

# Exploitation of Intellectual Property Rights by Pharmaceutical Companies in the Philippines



## HIGHLIGHTS

- Originator companies use patents and the patent system for the purpose of avoiding infringement, acquiring patent rights, preventing acquisition of rights, research and development, technology transfer, business strategy and industry development. Generic companies, on the other hand, conduct patent searches to avoid patent infringement. They also use the patent system to innovate and improve on existing products or processes.
- Pharmaceutical companies also utilize other intellectual property rights such as (a) trademarks, to protect their investment and to promote public health; (b) copyright, to protect original works necessary in research and development, securing regulatory approval, pharmacovigilance and product support; and (c) trade secrets to protect vital but un-patentable proprietary information such as clinical trial data, product formulations and manufacturing process.
- The government must adopt an integrated and holistic approach that seeks to strike a balance between IPR protection and access to medicines. Fair competition in the pharmaceutical industry must be promoted. Cooperation between government and industry must be strengthened with the view of establishing an environment that stimulates innovation, while ensuring widespread access to quality and affordable medicines.



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## I. INTRODUCTION

The aim of the study is to provide a baseline assessment on how originator and generic pharmaceutical companies in the Philippines utilize intellectual property rights (IPR) in the various aspects of their operations and at different stages of drug development from conceptualization to commercialization. The motivation for the study is the increased prominence of IPR provisions in new emerging free trade agreements, which will require informed judgment on the part of policymakers in order to determine the extent to which such provisions would be acceptable. The study seeks to provide a clear picture on how existing IPR laws in the Philippines, particularly the Intellectual Property Code or “IP Code” (Republic Act 8293), as amended and the Universally Accessible Cheaper and Quality Medicines Act or “QUAMA” (Republic Act 9502), impact the business and operations of originator and generic pharmaceutical companies operating in the country. This analysis in the Philippine setting could help guide the country’s trade negotiators in defining the country’s position vis-à-vis such IPR provisions, which have tended to be among the most contentious issues in recent trade agreements.

## II. STUDY APPROACH AND METHODOLOGY

The study employed the following tools to gather data and insights from the domestic pharmaceutical industry from the perspective of the various types of stakeholders therein:

1. Focus Group Discussions (FGDs) - To achieve the purpose of the study, FGDs with select originator and generic pharmaceutical companies were held last February 13 and 15, 2017 to: (1) identify the various activities undertaken by them in the Philippines; (2) identify what IPR are utilized, how, and up to what extent such IPR are used at each stage of operations; and (3) assess how Philippine IPR laws, rules and regulations affect their business. Pharmaceutical companies controlling about 45% of the market share participated in the FGDs.

2. Survey - Based on the outcome of the FGDs, detailed survey questionnaires for originator and generic pharmaceutical companies, attached as Annexes “A” and “B” to this study, were crafted and sent to pharmaceutical companies, to confirm the FGD results and to obtain a more

comprehensive and detailed response as to what IPR are used, the manner and extent of IPR use in pharmaceutical business operations, and the impact of the current IPR legal and regulatory framework on such operations. Pharmaceutical companies controlling about 29.5% of the market share in the country participated in the survey.

3. Desk Research – To complement the results of the FGDs and the survey, data were also secured from the IPOPHIL on the patent and trademark filing activities of pharmaceutical companies as well as patent and trademark infringement cases filed before the IPOPHIL. Data on trademark opposition/cancellation cases and patent cancellation cases filed with the IPOPHIL were also requested, but the Bureau of Legal Affairs (BLA) is still in the process of making an inventory of such cases. While data from the IP courts on the number and nature of IP cases filed before them is desired, the logistical and time limitations of this study have not allowed the gathering of such data. As part of the research, a review of current IPR laws and existing literature on the operations of pharmaceutical companies in the Philippines was also undertaken.

4. Data Analysis - Data gathered from the FGD, survey responses, data from the IPOPHIL and from existing literature were analyzed in order to present a comprehensive and detailed study, as much as is possible from the extent of data gathered.

## III. THE PHILIPPINE PHARMACEUTICAL INDUSTRY

The Philippines is considered as one of the biggest pharmaceutical markets in the ASEAN region, third largest after Indonesia and Thailand. The Philippines’ pharmaceutical industry is one of the fastest growing industries in the country. It has been seeing stable growth for the past decade and is expected to continue for the next few years, as shown in Figure 1 (see next page):

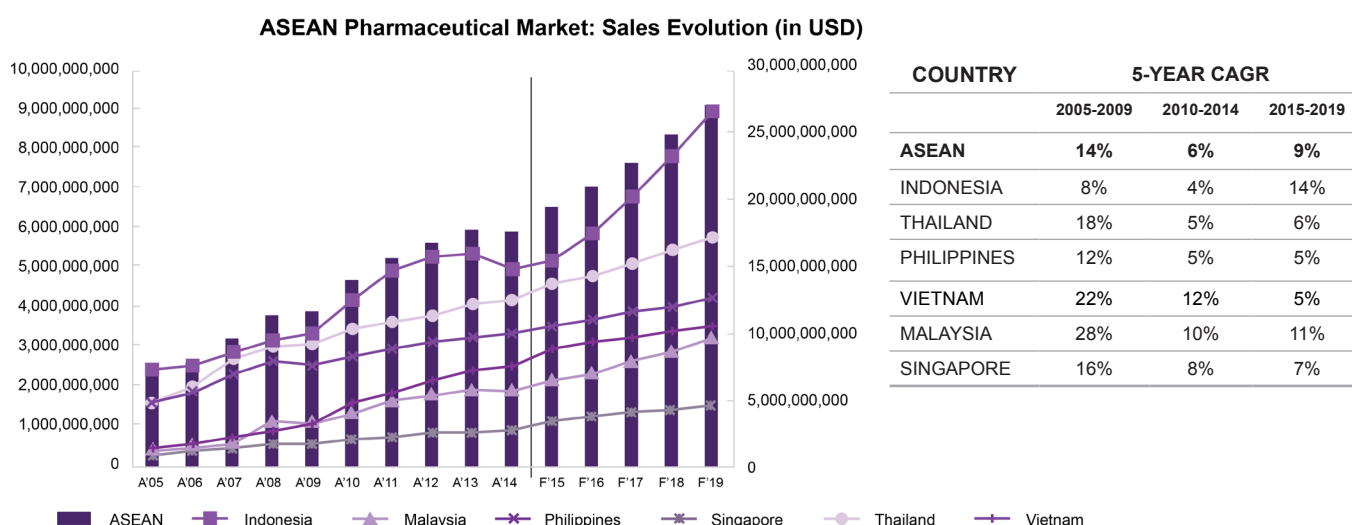
The industry’s value in the year 2013 was noted to be at US\$4.3 billion and is projected to reach US\$8 billion by 2020. The expected increase can be explained by the government’s involvement in regulating the prices of medicine and the growing public awareness and acceptance of generic variants of medicines.<sup>1</sup>

The imposition of the Maximum Drug Retail Price or the MDRP resulted in a drop of 51%)

<sup>1</sup> Oxford Business Group, The Report, The Philippines (2015)

<sup>2</sup> Ibid.

FIGURE 1. THE ASEAN PHARMACEUTICAL MARKET



Source: IMS Health MIDAS, July 2015 | 2015-2019 forecast data is unevented

on 21 molecules in the year 2008.<sup>2</sup> And with the implementation of the Universally Accessible Cheaper and Quality Medicines Act or QUAMA (Republic Act 9502) the following year, generic drugs have become widely available and better implemented into the different treatments provided by both private and public hospitals. As the variant has become more publicly accepted, more competition was also fostered by the retail pharmacies like Watsons and Rose, by opening dedicated generic drug retail stores.<sup>3</sup>

These developments posed a challenge to the big pharmaceutical players who were negatively affected. The big pharmaceutical companies experienced negative growth in the succeeding years because the prices of medicines were cut by 60%. The negative impact from the business perspective, however, was compensated by the rise of the generics market that was considered the fastest-growing segment in the pharmaceutical industry. The passage of QUAMA propelled the growth of the generic industry because of the importation of cheap drugs from Pakistan and India.<sup>4</sup> To compete with the generic and off-brand products, many multinational companies are reducing the prices of some brand name drugs by as much as 50%.<sup>5</sup>

In its June 2015 publication, “Contributions of the Philippine Pharmaceutical Industry to Health and Economy,” the Pharmaceutical and Healthcare Association of the Philippines (PHAP) reported that between 80% and 90% of essential medicines, as defined by the World Health Organization (WHO), are already off-patent, thereby giving consumers more affordable options.<sup>6</sup> The availability of both originator and generic pharmaceutical products has allowed patients and physicians to choose medicines based on their own preferences and needs. Generics account for 65% of the total pharmaceutical market, with an annual growth of 6% since 2010. Originator products account for only 35% of the pharmaceutical market in the Philippines. The Philippines has a higher utilization rate of lower-cost generics than other Asia-Pacific countries with comparable GDPs.<sup>7</sup> Prescription trends indicate that generic prescribing by physicians has also increased by seven (7) percentage points since 2011 (from 66% in June 2011 to 73% in June 2014) and will enhance patient access, which is further supported by the nationwide expansion of generics-only drugstore chains.<sup>8</sup>

In a 2016 World Intellectual Property Organization (WIPO) study by Beall entitled “Patents and the

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Khan, J., “Philippines Pharmaceutical Market in 2020” (August 2015); <https://www.linkedin.com/pulse/philippines-pharmaceutical-market-2020-dr-> (last accessed, 18 June 2017)

<sup>6</sup> IMS Market Prognosis, IMS MIDAS 2010-2014.

