for them to promote a certain market if they see that it cannot reap profits or cover the costs for its R&D. Though it is still premature to give comment on the possible effects on the MNCs revenues and profits in the Philippines, this situation can push foreign companies to pull out their investment. Let us take the case of Thailand when its government imposed compulsory licensing on expensive drugs like those for AIDS. Foreign companies were threatened that they sent their respective representatives and even reached the point of foreign investors threatening the Thai government to pull-out their investment from the country\textsuperscript{32}.

On the brighter side, the IP Code amendment can also persuade foreign companies to invest in the country specially those foreign companies that manufacture generic medicines. We can expect that generic companies from other countries will venture in the Philippines since the local market is more open to their products. As Philippines will be more open to generic medicines, foreign generic companies will be attracted to introduce their own generic medicines in the market. These new investments can create more jobs, increase tax collection and later contribute to the national revenues.

4.2.3 Multinationals

With the IP Code opening doors to local pharmaceutical companies to introduce their products and their projected expansion, does this mean that multinational companies will be downsizing? Though it is undeniable that profits and revenues are affected specifically

\textsuperscript{32} Based on the interview conducted to one of the representative of the Japan Pharmaceutical Manufacturing Association.
those profits made from affected products, multinational companies especially the larger ones are even expanding. There are MNCs that have merging and new acquisitions like Pfizer and GlaxoSmithKline. Pfizer bought Wyeth which can expand the product line of Pfizer like nutritional (milk, etc) while GlaxoSmithKline acquired Stiefel and UCB. Stiefel is the leader in dermatology department while UCB is with neuroscience. Though the amendment affected their companies, it still won’t stop them from expanding.

Multinational companies are undeniable experiencing a little difficulty but this is not primarily due to the changing patent laws in the Philippines but rather with the Maximum Retail Price that the government imposed on “essential drugs”. If we base it purely with patents, MNCs will not be significantly affected since they only have two or more products with incoming patent expiration. The problem is the future medicines that they will introduce in the Philippines which for them will have weak patent protection.

Profits that will be affected due to changes in patent requirements and policies are those royalties that patent owners get from those companies who want to have their own versions of the “branded” medicines or use their discoveries and process for experimentation. With narrow patent scope, companies don’t have to seek license (and pay royalties) to patent owners.

The foremost impact of the amended IP Code for these MNCs is competition – gone are the days that they have long years of monopoly over the market. With generic versions of their drugs available in the market, they have to face these competitions.

---

33 UCB Philippines only
34 Based on the interview with a medical representative. Names and other information are not to be disclosed.
35 Multinational companies argue that some of the “essential drugs” are not really essential based on the definition of the World Health Organization.
4.3 Patent Activity

Before tackling the issue on how patent activity will be affected with the amendment of the IP Code, let us first look back on the patent activity in the Philippines before the said changes in patent requirements and policies.

In the Philippines, pharmaceutical companies file for patent applications year after year.

<table>
<thead>
<tr>
<th>Year</th>
<th>Invention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local</td>
<td>Foreign</td>
</tr>
<tr>
<td>2000</td>
<td>154</td>
<td>3482</td>
</tr>
<tr>
<td>2001</td>
<td>135</td>
<td>2470</td>
</tr>
<tr>
<td>2002</td>
<td>149</td>
<td>705</td>
</tr>
<tr>
<td>2003</td>
<td>141</td>
<td>433</td>
</tr>
<tr>
<td>2004</td>
<td>157</td>
<td>413</td>
</tr>
</tbody>
</table>

Table 3 and Table 4 show the patent activity of both local and MNCs pharmaceutical companies from 2001-2005.

Table 4
Number of Published Pharmaceutical Patent Applications filed 2001 to 2005

<table>
<thead>
<tr>
<th>Year Published</th>
<th>Number of Local Pharmaceutical Patent Applications Filed</th>
<th>Number of Foreign Pharmaceutical Patent Applications Filed</th>
<th>Total Number of Pharmaceutical Patent Applications Filed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>9</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>2002</td>
<td>12</td>
<td>100</td>
<td>112</td>
</tr>
<tr>
<td>2003</td>
<td>1</td>
<td>54</td>
<td>55</td>
</tr>
<tr>
<td>2004</td>
<td>0</td>
<td>14</td>
<td>14</td>
</tr>
</tbody>
</table>

Tables 3 and 4 show that both local and foreign pharmaceutical companies are interested to see patent protection by filing patents. However, foreign companies are more active in filing for patent protections compared to local pharmaceutical companies. The explanation for this is that majority of these multinational companies develop their own
medicines through R&D, hence they run to patents to secure their product and investment. On the other hand, most local pharmaceutical companies are small-scale and family-run businesses. In line with this, local pharmaceutical companies don’t have the resources, capital and technology to invest in R and D to develop their own products. This statement is supported by an IP examiner in the Philippines that one of the reasons why there is low patent filing among local companies in the Philippines is due to low research and development capability. In effect, most local companies are generating generic medicines that came from off-patented drugs but sold in markets in much cheaper prices. Next to filing for patent application is granting and issuing patents. Let us take a look at Tables 5 and 6.