Oxford Business Group, The Report, The Philippines (2015)

<sup>7</sup> Ibid.

<sup>8</sup> Ibid.

WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate between IP and Access",<sup>9</sup> it was reported that 95% of the 375 drugs on the Model List of Essential Medicines (MLEM) are off-patent. The remaining 5% or 20 drugs are largely for antivirals, especially HIV (13 of 20). The percentage of the developing countries covered by each of the 20 patent portfolios varies widely from less than 1% to 44% with a median of 15%. Patents for essential drugs appear more commonly in higher income countries with larger populations where there are relatively more market and manufacturing opportunities.<sup>10</sup> In the study sample of 137 developing countries, patents appeared more frequently in Brazil, Bulgaria, China, India, Indonesia, Mexico, **the Philippines**, Romania, South Africa, and Turkey. The percentage of active patent coverage across the 375 MLEM items and the 137 developing countries is 0.95%; when restricting this calculation to the 20 patented drugs, the active patent coverage is 17%.<sup>11</sup> Considering that most MLEM products are off-patent in most developing income countries, there is great opportunity for potential manufacturers and exporters of essential medicines.

With the passage of the QUAMA, the generics segment has become increasingly important in the Philippines. Among domestic drug companies, United Laboratories, Pascual Laboratories, GC International and Natrapharm are the largest. In addition to local manufacturers, many foreign manufacturers are entering the market. Some of the fastest growing companies include Novartis' generic arm Sandoz, Taiwan's Orient Europharma (OEP) and Getz Pharma of Pakistan.<sup>12</sup>

There are more than 500 drug traders, 700 drug importers, and 5,000 drug distributors in the Philippines. Three quarters of the top twenty (20) pharmaceutical companies in terms of market share are multinationals, controlling 66% of total industry sales, while 30% of pharmaceutical sales

are accounted for by domestic Filipino companies.<sup>13</sup> The top 20 pharmaceutical companies in terms of market share are listed in Table 1.

**TABLE 1. TOP TWENTY COMPANIES IN TERMS OF MARKET SHARE (%)**

COMPANIES (1ST TO 10TH)	MARKET SHARE	COMPANIES (11TH TO 20TH)	MARKET SHARE
UNITED LAB	25.9	AMBICA	2.3
PFIZER INC.	7.1	BAYER	2.0
GLAXOSMITHKLINE	4.8	NATRAPHARM	2.0
SANOFI-AVENTIS	3.8	ASTRAZENECA	2.0
ABBOTT LAB	3.7	SERVIER	1.4
		PHILS	
BOE. INGELHEIM	3.0	TAISHO	1.2
		PHARM	
NOVARTIS	2.8	MERCK INC	1.2
CATHAY DRUG CO	2.7	GETZ PHARMA	1.2
MERCK SHARP&DOHME	2.5	ROCHE	1.2
JOHNSON	2.4	MENARINI	1.1

Source: IMS, 2016

Multinational pharmaceutical companies in the Philippines are primarily traders. Most of them import a large portion of their products from abroad. These companies have two (2) common characteristics. First, a big number of these companies hire the manufacturing services of InterPhil, a giant toll manufacturer, which is a locally-owned subsidiary of the multinational Manchester Holdings. Second, these companies subcontract a very small portion of their drugs to local toll manufacturers like Hizon Laboratories, Swiss Pharma, and Euro-Med Laboratories. Figure 2 (see next page) depicts a typical supply chain of a multinational drug trader:<sup>14</sup>

<sup>9</sup> Beall, R., "Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access" (April 2016); [http://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_gc\\_ip\\_ge\\_16/wipo\\_gc\\_ip\\_ge\\_16\\_brief.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_brief.pdf) (last accessed, August 9, 2017)

<sup>10</sup> Ibid., page 1 (Key Messages)

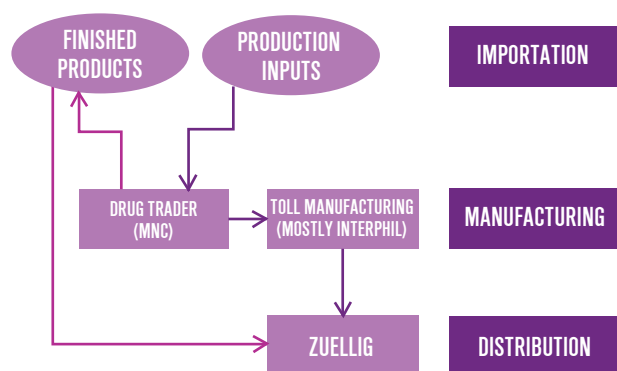
<sup>11</sup> Ibid., page 3

<sup>12</sup> Khan, J., "Philippines Pharmaceutical Market in 2020" (August 2015); <https://www.linkedin.com/pulse/philippines-pharmaceutical-market-2020-dr-> (last accessed, 18 June 2017)

<sup>13</sup> Wallace Pharmaceuticals Pvt. Ltd./ Dias, N., "Philippine Pharmaceutical Market Study: Trade Dynamics of the Filipino Market Place" (2017)

<sup>14</sup> Reyes, C., Lavado, R., Tabuga, A., Asis, R., and Datu, B., "A Profile of the Philippine Pharmaceutical Sector" Discussion Paper Series No. 2011-11. Philippine Institute of Development Studies (PIDS), (2011); <https://dirp4.pids.gov.ph/ris/dps/pidsdps1111.pdf> (last accessed, August 9, 2017)

**FIGURE 2. TYPICAL SUPPLY CHAIN OF A MULTINATIONAL DRUG TRADER**



Source: PIDS, 2011

Figure 2 above explains the flow of drugs from importation or production to manufacturing to distribution. As mentioned previously, most multinational companies are drug traders. They usually purchase both finished drugs and raw or intermediate materials. On one hand, the finished products go directly to its distribution unit (Zuellig), while the production inputs (raw and intermediate materials) go to its toll manufacturer. After the manufacturing and production stage, which include repacking and labelling, Interphil then dispatches the products to other affiliates like Zuellig for distribution. In some other cases, multinational companies are considered purely importers. The process from importation to distribution is shown in Figure 3:<sup>15</sup>

**FIGURE 3. PROCESS FROM IMPORTATION TO DISTRIBUTION**

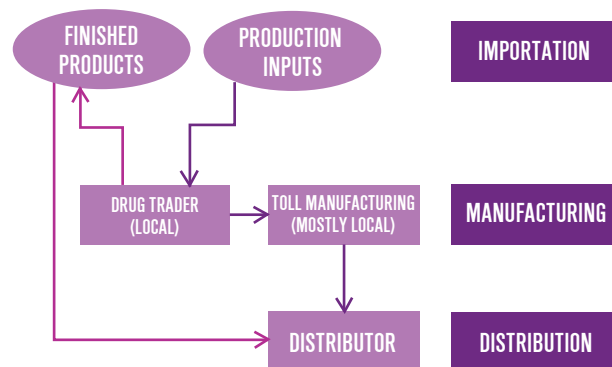


Source: PIDS, 2011

<sup>15</sup> Ibid.

Domestic drug companies can be characterized as a drug trader, a drug manufacturer or both. The local drug traders subcontract production of their drugs to local toll manufacturers. These local companies, at the same time import finished products and distribute to the local market through their own distribution units or affiliates. Figure 4 shows the typical supply chain of a local drug trader:<sup>16</sup>

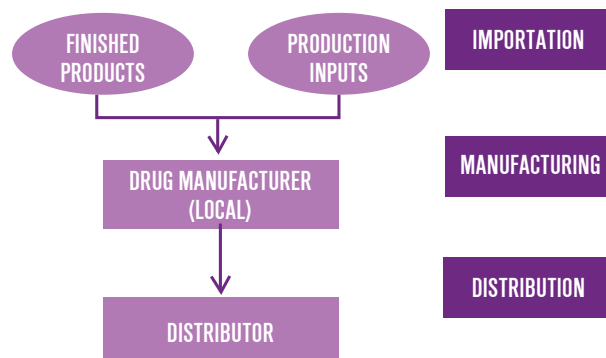
**FIGURE 4. TYPICAL SUPPLY CHAIN OF A LOCAL DRUG TRADER**



Source: PIDS, 2011

Local drug manufacturers are domestic companies that manufacture drugs or medicines for their own company and/or for other companies. An example is United Laboratories (along with its subsidiaries namely, Asian Antibiotics, Amherst, and Westmont). Other local drug manufacturers are Pascual Laboratories, AM-Europharma, AD Drugstel, Euro-med, to name a few. It is important to note that that these two groups of local drug companies are not mutually exclusive. A local drug company can be both a manufacturer and a trader. Figure 5 shows the typical supply chain of a local drug manufacturer:<sup>17</sup>

**FIGURE 5. TYPICAL SUPPLY CHAIN OF A LOCAL DRUG MANUFACTURER**



Source: PIDS, 2011

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

## IV. IPR LAWS AND THE PHARMACEUTICAL INDUSTRY

The primary law that governs the IPR of pharmaceutical companies in the Philippines is the IP Code as amended by the QUAMA. Under the IP Code, the term “IPR” includes patents, trademarks and service marks, copyright and the protection of undisclosed information or trade secrets.<sup>18</sup> Under the QUAMA, which was enacted in 1998 as a measure to enhance access to cheaper but quality generic drugs, certain provisions of the IP Code was amended to, among others, curtail the ever-greening of patents, allow the parallel importation of drugs and adopt the Bolar provision for the early working of patented drugs for purposes of securing licenses for commercialization.

The provisions of Republic Act 10667 otherwise known as the Philippine Competition Act are also relevant in terms of IPR and competition, particularly in the grant of compulsory licensing and special compulsory licensing and the use by the government of patented inventions as provided under the IP Code, as amended by the QUAMA.

### A. PATENTS

Drugs and medicines, the process for their production, or an improvement of any of the foregoing, which are new,<sup>19</sup> involve an inventive step,<sup>20</sup> and which are industrially applicable<sup>21</sup> are patentable under the IP Code.<sup>22</sup> Drugs and medicines, processes or improvements, which are new and industrially applicable but lack inventive

step, also qualify for registration as utility models.<sup>23</sup> “Drugs and medicines” refer to any chemical compound or biological substance, other than food, intended for use in the alleviation of symptoms and the treatment, prevention or diagnoses of diseases in humans or animals.<sup>24</sup> “Process” refers to the preparation/method of manufacture/method of producing a product or composition.<sup>25</sup>

### 1. Patentability

As amended by QUAMA, Section 22.1 of the IP Code provides that the following shall be excluded from patent protection: (a) 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 (b) the mere discovery of any new property or new use for a known substance; (c) or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.<sup>26</sup>

Because of public health considerations, applications for drugs and medicines involving known substances are granted letters patent only when they satisfy the eligibility standard requiring that the subject matter must not fall in any of the enumeration of non-patentable inventions while meeting the criteria of novelty, inventive step and industrial applicability.<sup>27</sup>

In the case of drugs and medicines, there is no inventive step if the invention results from the

<sup>18</sup> Section 4, IP Code.

<sup>19</sup> An invention shall not be considered new if it forms part of a prior art; Section 23, IP Code

<sup>20</sup> An invention involves an inventive step if, having regard to prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention; Section 26, IP Code

<sup>21</sup> An invention that can be produced and used in any industry shall be industrially applicable; Section 27, IP Code

<sup>22</sup> Section 21, IP Code

<sup>23</sup> Section 109.1(a), IP Code

<sup>24</sup> Section 2(a), IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances; “Drugs and medicines” include but are not limited to: (1) Articles recognized in the current official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, official Philippine National Drug Formulary (PNDF), British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them; (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Articles other than food intended to affect the structure or any function of the human body or animals; (4) Articles intended for use as a component of articles specified in clauses (1), (2), or (3) not including devices or their components, parts, or accessories; and (5) Herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine that are: (i) Recognized in the Philippine National Drug Formulary Vol. I (Essential Drugs List); (ii) Intended for use in the treatment, cure or mitigation of disease symptoms, injury or body defects in humans; (iii) Other than food, intended to affect the structure or any function of the human body; (iv) In finished or ready-to-use dosage form; and (v) Intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv).

<sup>25</sup> Section 2(f), IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances

<sup>26</sup> For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy (Section 22.1, IP Code)

<sup>27</sup> Introduction, IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances

mere discovery<sup>28</sup> of a new form<sup>29</sup> or new property of a known substance<sup>30</sup> 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<sup>31</sup> 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.<sup>32</sup>

In order to implement the QUAMA, the IPOPHIL adopted the IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances in 2008.<sup>33</sup>

## 2. Patent Rights and Limitations

A patentee of a drug or medicine has the exclusive right to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product. On the other hand, the patentee of a process for the manufacture or production of drugs and medicines has the exclusive right to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.<sup>35</sup> A patentee also has the right to assign, or transfer by succession the patent, and to conclude licensing contracts for the same.<sup>36</sup>

Under Section 15 of the Philippine Competition Act: (a) permissible franchising, licensing, exclusive merchandising or exclusive distributorship agreements such as those which give each party the right to unilaterally terminate the agreement; or (b) agreements protecting intellectual property rights, confidential information, or trade secrets, are not prohibited or rendered unlawful under

said Act. Section 27 also provides that the acquiring, maintaining and increasing of market share through legitimate means not substantially preventing, restricting, or lessening competition in the market, such as the enjoyment and use of IPR, is not violative of said Act.

The term of a patent is twenty (20) years from the filing date of the application.<sup>37</sup> The term of a utility model is seven (7) years from the filing date of the application.<sup>38</sup>

As amended by the QUAMA, the IP Code provides for an international exhaustion of patents regime for drugs and medicines. Under Section 72.1 of the IP Code, as amended, the patent rights holder “has no right to prevent third parties, without his authorization from using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market: Provided, that, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention; *Provided*, further, that the right to import the drugs and medicines contemplated in this sections shall be available to any government agency or any private third party.”

International exhaustion of patents allows the parallel importation of drugs and medicines already released in the international market. Parallel importation refers to the practice where a third party, without the authorization of the patent holder, imports a foreign manufactured product put on the market abroad by the patent holder,

<sup>28</sup> The Doctrine of Inherency is adopted to articulate on the meaning of “mere discovery”. Inherent new form or new use of a known substance would be considered as mere discoveries, hence not a patentable subject matter within the purview of the QUAMA provision. A mere use of known process not resulting to a new product and not employing at least one new reactant is also considered as inherent, hence not a patentable subject matter in view of the QUAMA provision; General Guidelines, IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances

<sup>29</sup> “New form” refers to salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance; Section 2(c), IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances;

<sup>30</sup> “Known substance” refers to known compound or composition wherever applicable; Section 2(b), IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances

<sup>31</sup> Section 2(e), IPOPHIL Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances;

“New use” refers to second or further medical use of a known compound or composition.

<sup>32</sup> Section 26.2, IP Code

<sup>33</sup> [https://www.IPOPHILphil.gov.ph/images/Patents/IRRs/QUAMA\\_EXAMINATION\\_GUIDELINES\\_OFFICIALCOPY.pdf](https://www.IPOPHILphil.gov.ph/images/Patents/IRRs/QUAMA_EXAMINATION_GUIDELINES_OFFICIALCOPY.pdf) (last accessed, August 9, 2017)

<sup>34</sup> Section 71.1(a), IP Code

<sup>35</sup> Section 71.1(b), IP Code

<sup>36</sup> Section 72, IP Code.

<sup>37</sup> Section 54, IP Code.

<sup>38</sup> Section 109.3, IP Code

his licensee or in another legitimate manner in competition with imports or locally manufactured products by the patent holder or his licensee. The practice is based on the principle that the patent holder has been remunerated through the first sale of the product and his further control over the resale of the product would unreasonably restrain trade and stifle competition.<sup>39</sup>

The IP Code, as amended by QUAMA, also adopted the Bolar provision, which allows generic drugs companies to use the patented active ingredient or innovator drug to obtain regulatory approval, without the patentee's consent, before the expiration of the patent. The Bolar provision covers acts considered as preparatory steps for generic drugs companies to be able to market their generic drugs immediately upon the expiration of the patents of innovative drug companies. Section 72.4 of the IP Code, as amended by the QUAMA, restricts the allowed acts to "testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies."<sup>40</sup>

Under Section 93 of the IP Code, the Director of the BLA has the authority to grant compulsory 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: (a) national emergency or other circumstances of extreme urgency; (b) where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the economy as determined by the appropriate agency of the Government, so requires; (c) where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; (d) in case of public non-commercial use of the patent by the patentee, without satisfactory reason; (e) if the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason, provided, that the importation of the patented article shall constitute working or using the patent; and (f) where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health.

<sup>39</sup> Lucenaro, D., "IP Utilization of Innovative Drug Companies", lecture given during the November 16, 2016 IPAA Seminar entitled "Technology Protection and IPR in Healthcare", held at the Dusit Thani (Manila)

<sup>40</sup> Ibid.

As amended by the QUAMA, the IP Code under Section 93-A.1 also provides that the Director General of the IPOPHIL, upon the 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. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision. The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

Section 93-A.2 provides that compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: Provided, that, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

The right to grant a special compulsory license under Section 93-A shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippine laws, particularly Section 72.1 and Section 74 of the Intellectual Property Code, as amended under the QUAMA. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws.<sup>41</sup>

<sup>41</sup> Section 93-A.3, QUAMA

### 3. Actions for Patent Infringement

Under Section 76.1 of the IP Code, as amended, “the making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement: *Provided*, that, this shall not apply to instances covered by S Sections 72.1 and 72.4 (Limitations of Patent Rights); Section 74 (Use of Invention by Government); Section 93.6 (Compulsory Licensing); and Section 93-A (Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement) of the IP Code.”