Table 5
Patents Granted from 2002-2005

<table>
<thead>
<tr>
<th>Year</th>
<th>Local Invention</th>
<th>Foreign Invention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>2</td>
<td>122</td>
<td>124</td>
</tr>
<tr>
<td>2003</td>
<td>6</td>
<td>454</td>
<td>460</td>
</tr>
<tr>
<td>2004</td>
<td>8</td>
<td>849</td>
<td>857</td>
</tr>
<tr>
<td>2005</td>
<td>11</td>
<td>1276</td>
<td>1287</td>
</tr>
</tbody>
</table>

Table 6
Number of Pharmaceutical Patents Issued from 2001 – 2004

<table>
<thead>
<tr>
<th>Year Issued</th>
<th>Number of Foreign Pharmaceutical Patents Issued</th>
<th>Number of Local Pharmaceutical Patents Issued</th>
<th>Total Number of Pharmaceutical Patents Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>448</td>
<td>1</td>
<td>449</td>
</tr>
<tr>
<td>2002</td>
<td>363</td>
<td>0</td>
<td>363</td>
</tr>
<tr>
<td>2003</td>
<td>351</td>
<td>0</td>
<td>351</td>
</tr>
<tr>
<td>2004</td>
<td>531</td>
<td>0</td>
<td>531</td>
</tr>
</tbody>
</table>

Table 5 and 6 shows the number of patents granted for both local and foreign companies. Based on the table above, it shows that foreign companies are granted more patents that the local companies. This scenario is self-explanatory since foreign companies have more patent applications than the local companies. Hence, it goes to say that majority of
patents involving pharmaceutical products are owned by foreign pharmaceutical companies.

Table 5 and 6 shows the number of patents granted for both local and foreign companies. Based on the table above, it shows that foreign companies are granted more patents that the local companies. This scenario is self-explanatory since foreign companies have more patent applications than the local companies. Hence, it goes to say that majority of patents involving pharmaceutical products are owned by foreign pharmaceutical companies.

We can say that the impacts on the amendment of the IP Code with regards to patent activity are more applicable to those companies who discover and develop their own medicines. With the new patent requirements and policies minimize patent applications among these companies? As of now, companies like the MNCs says that their patent activity will not be affected in such a way that they will not file for patent protections. In fact they will continue to seek patent protection hence, file for patents for their products. The IP Office in the Philippines has its main goal to strengthen its patent protection so that they can motivate pharmaceutical companies to file for patents.

But if we follow the experiences of other countries who have revised their patent system like that of Japan as a model, there is a big chance of increase in patent activity in the Philippines. Table 7 shows the number of patents granted in Japan from 2000-2007.

<table>
<thead>
<tr>
<th>Year</th>
<th>Domestic</th>
<th>Foreign</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: JPMA Data Book
Table 7 provides as good evidence that patent system has can affect on pharmaceutical industry. With a strong and stable patent system like Japan, both local and foreign companies file and seek for patent protection for their respective products and in return, successfully own a patent.

### 4.4 Society and Healthcare

More than business and trade, the amendments to the IP Code can in the end affect the Philippine society and the whole healthcare system as well. After all, the intention of the Universally Accessible Quality and Cheaper Medicine Act of 2008 is to provide a better healthcare system through cheaper medicines. Will the changes in the patent system of the Philippines beneficial to the public. As mentioned by United Laboratories, the IP Office is reliable to the public more than anyone else.

With IP Code being amended and with the entry of generics, the public can now have more choices in regards to their medicine. Unlike before, they have to buy the more expensive drugs since there are no generic versions. Drugstores selling generic medicines like the government’s Botika ng Bayan will have more products to offer to the public. In connection, medicines in the Philippines will be cheaper courtesy of these generic medicines as he IP Code was amended. Atty. Ochave of United Laboratories, thinks that prohibiting patent grant for new use of a known drug substance or 2nd medical use can expedite price erosion to the benefit of the public since it allow earlier entry by generic competitors.

For health practitioner, they will also have more choices on which medicine to prescribe. They can now offer generic if the patient cannot afford the “branded” ones; given that the said health practitioner’s decision to prescribe is not influenced by pharmaceutical companies.\(^{36}\)

---

\(^{36}\) Allegations that doctors prescriptions are influenced by some pharmaceutical companies like perks and other sponsorships as part of their marketing strategy. Hence, prescribing based on their “affiliated” pharmaceutical companies not purely on what they think is the best medicine.
The immediate implication of the IP Code Amendment is cheaper and more affordable medicine. This is a very good news for a society who cannot prioritize health due to the high prices of medicines. With amendments of the IP Code\textsuperscript{37}, medicines are now cheaper which as a result becomes accessible for many citizens.