Any patentee, or anyone possessing any right, title or interest in and to the patented invention, whose rights have been infringed, may bring a civil action before a court of competent jurisdiction, to recover from the infringer such damages sustained thereby, plus attorney’s fees and other expenses of litigation, and to secure an injunction for the protection of his rights.<sup>42</sup> If infringement is repeated by the infringer or by anyone in connivance with him after finality of the judgment of the court against the infringer, the offenders shall, without prejudice to the institution of a civil action for damages, be criminally liable therefor.<sup>43</sup>

### 4. Data Exclusivity and Patent Linkage

The IP Code does not provide for data exclusivity whereby, for a fixed period, drug regulatory authorities do not allow the registration data of an innovator drug to be used in registering a therapeutically equivalent generic version of that medicine. In fact, Chapter II, Rule 9 of the Implementing Rules and Regulations (IRR) of the QUAMA states that the Food and Drug Administration (FDA) (then, the Bureau of Food and Drugs) shall not be precluded from using all data, including, but not limited to, pre-clinical and clinical trials, of an applicant when evaluating other

applications. However, Section 72.4 of the IP Code, as amended by QUAMA and the IRR provide that the data submitted by the original patent holder shall be protected against unfair commercial use, pursuant to Article 39.3 of the TRIPS Agreement.

The “protection of undisclosed information” is a category of IPR recognized under Article 39.3 of the TRIPS Agreement, which provides that: “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical entities, the submission of undisclosed test or other data the origination of which involves a considerable effort, shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

The IPR referred to in Article 39.3 is referred to as “Data Exclusivity” in the US and “Data Protection” or “Regulatory Data Protection” in the European Union. While used interchangeably, the term “data protection” is, however, not the same as “data exclusivity”. “Data protection” as provided in the Article 39.3 of the TRIPS Agreement refers to the protection of undisclosed test or data, submitted by pharmaceutical companies to regulatory agencies in the application for approval of an originator product, against unnecessary disclosure and against unfair commercial use. On the other hand, “Data exclusivity” may be defined as the right to exclude, for a limited period of time, third parties from using, either directly or indirectly, test data submitted with the application of an originator pharmaceutical product, for the purpose of approval of a subsequent (generic) pharmaceutical product.<sup>44</sup> Data exclusivity is not required under the TRIPS Agreement and neither is it provided under the IP Code.

There is also no IP Code provision for patent linkage, a regulatory system where marketing approval of generic drugs is not granted until the expiration of the patent of the original drug. The FDA used to implement a patent linkage scheme,<sup>45</sup>

<sup>42</sup> Section 76.2, IP Code

<sup>43</sup> Section 84, IP Code

<sup>44</sup> Shaikh, O., “Access to Medicine Versus Test Data Exclusivity – Safeguarding Flexibilities Under International Law; [https://books.google.com.ph/books?id=NEK8DAAAQBAJ&pg=PA62&lpg=PA62&dq=data+exclusivity+vis-a-vis+data+protection&source=bl&ots=L9GjePCZmT&sig=gqa-X37yYsrpsALhUzriZcrX3TyA&hl=en&sa=X&redir\\_esc=y#v=onepage&q=-data%20exclusivity%20vis-a-vis%20data%20protection&f=false](https://books.google.com.ph/books?id=NEK8DAAAQBAJ&pg=PA62&lpg=PA62&dq=data+exclusivity+vis-a-vis+data+protection&source=bl&ots=L9GjePCZmT&sig=gqa-X37yYsrpsALhUzriZcrX3TyA&hl=en&sa=X&redir_esc=y#v=onepage&q=-data%20exclusivity%20vis-a-vis%20data%20protection&f=false) (last accessed, August 9, 2017)

US FDA Requires applicant to list patents that cover the drug as part of NDA filing in the Orange Book, a listing administered by the US FDA.

<sup>45</sup> This system was a simple compliance to the formal requirements by the BFAD application forms where generic applicants had to disclose any information known to them about the patent status of the active pharmaceutical ingredient(API) they wished to manufacture. But as to formal patent linkage system, such as that existing in the US, there is no indication of such. The US Patent Linkage System has a formal regime for generic applicants and originators as well. For example, New Drug Application(NDA) must include patent information and the FDA considers the existence of patents as part of the approval process for certain drug applications (<https://www.uspto.gov/web/offices/dcom/olia/conf.../jordanPTEandPTA.ppt>).

which was abandoned upon the issuance of Department of Health (DOH) Administrative Order No. 2005-0001.<sup>46</sup> Prior to 2005, the FDA (then, BFAD) required applicants for generic drug approval to disclose in their applications any information known to them about the status of the active pharmaceutical ingredient they intended to import or manufacture. However, due to the regulatory challenges which resulted in the lawsuit filed by Pfizer, Ltd. UK and Pfizer Philippines, Inc. against government agencies Philippine International Trading Corporation (PITC) and BFAD, for allegedly infringing on the patent rights of the anti-hypertensive drug Amlodipine Besylate or Norvasc,<sup>47</sup> the DOH removed IPR protection from the responsibilities of the BFAD. Through Administrative Order No. 2005-0001, the FDA was allowed to accept and process applications for product registration without the need to verify whether there is a relevant patent.

## B. TRADEMARKS

### 1. Trademark Rights

Section 147 of the IP Code, as amended by the QUAMA, provides that “except in cases of importation of drugs and medicines allowed under Section 72.1 of the IP Code and of off-patent drugs and medicines, the owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner’s consent from using in the course of trade identical or similar signs or containers for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. There shall be no infringement of trademarks or trade names of

imported or sold patented drugs and medicines allowed under Section 72.1 of the IP Code, as well as imported or sold off-patent drugs and medicines: *Provided*, that, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of the IP Code.”

A trademark registration certificate remains in force for 10 years, renewable for periods of 10 years: *Provided*, that the registrant shall file a declaration of actual use and evidence to that effect, or shall show valid reasons based on the existence of obstacles to such use, as prescribed by the Regulations<sup>48</sup>. Otherwise, the mark shall be removed from the Register by the IPOPHIL.<sup>49</sup>

### 2. Actions for Trademark Infringement and Limitations

The IP Code provides that any person who commits the acts enumerated under Section 155<sup>50</sup> thereof shall be liable in a civil action for infringement by the registrant for the remedies set forth therein. The civil remedies include the recovery of damages from the infringer,<sup>51</sup> injunction<sup>52</sup>, the destruction or disposal of the infringing goods outside the channels of trade without compensation, and the destructions of all labels, signs, prints, packages, wrappers, receptacles and advertisements in the possession of the defendant, bearing the registered mark or trade name or any reproduction, counterfeit, copy or colorable imitation thereof, all plates, molds, matrices and other means of making the same<sup>53</sup>. Section 170 of the IP Code also provide for criminal penalties of imprisonment and fine on any person found guilty of committing trademark infringement.

<sup>46</sup> DOH Administrative Order No. 2005-0001 provides: The acceptance for CPR applications by BFAD (now FDA) shall not be interpreted, nor construed, as an approval, endorsement, or representation that the applicant has legal right or title over any intellectual property attached to the pharmaceutical product applied for.

<sup>47</sup> Civil Case No. 06-172 filed before the Regional Trial Court of Makati City in March 2006.

<sup>48</sup> Rules and Regulations on Trademarks, Service Marks, Trade Names and Marked or Stamped Containers of 2017 or the Trademark Regulations of 2017. (Memorandum Circular No. 17-010, which took effect on 01 August 2017.

<sup>49</sup> Section 145, IP Code

<sup>50</sup> Sec. 155. Remedies; Infringement. - Any person who shall, without the consent of the owner of the registered mark: 155.1. Use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark or the same container or a dominant feature thereof in connection with the sale, offering for sale, distribution, advertising of any goods or services including other preparatory steps necessary

to carry out the sale of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or 155.2. Reproduce, counterfeit, copy or colorably imitate a registered mark or a dominant feature thereof and apply such reproduction, counterfeit, copy or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive, shall be liable in a civil action for infringement by the registrant for the remedies hereinafter set forth: *Provided*, That the infringement takes place at the moment any of the acts stated in Subsection 155.1 or this subsection are committed regardless of whether there is actual sale of goods or services using the infringing material.

<sup>51</sup> Sections 156.1 and 156.3, IP Code

<sup>52</sup> Section, 156.4, IP Code

<sup>53</sup> Section 157.1, IP Code

Section 159.4 of the IP Code, as amended by the QUAMA reiterates that, as a limitation to actions for trademark infringement, “there shall be no infringement of trademarks or trade names of imported or sold patented drugs and medicines allowed under Section 72.1 thereof, as well as imported or sold off-patent drugs and medicines: *Provided*, that, said drugs and medicines bear the registered marks that have not been tampered, unlawfully modified, or infringed upon, under Section 155 of the IP Code.” This allows the parallel importation of drugs and medicines already released in the international market.

### 3. Actions for unfair competition

Under Section 168.1 of the IP Code, a person who has identified in the mind of the public the goods he manufactures or deals in, his business or services from those of others, whether or not a registered mark is employed, has a property right in the goodwill of the said goods, business or services so identified, which will be protected in the same manner as other property rights. Any person who shall employ deception or any other means contrary to good faith by which he shall pass off the goods manufactured by him or in which he deals, or his business, or services for those of the one having established such goodwill, or who shall commit any acts calculated to produce said result, shall be guilty of unfair competition, and shall be subject to an action therefor.<sup>54</sup> The same remedies provided in cases of trademark infringement are available to trademark owners in cases of unfair competition.<sup>55</sup>

### C. COPYRIGHT

The rights of pharmaceutical companies to their original intellectual creations or “works” such as books, pamphlets, articles and other writings; periodicals and newspapers; pictorial illustrations and advertisements; and other literary, scholarly, scientific and artistic works are protected by copyright from the moment of creation.<sup>56</sup> Copyright includes the exclusive right to carry out, authorize or prevent the reproduction of the work or substantial portion of the work; translation, abridgment, other transformation of the work; the first public distribution of the original and each

copy of the work by sale or other forms of transfer of ownership; and other communication to the public of the work. Sections 184 and 185 of the IP Code, as amended by Republic Act 10372,<sup>57</sup> respectively provide for limitations of copyright and fair use of copyrighted work.

Civil remedies for copyright infringement are provided under Section 216.1 of the IP Code, which include injunction, damages, destruction without compensation of all infringing copies or devices, as well as all plates, molds, or other means for making such infringing copies as the court may order. Criminal penalties for copyright infringement are also provided under Section 217 of the IP Code, as amended.

### D. PROTECTION OF UNDISCLOSED INFORMATION OR TRADE SECRETS

Trade secrets or undisclosed information are protected under existing Philippine laws. Section 4.1 of the IP Code includes in the enumeration of IPR the “protection of undisclosed information”. While the IP Code does not define trade secrets or provide for their manner of protection, the Supreme Court, in the case of *Air Philippines Corporation v. Penswell, Inc.*<sup>58</sup>, defined a trade secret as: “(1) a plan or process, tool, mechanism or compound known only to its owner and those of his employees to whom it is necessary to confide it. (2) The definition also extends to a secret formula or process not patented, but known only to certain individuals using it in compounding some article of trade having a commercial value. (3) A trade secret may consist of any formula, pattern, device, or compilation of information that: (a) is used in one’s business; possess the information. (4) Generally, a trade secret is a process or device intended for continuous use in the operation of the business, for example, a machine or formula, but can be a price list or catalogue or specialized customer list. It is indubitable that trade secrets constitute proprietary rights. The inventor, discoverer, or possessor of a trade secret or similar innovation has rights therein which may be treated as property, and ordinarily an injunction will be granted to prevent the disclosure of the trade secret by one who obtained the information “in confidence” or through a “confidential relationship.”<sup>59</sup>

<sup>54</sup> Sections 168.2 and 168.3, IP Code

<sup>55</sup> Section 168.4, IP Code

<sup>56</sup> Section 172.1, IP Code

<sup>57</sup> An Act Amending Certain Provisions of Republic Act 8293, Otherwise Known as the Intellectual Property Code of the Philippines, and for Other Purposes

<sup>58</sup> G.R. No. 172835, December 13, 2007

<sup>59</sup> Ibid.

There are several laws that prohibit revelation of trade secrets such as Section 40(f) of the Consumer Act, which prohibits any person from using to his own advantage, or revealing (other than to the DTI or to the courts when relevant in any judicial proceeding under the Act), any information concerning any method or process which as a trade secret is entitled to protection.

The Revised Penal Code also penalizes any manager, employee or servant who, in such capacity, shall learn the secrets of his principal or master and shall reveal such secrets (Article 291) and upon the person in charge, employee or workman of any manufacturing or industrial establishment who, to the prejudice of the owner thereof, shall reveal the secrets of the industry of the latter (Article 292).

Section 5(c) of the Cybercrime Prevention Act includes among other cyber-crimes all crimes defined and penalized by the Revised Penal Code and special laws, if committed by, through and with the use of information and communications technologies. Section 4(6) further mandates that the penalty to be imposed shall be one (1) degree higher than that provided for by the Revised Penal Code and special laws, as the case may be.

Section 33(a) of the Electronic Commerce Act prohibits hacking or cracking which refers to unauthorized access into or interference in a computer system/server or information and communication system; or any access in order to corrupt, alter, steal, or destroy using a computer or other similar information and communication devices, without the knowledge and consent of the owner of the computer or information and communication system, including the introduction of computer viruses and the like, resulting in the corruption, destruction, alteration, theft or loss of electronic data messages or electronic documents. Section 33(c) of the Electronic Commerce Act also penalizes the violation of the Consumer Act or Republic Act No. 7394 and other relevant or pertinent laws through transactions covered by

or using electronic data messages or electronic documents with the same penalties as provided in those laws.

## V. USES OF IPR IN THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies in the Philippines carry out various activities in the conduct of their business operations, which involve clinical trials, manufacture or importation, and distribution and sale of drugs and medicines for originator companies and in the case of generic companies, research and innovation for product or process improvement, manufacture or importation, and distribution and sale of drugs and medicines.

Except for few originator companies, such as GlaxoSmithKline which conducts its own manufacturing in the country for both the Philippines and other Southeast Asian markets, most originator companies, which are multinationals, import and distribute finished pharmaceutical products, or import drug ingredients and outsource production to local manufacturers.<sup>60</sup> Most generic companies also import finished pharmaceutical products for distribution and sale in the country while some generic companies, such as United Laboratories, also manufacture their own products and conduct research and development to improve and innovate on existing products or production/manufacturing processes.<sup>61</sup>

The Philippine pharmaceutical industry depends heavily on imports for both raw materials and finished products.<sup>62</sup> About 95% of the materials compounded in the country are imported, and the industry is concentrated on manufacturing products discovered and developed elsewhere. Though the Philippines has a number of pharmaceutical laboratories, these laboratories are, however, geared towards toll or contract-manufacturing, not drug development.<sup>63</sup>

Originator drug companies are now seeking to undertake sustained research and development

<sup>60</sup> Wallace Pharmaceuticals Pvt. Ltd./ Dias, N., "Philippine Pharmaceutical Market Study: Trade Dynamics of the Filipino Market Place" (2017)

<sup>61</sup> Santos, R., "IP Utilization at Unilab", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>62</sup> Wallace Pharmaceuticals Pvt. Ltd./ Dias, N., "Philippine Pharmaceutical Market Study: Trade Dynamics of the Filipino Market Place" (2017)

<sup>63</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", lecture given during the November 16, 2016 IPAA Seminar entitled "Technology Protection and IPR in Healthcare", held at the Dusit Thani (Manila); citing Laman, Noel "The Use of Patents in Research and Development in the Pharmaceutical Industry" (2007).

<sup>64</sup> PHAP/IMS Consulting Group, "Partnering for Nation Building: The Contributions of the Philippine Pharmaceutical Industry to Health and Economy" (2015)

on new medicines and vaccines. According to the 2015 study made by the PHAP,<sup>64</sup> there are currently 461 ongoing local clinical trials in the Philippines, placing the country third after Singapore and Thailand in Southeast Asia. The Philippines ranks number 8 worldwide in the number of pharmaceutical industry-sponsored clinical trials. Most of these trials are part of global clinical trials. In the Philippines, the pharmaceutical industry has invested over P1 billion in R&D in 2013.<sup>65</sup> According to the Philippine Council for Health Research and Development, there was a three-fold increase in research studies and clinical trials in 2013. Around 65 research studies were funded by Contract Research Organizations (CROs) and research-based pharmaceutical companies, which are also partnering with CROs.<sup>66</sup>

Research and development has enabled originator companies to launch 21 new medicines for the country's top non-communicable diseases (cardiovascular diseases, cancer, diabetes, respiratory disease) in 2014. Originator companies have also made available to Filipinos, over the past five (5) years, 55 vaccines that prevent childhood mortality and combat communicable diseases, such as pneumonia and diarrhea. Over the last four (4) years, a total of 76 new molecules or combinations for cardiovascular diseases, cancer, diabetes and respiratory diseases were introduced by the originator companies.<sup>67</sup>

## A. PATENTS

The FGD and survey results, data from the IPOPHIL and from secondary sources show that both originator and generic drug companies use IPR in the conduct of the various activities of their business. In her presentation<sup>68</sup> made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in

Healthcare",<sup>69</sup> Lucenario<sup>70</sup> identified seven (7) strategic uses of the patent system: (1) avoidance of infringement; (2) effective acquisition of rights; (3) prevention of acquisition of rights; (4) research and development; (5) technology transfer; (6) business strategy; and (7) development of industry.

### 1. Avoidance of Infringement

Pharmaceutical companies conduct patent searches to avoid infringing the patents of others. For originator drug companies, the research, development and commercialization of new drugs are costly. Patent search is thus imperative for an originator drug company to find out whether or not the product or process that it intends to research on and develop infringes the rights of other companies. Patent search helps avoid the expenditure of funds on research and development of an already protected pharmaceutical product or process, and on defending against infringement suits.<sup>71</sup> Prior to the conduct of clinical trials in the Philippines, it is expected that originator companies would have already conducted patent searches as early as the stage of basic research.