Congressman Abaya expressed that compulsory licensing will make the government “easier and quicker to respond to public health threats without the fear of lawsuits.” Compulsory licensing can make the government impose its powers to make medicines available to the public especially during any health emergencies.

On the other hand, some are threatened of policies like parallel importation when taken advantage by evil sectors. With parallel importation, “Philippines will be prone to hoarding and another price manipulators”\textsuperscript{38} while Dr. Hartigan-Go says that “counterfeit and substandard drugs might inflict the market which can affect true quality generics products”.

\textsuperscript{37} Together with the price system imposed by the government
Chapter V

5. Summary, Conclusion and Recommendation

As a developing country, the Philippines needs to improve many aspects of its society and one of these is the plight of its healthcare system. With many of its citizens belonging to the marginal income bracket, buying medicines even for simple disease is a luxury. Filipinos would rather put food in the table than spend money on medicines. Added to this is the fact that prices of medicines in the Philippines are much more expensive compared to other Asian countries, the Philippines has the second most expensive medicines in Asia with Japan as the most expensive.

With low purchasing power topped with high prices, medicines in the Philippines are no doubt inaccessible. Many laws and legislative proposals were made to address this issue – to lower the prices of medicines and make it accessible to every Filipino. And the most recent is the implementation of the Universally Accessible Quality and Cheaper Medicine Act of 2008 which also covered the amendment of the Intellectual Property. The government feels that patent gives many pharmaceutical companies the chance to monopolize the market and affect price. By changing the patent protection on their products and introducing some regimes in the policies, medicines will be cheaper and accessible.

Patents are regarded as the safety-nets among pharmaceutical companies specifically for multinational companies. And it is not surprising that these companies have negative feelings towards the amendments to the IP Code will no doubt result to cheaper medicines and more generic versions of branded medicines. With this, local pharmaceutical companies who are more centered on manufacturing generic companies are most likely to reap rewards from these amendments. Now, it will be easier and faster for them to launch their generic versions which are cheaper than those branded medicines. The new policies and requirements will pave the way for these generic companies to introduce more drugs to the market.
At first glance, we might think that patent owners like most MNCs are in the losing end with these amendments. But if we analyze it, cheaper drugs will lead to more consumption since Filipinos now can afford to buy medicine even those for maintenance like drugs for hypertension. And as a result this increase in consumption and high demand will result to bigger profits. With price control imposed on many branded products, MNCs can also take advantage on how Filipinos are now willing to buy medications since they are cheaper.

The amendment of the IP Code will not only yield to cheaper and more affordable medicines for the Filipino public but also to create fair competition in the market. The once MNC-centered market will now be open for small generic companies and will lead to their expansion. If we based in with India’s experience, it would most likely that with these amendments, the future of our local pharmaceutical industry is bright. And with competition, along with the protection regulation and supervision from different government agencies, the whole industry will undoubtedly benefit and later become competitive.

On the other hand, we cannot deny that some sectors are against the amendment of the IP Code and the Universally Accessible Quality and Cheaper Act of 2008 as a whole. For them, lowering the price of medicines will not automatically mean better healthcare for Filipinos. And with policies like parallel importation, they perceive the influx of counterfeit drugs which is obviously harmful for consumers. With this, it is highly recommended that government agencies concerned should be vigilant in preventing evil elements who want to take advantage of the IP amendments.

Likewise, in support of this new decree for cheaper medicines, government should increase their funding for medicines. Philippine Health Insurance or PhilHealth must be strengthened to give more subsidy and benefits. The Bureau of Food and Drugs (BFAD) can also do their share by being vigilant against counterfeit drugs like labeling fake rugs as branded.
Lastly, the government and the whole nation can take advantage of this development of the IP Code for the benefit of its healthcare system. The new IP Code of the Philippine has many provisions that Philippines can utilize for their own good like affordable medicines. Local companies must also grab the opportunity that the IP Code is now more open to generic drugs than before. Philippines should learn from the experiences of other countries like Japan who made use of the changes in their patent system to make their pharmaceutical industry competitive as they help save lives and improve the healthcare of its citizens. It is up to the Filipino nation to see the importance and value of the amendments of its IP Code to elevate the status of its healthcare system.
References

Articles:


Journals


Reports


Research Reports and Working Papers


Homepages

World Intellectual Property Organization http://www.wipo.int/

Documents

The Cheaper Medicine Bill (Republic Act 9502)
Universally Accessible Quality and Cheaper Medicine Act of 2008
Japan Pharmaceutical Manufacturing Association Factbook.

Interviews

Ochavare, J.M. ( thru e-mail, June 30 and July 14, 2009)

Books