On the other hand, generic drug companies conduct patent searches to determine whether the drug or medicine they intend to import or manufacture are covered by patent. If the product is covered by a patent, the generic company has the option to secure a license from the patentee for the manufacture or importation and sale of the patented product. If the drug or medicine is not covered by a patent, but the process for its production or manufacture is patented, the generic company can opt to license the method of production from the patentee, look for other methods of production, or develop its own method, which will not infringe on the patented process to manufacture the desired drug or medicine.<sup>72</sup>

<sup>65</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila; citing PHAP/IMS Consulting Group, "Partnering for Nation Building: The Contributions of the Philippine Pharmaceutical Industry to Health and Economy" (2015)

<sup>66</sup> Ibid.

<sup>67</sup> Ibid.

<sup>68</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>69</sup> Held on 15-16 November 2017, the seminar was organized by the Japan Patent Office (JPO), supported by Department of Intellectual Property, Ministry of Commerce (MOC, Japan) with the cooperation

of the Intellectual Property Office of the Philippines (IPPHL) and was conducted by Japan Institute for Promoting Invention and Innovation (JIPPI)

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<sup>71</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>72</sup> Santos, R., "IP Utilization at Unilab", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

A patent search is also helpful in validating acquired rights. The different types of patent searches include: (a) Compound *per se* search or equivalent search - this kind of search is carried out to identify the Philippine patent covering a certain compound or molecule; (b) Equivalent patent search - this kind of search is carried out to determine the equivalent Philippine patent of a particular patent which has been granted or filed in another country; (c) Comprehensive search – this search is conducted to identify all Philippine patents related to a particular field of invention, taking into account the new features of that invention; and (d) Legal status search – conducted to determine if a patent is still valid.<sup>73</sup>

## 2. Effective Acquisition of Rights

Originator and generic companies, whether resident or non-resident,<sup>74</sup> file applications to secure patent rights to their inventions and innovations. Data from the IPOPHIL show that from 1996 to 2016, resident pharmaceutical corporations filed a total of 129 applications for invention patents and 253 applications for utility model registrations. Non-resident pharmaceutical corporations filed a total of 17,765 applications for invention patents and two (2) applications for utility model registrations. For the past for the past twenty years, resident and non-resident pharmaceutical companies filed a total of 17,894 invention applications and 255 application for utility model registrations.

<sup>73</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>74</sup> In its database, the IPOPHIL classified pharmaceutical companies as either resident or non-resident. An applicant with a Philippine address stated in its patent application is considered as a resident while an applicant with a foreign address is considered a non-resident. A multinational originator company using the address of its Philippine branch is considered a resident.

<sup>75</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies," a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>76</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>77</sup> IMS, February 2017

<sup>78</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

Table 2 gives a break-down of the invention patent and utility model applications filed by resident and non-resident pharmaceutical companies, on a yearly basis, for the past twenty (20) years.

**TABLE 2. PATENT AND UTILITY MODEL APPLICATIONS (1996-2016)**

YEAR FILED	INVENTION		UTILITY MODEL	
	RESIDENT	NON-RESIDENT	RESIDENT	NON-RESIDENT
2016	14	765	36	
2015	9	938	31	
2014	8	862	17	
2013	10	832	11	1
2012	2	889	21	
2011	4	1041	24	1
2010	12	1036	29	
2009	5	1019	22	
2008	6	1233	24	
2007	2	1283	9	
2006	14	1192	5	
2005	9	975	4	
2004	2	985	2	
2003	1	617	3	
2002	7	114	2	
2001	3	652	2	
2000	8	992	4	
1999	8	789	1	
1998	1	852	5	
1997	3	361	1	
1996	1	338		

Source: IPOPHIL Database (As of 15 June 2017)

The top 10 patent filers from 2011-2015 are originator companies led by Novartis, Bayer, Boehringer Ingelheim, Roche, Abbott, Johnson & Johnson, Pfizer, Eli Lilly, Astra Zeneca, and GlaxoSmithKline. Except for Novartis and Bayer, which maintained their lead, most of the above companies showed a drop of patent filings in 2012-2014 with some of them (like Roche, Pfizer) recovering by 2015.<sup>75</sup>

Pascual Laboratories, a local generic company filed five (5) patent applications in 2011.<sup>76</sup> Survey results also show that United Laboratories, the leading generic company which has 25.9% of the industry market share as of February 2017,<sup>77</sup> has seven (7) pending patent applications with the IPOPHIL and seven (7) registered patents.

## 3. Prevention of Acquisition of Rights

Patents protect exclusivity. It is a grant by the state of exclusive rights for a limited time in respect of a new, inventive and useful invention. It includes

the right to prevent others from carrying out the invention claimed. Under the Philippine patent system, such right may be protected by the patentee through two kinds of actions: patent cancellation and patent infringement action.<sup>78</sup>

#### *a. Patent Cancellation*

The IP Code does not provide for pre-grant opposition proceedings similar to those found in the laws of other countries, though it provides for a procedure by which a third party may state in writing his observation on the application.<sup>79</sup> It, however, establishes a patent cancellation procedure. Under the IP Code, an interested person may petition to cancel the patent or any claim thereof, or part of the claim on any of the following grounds: (i) that what is claimed as the invention is not new or patentable; (ii) that the patent does not disclose the invention in any manner sufficiently clear and complete for it to be carried out by any person skilled in the art; or (iii) that the patent is contrary to public order or morality.<sup>80</sup> In practice, there are instances where patent cancellation is used by alleged infringers as defense against patent infringement suits, with grounds for patent cancellation be used as a defense.<sup>81</sup>

#### *b. Patent Infringement Action*

The making, using, offering for sale, selling, or importing a patented product or a product obtained directly from a patented process, or the use of a patented process without authorization of the patentee constitutes patent infringement. Under the IP Code, patent infringement suits are generally civil actions in nature. But repetition of infringement will provide an avenue for a criminal action for infringement.<sup>82</sup>

Prior to the filing of an infringement action, a patent owner has the remedy of applying with the appropriate IP Court, for the issuance of a warrant for the search and seizure of infringing goods. Originator drug companies have availed of this remedy to protect their patent rights. For example, a respondent to the survey stated that within the

last five years (2012-2016), it has undertaken three (3) actions for the search and seizure of products infringing two (2) of their product patents. They also filed a civil infringement case in court and an administrative case with the IPOPHIL.

As per IPOPHIL data, pharmaceutical companies have filed a total of 21 patent infringement cases with the BLA from 2010 to 2016.

### 4. Research and Development

Patent protection allows pharmaceutical companies to recoup investments made in the research and development of new products. This encourages pharmaceutical companies to make further investments, which stimulates research and development of new drugs and facilitates the creation of more effective drugs.<sup>83</sup>

### 5. Technology Transfer

Patents give pharmaceutical companies more control in terms of technology transfer, usually in the form of Technology Transfer Agreements (TTA). Section 4.2 of the IP Code defines TTAs as “contracts or agreements involving the transfer of systematic knowledge for the manufacture of a product, the application of a process, or rendering of a service including management contracts; and the transfer, assignment or licensing of all forms of intellectual property rights.”<sup>84</sup>

### 6. Business Strategy

Originator pharmaceutical companies may invoke its patent protection to assail the entry of generics into the market. Patent information may also be used for competitive intelligence. Pharmaceutical companies are now entering into the following arrangements to maximize their patented products: (a) *Licensing agreements*, where the patent holder grants a licensee the right to produce and sell goods, apply a brand name or trademark, or use patented technology; (b) *Co-marketing agreements*, which calls for the sale and marketing of a certain product conducted independently and under different trademarks by each party. The company that agrees to co-market the patented drug pays a certain amount as royalty

<sup>79</sup> While the IP Code does not provide for pre-grant opposition proceedings, there is a mechanism (Third Party Observation) that provides an opportunity for the public to present observations in writing on the patentability of the invention in Sec. 47.

<sup>80</sup> Ibid.

<sup>81</sup> Ibid.

<sup>82</sup> Ibid.

<sup>83</sup> Ibid.

<sup>84</sup> Ibid.

or agrees to source its supply of such drug from the patentee; and (c) *Co-promotion agreements*, which is a straight-forward licensing arrangement whereby the patent holder allows the licensee to promote and sell the patented product bearing the patent owner's mark, provided that the licensee pays the patent holder royalty fees or sources its supply from the patent holder.<sup>85</sup>

## 7. Development of Industry

Patent protection fosters research and development and incentivizes pharmaceutical companies to develop more effective drugs which treat a wider range of diseases. This promotes the pharmaceutical industry's role in improving public health.<sup>86</sup>

## B. TRADEMARKS

Trademark registration grants exclusive rights to the trademark owner to use, or authorize the use, of the registered mark on the goods covered by the registration, as well as on similar goods, for commercial purposes. Trademarks or brand names have two (2) important uses to the pharmaceutical industry: (1) protection of investment; and (2) protection of public health.<sup>87</sup>

### 1. Protection of Investment

A good trademark or brand is a valuable asset to pharmaceutical companies. For a generic pharmaceutical company, a trademark is what distinguishes its product from the same or similar drug sold by another generic company. Trademark acts as a source identifier of the goods and serves as quality assurance to the consumer, who is faced with a range of the same or similar competing generic drugs.

For originator companies, a respected and proven brand allows originator companies to continue earning substantial amounts from its off-patent drug, long after the patent for the drug has expired. For example, off-patent products like Lipitor and Norvasc remain to be among the top 20 selling drugs in the country.<sup>88</sup> Despite there being generic counterparts to branded drugs, much of the population opt to take higher priced branded drugs, upon the belief that higher-priced drugs are of a superior quality.<sup>89</sup>

The brand represents the goodwill that a product has gained through years of proven performance and efficacy. A strong brand benefits from high consumer loyalty. As of February 2017,<sup>90</sup> the brands of top products in terms of sales in the country are as follows:

<sup>85</sup> Ibid.

<sup>86</sup> Ibid.

<sup>87</sup> Ibid.

**TABLE 3. TOP PRODUCTS IN TERMS OF SALES (AS OF FEBRUARY 2017)**

YEAR		PRODUCTS/BRANDS
02/2017	02/2016	
1	1	MYRA E
2	3	ENSURE
3	2	BIOGESIC
4	6	TEMPRA
5	7	ENERVON C
6	5	SOLMUX
7	4	NEOZEP
8	9	TWYNSTA
9	8	CEELIN
10	18	BIOFLU
11	15	JANUMET
12	10	LIPITOR
13	11	VENTOLIN
14	28	TRAJENTA
15	24	CEELIN PLUS
16	16	LANTUS
17	17	MICARDIS
18	12	NORVASC
19	20	DIAMICRON
20	25	PIPTAZ

Source: IMS (February 2017)

Pharmaceutical companies protect their trademarks in three (3) ways: (a) through registration; (b) trademark opposition or cancellation; and (c) infringement action.

#### *a. Registration*

Originator and generic companies, resident and non-resident,<sup>91</sup> obtain trademark registrations to protect their exclusive rights to their trademarks. Data from the IPOPHIL show that from 1996 to 2016, resident pharmaceutical corporations filed a total of 37,960 trademark applications by direct filing. Non-resident pharmaceutical corporations filed a total of 42,882 trademark applications by direct filing and 4,620 applications via the Madrid system or a total of 47,502 trademark applications.

<sup>88</sup> IMS, February 2017 Drugstore + Hospital Sales

<sup>89</sup> Wallace Pharmaceuticals Pvt. Ltd./ Dias, N., "Philippine Pharmaceutical Market Study: Trade Dynamics of the Filipino Market Place" (2017)

<sup>90</sup> IMS, February 2017

<sup>91</sup> In its database, the IPOPHIL classified pharmaceutical companies as either resident or non-resident. An applicant with a Philippine address stated in its trademark application is considered as a resident while an applicant with a foreign address is considered a non-resident. A multinational originator using the address of its Philippine branch is considered a resident.

Table 4 gives a break-down of the trademark applications filed by resident and non-resident pharmaceutical companies, on a yearly basis, for the past twenty (20) years:

**TABLE 4. TRADEMARK APPLICATIONS (1996-2016)**

YEAR FILED	DIRECT		MADRID	
	RESIDENT	NON- RESIDENT	RESIDENT	NON- RESIDENT
2016	3521	2330		1263
2015	3646	2357		1475
2014	3478	2644		941
2013	3053	2293		852
2012	2775	2548		89
2011	2504	2610		
2010	2581	2407		
2009	2345	2287		
2008	2298	2487		
2007	2065	2294		
2006	1820	2043		
2005	1579	2031		
2004	1229	1907		
2003	1135	1794		
2002	949	1726		
2001	717	1486		
2000	565	1498		
1999	777	1557		
1998	425	1534		
1997	279	1596		
1996	219	1453		

Source: IPOPHIL Database (As of 15 June 2017)

The top 10 trademark filers from 2011-2015 are Johnson & Johnson, Novartis, Boehringer Ingelheim, Abbott, GlaxoSmithKline, United Laboratories, Bayer, Merck Sharp and Dohme, Innogen Pharma Group, and Getz Pharma.

Statistics shows that originator companies lead in terms of filing patent applications while generic companies (United Laboratories, Innogen Pharma, Getz Pharma) are strong on trademark filings.<sup>92</sup> Survey results show that in 2016 alone, United Laboratories filed 145 applications and 44 trademark renewals.

<sup>92</sup> Lucenario, D., "IP Utilization of Innovative Drug Companies", a presentation made at the Intellectual Property Alumni Association (IPAA) seminar on "Technology Protection and IPR in Healthcare", held on November 15-16, 2017 at the Dusit Thani, Manila

<sup>93</sup> Section, 156.4, IP Code

## *b. Opposition and Cancellation*

Under the IP Code, a mark that is identical or confusingly similar to a registered mark, used on identical or similar products, cannot be registered. Any person who believes that he will be damaged by the registration of a mark has the remedy of filing an apposition to its registration or the cancellation of an identical or confusingly similar mark once the same has already been registered.

Due to the health risks that can be posed by a confusingly similar mark, pharmaceutical companies closely monitor any possible infringement of their trademarks and resort to filing the necessary opposition or cancellation cases with the BLA of the IPOPHIL. For example, survey shows that in 2016 alone, United Laboratories filed 91 opposition cases and has a total of 278 *inter-partes* cases pending with the IPOPHIL.

## *c. Infringement Action*

Under the IP Code, a trademark owner has the remedy of filing an action for infringement, which can be civil or criminal or both. Civil remedies include injunction<sup>93</sup> and the recovery of damages from the infringer<sup>94</sup> while the imposable criminal penalties are imprisonment and fine.<sup>95</sup>

Prior to the filing of an infringement action, a trademark owner has the remedy of applying with the appropriate IP Court, for the issuance of a warrant for the search and seizure of infringing goods. Originator and generic drug companies have availed of this remedy to protect their trademark rights. For example, a generic company, respondent to the survey, stated that in 2016, it conducted 10 raids against drugstores and warehouses as part of its efforts against counterfeit products.

## **2. Public Health Protection**

Pharmaceutical trademarks promote the protection of public health in three (3) ways. Trademarks (a) assist health professionals reduce medication errors; (b) enable consumers to choose the medications that are right for them; and (c) provides

<sup>94</sup> Sections 156.1 and 156.3, IP Code

<sup>95</sup> Section 170, IP Code

manufacturers with the incentive to develop new drugs and monitor the safety of existing drugs.<sup>96</sup>

“Trademarks provide the best method by which pharmaceuticals can be prescribed and prescriptions filled. Though no system is foolproof, the use of pharmaceutical trademarks, in conjunction with ongoing efforts to encourage health care providers to be mindful of look-alike/sound-alike drug names, is far more likely to minimize medication errors than any other alternative. Pharmaceutical trademarks allow health care professionals to minimize prescription errors, allow consumers to readily identify the specific medications they are taking and allow drug manufacturers to monitor their products, and to take steps to fight counterfeiting as well as providing manufacturers with the incentive to develop new drugs. Pharmaceutical trademarks, therefore, benefit the health and safety of the patient and in turn, the entire healthcare system.”<sup>97</sup>

### C. COPYRIGHT

The pharmaceutical industry is highly dependent on scientific, technical and medical literature. Published information is needed in all stages of drug development and post market surveillance. Pharmaceutical companies are both heavy users of copyright material and key contributors of scientific, technical and medical literature.<sup>98</sup>

Pharmaceutical companies use copyrighted materials in all aspects of business operations. For example, at the stage of clinical trial, many of which take place in the country, collaboration among peers is vital. Sharing scientific content from published works throughout the organization and across borders is essential to the ongoing exchange of ideas. Researchers quite often share information with their peers, yet many of them are unaware of their responsibilities when it comes to using copyrighted material. Some companies adopt copyright policies to educate and guide their employees on copyright compliance.<sup>99</sup>

Pharmaceutical companies also use copyrighted materials in obtaining regulatory approval. The FDA requires manufacturers and applicants for new drugs to promptly report any adverse reactions to medicines. Copyright compliance becomes important when previously published material is used in the process of obtaining regulatory clearance for drugs and medicines.<sup>100</sup>

For drug monitoring purposes, pharmaceutical companies maintain pharmaco-vigilance databases of their products. Drug monitoring helps ensure the safety of drugs in the development pipeline and those already approved for marketing. Storing published information about the company's products in up-to-date databases allows the pharmaceutical company's pharmacovigilance department to distribute time-sensitive information quickly as an early warning tool for the detection, assessment and prevention of possible adverse effects.<sup>101</sup>

Another area where copyrighted material is used is in product support. Doctors and other healthcare professionals often ask pharmaceutical companies to provide scientifically-validated information, including full-text articles from peer-reviewed journals. These published works typically come with specific permissions and restrictions guiding how they can be distributed.<sup>102</sup> For example, an originator company, respondent to the survey, stated that they use their copyright in the importation, distribution and sale of their products to prevent unauthorized copying of their marketing materials and position papers.

### D. TRADE SECRETS

Trade secrets are confidential information that: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c)

<sup>96</sup> INTA/Greene, D., et.al., “International Trademark Association Educational Brief: The Importance of Pharmaceutical Trademarks in Protecting Health” (2007); <http://www.inta.org/Advocacy/Documents/INTAPharmaceuticalTrademarksPublicHealth2007.pdf> (last accessed, 16 June 2017)

<sup>97</sup> Ibid.

<sup>98</sup> Scott, E., “Copyright and the Pharmaceutical Industry”, Glaxo Wellcome plc., Greenford Middlesex U.K., (1997)

<sup>99</sup> Alzapiedi K., “Copyright Compliance in the Life Sciences Industry” (2014), LSIPR Newsletter 03.14; [https://www.rightsdirect.com/wp-content/uploads/sites/6/2015/04/rd\\_byline\\_lsipr\\_03\\_2014.pdf](https://www.rightsdirect.com/wp-content/uploads/sites/6/2015/04/rd_byline_lsipr_03_2014.pdf) (last accessed 17 June 2017)

<sup>100</sup> Ibid.

<sup>101</sup> Ibid.

<sup>102</sup> Ibid.

has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.<sup>103</sup> A trade secret derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use.

Unlike patents, there is no requirement for a trade secret to demonstrate any statutory requirements before qualifying for protection. Therefore, trade secrets relating to subject matter excluded from patentability, such as abstract ideas, client information and experimental data may represent valuable assets.<sup>104</sup>

Trade secrets include such things as a company's manufacturing processes and precise product formulations. In the pharmaceutical industry, trade secrets are used to protect laboratory books, drug and clinical test data, product formulas and production processes and know-how that underlie patents. Data generated from clinical research is crucial to shaping drug development and is, thus, a coveted IP asset. However, while details of clinical trial methodologies and primary data are extremely valuable, these are generally not patentable.<sup>105</sup> Data from clinical tests conducted in the Philippines are protected as trade secrets.

Trade secrets, unlike patents, do not confer exclusivity. The proprietor of a trade secret cannot enforce any rights over parties who independently derive or reverse-engineer the same information. A competitor who discloses the trade secret, irrespective of means, could also render it worthless.<sup>106</sup> In order to protect their trade secrets, pharmaceutical companies generally have a strict policy regarding the proprietary nature of all information relating to R&D and manufacture. For example, under GSK's internal policies, GSK information could not be released externally unless it had been "approved for external release" to a third party under an appropriate confidentiality agreement, or a disclosure required by law.<sup>107</sup>

<sup>103</sup> Article 39.2, TRIPS Agreement

<sup>104</sup> Sanderson, A. and Zhuang L., "Life Sciences Intellectual Property Review: The Value of Secrecy for Big Pharma" (2016); <http://www.lifesciencesipreview.com/contributed-article/the-value-of-secrecy-for-big-pharma> (last accessed, 17 June 2017)

<sup>105</sup> Ibid.

<sup>106</sup> Ibid.

<sup>107</sup> Armstrong, A. "Trade Secret Protection in the Pharma Industry", *Pharmaceutical Patent Analyst*, September 2016, Vol. 5, No. 5, Pages 285-288; <http://www.future-science.com/doi/abs/10.4155/ppa-2016-0022?journalCode=ppa> (last accessed, 17 June 2017)

An originator company, respondent to the survey, stated that they utilize confidentiality agreements to prevent unauthorized copying of their study designs and manufacturing process and to prevent gaining insight into their financials. Another respondent, a generic drug company, stated that they execute confidentiality agreements with the toll manufacturers of their products.

## VI. IPR CONCERNS

During the FGD and in response to the survey questionnaires, pharmaceutical companies, particularly originator companies, raised their concern as to the need for effective patent enforcement in the country. Three particular issues/recommendations were raised as to this matter: (1) the adoption of best practices in implementing the Bolar provision; (2) the adoption of a patent linkage system in the regulatory approval of drugs; and (3) the adoption of measures to address the lengthy period taken in resolving patent cases.

### A. BOLAR PROVISION

Under Article 72.4 of the IP Code, as amended by the QUAMA, the act of testing, using, making or selling drugs and medicines including any related data, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product, is allowed as a limitation of patent rights.

Section 72.4 of the IP Code also provides that, in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 TRIPS Agreement, the IPOPHIL, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary, not later than 120 days after the enactment of this law. Pursuant thereto, the DoH, the DTI, the IPOPHIL and the BFAD (now, FDA) adopted Joint Administrative Order 2008-01 implementing the QUAMA.

The IRR, however, did not provide specific guidelines on the implementation of the Bolar provision. Originator drug companies recommended that best practices used in other countries be likewise adopted in the Philippines. For example, it is suggested that the period for early working should be defined as against the current practice of generic companies working the patented product 10 to 15 years before the patent expiration. Originator

companies stated that the absence of a defined period for early working, coupled with the lack of a patent linkage system, has allowed unauthorized third parties to commercialize their products even before the patent has expired. The monitoring of these activities is resource-intensive on the part of originator companies, who point out that they can use such resources in more productive ways, such as in research and development of new and more effective drugs.

A generic company, which has availed of this provision, stated that for them to start working a patented product 10 to 15 years before the expiration of the patent is impractical, if not improbable, since a Certificate of Product Registration (CPR) only has a validity period of five (5) years. It was pointed out that the development, testing and experimental work for the development of generic medicine may last from six (6) month to two (2) years. The period allowed for early working must be such that will allow generic products to be commercially available as soon as the patent expires. An unreasonably short period will only delay the entry of generic medicines into the country.

The establishment of specific and clear guidelines to implement the Bolar provision is recommended, adopting the best practices in other jurisdictions, which are applicable in the Philippines and which will ensure a balance between IPR protection and access to essential medicines. With regard to fixing a specific period for early working, the duration must be sufficient to allow generic products to be commercially available as soon as the patent expires.

## **B. PATENT LINKAGE**

Patent linkage is a system whereby the issuance by the regulatory authority of marketing approval to any third person seeking to market a patented pharmaceutical product is precluded, unless by consent or acquiescence of the patent holder, based on patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office.

The Philippines had in place a patent-linkage scheme which was abandoned in 2005 when the DoH issued Administrative Order No. 2005-0001, which removed patent linkage, and IPR protection in general, from the responsibilities of the FDA (then, BFAD). The BFAD was allowed to accept and process applications for product registration

without the need to verify whether there is a relevant patent. The purpose of the removal was to enable the BFAD to perform its core mandate of ensuring the safety, efficacy and quality of medicines in the country, without being embroiled in patent conflicts.

The removal of the patent linkage scheme is a major concern for originator pharmaceutical companies, which recommend the repeal of A.O. 2005-0001 and the adoption of mechanisms for the timely resolution of patent issues prior to the marketing of follow-on products by third parties. Originator companies stated that the removal of patent linkage has resulted in them having to pursue costly and time consuming legal remedies requiring lengthy litigation to protect products from patent infringement prior to patent expiration. They submitted that if a patent linkage system was in place, the government could alleviate the legal resource burdens as well as restore the rights of patent holders. Originator pharmaceutical companies recommend that the government take a holistic approach with respect to IPR to ensure that patents are effectively enforced. This would include a coordinated effort with the IPOPHIL and the FDA to, among others, preclude issuance of a certificate of product registration for a follow-on medicine by the FDA until the relevant patents on the originator product have expired, or there has been a timely resolution of patent infringement issues.

Generic companies, on the other hand, point out that the role of drug regulatory agencies is to protect public health, not to take part in private disputes about intellectual property protection. Generic companies object to this system, not only because patent linkage offers pharmaceutical patent holders an advantage not available to patent holders in other areas of technology, i.e., the use of the health and regulatory mechanism to facilitate the enforcement of their patents, but also because patent linkage can create an additional burden on medicines regulators.

Moreover, it is argued that patent linkage can unnecessarily delay the entry of generic medicine into the country. As an example, a generic company cited the case of felodipine, where the then BFAD stopped processing applications for marketing approval of generic versions of felodipine, on the basis of a letter they received from the patent owner, asking them to cease and desist from processing generic drug applications because it had a patent over the product. For fear of being sued, BFAD stopped processing generic drug applications for felodipine, without even knowing

what the relevant patent was. It turned out that it was a process patent, not a molecular patent, and the generic applicant was using another process which was in fact non-infringing and even had a US patent of its own. In the case of process patents, unlike product patents, there is no way to determine whether the process being used by the other party is infringing unless an infringement case is filed in court. One cannot determine process infringement simply by looking at the product. The patent linkage system was removed because the DOH saw the problem of linking patents with drug registration. To insulate itself from further being embroiled in patent disputes, it incorporated the “free and harmless” provision in its Certificates of Product Registration (CPR).

Health activists claim that the development implications of patent linkage provisions may be substantial, as they may unduly restrain generic competition that reduces drug prices and increases access to medicines.<sup>108</sup> The United Nations Rapporteur on the Right to Health has cautioned developing countries against adopting a system of patent linkage.<sup>109</sup> It was pointed out that patent linkage is not required by the TRIPS Agreement as a means of patent protection and is not implemented in the European Union.

A careful consideration of the pros and cons of patent linkage must be made before initiating any move to establish a patent linkage system. The goal must be to strike a workable balance between providing effective IPR protection and ensuring access to essential medicines. The capacity of the FDA and the IPOPHIL to implement a patent linkage system, in terms of fiscal and human resources, must also be considered.

A very important factor to consider is the fact that the TRIPS Agreement does not require patent linkage as a means of patent protection and that it is not implemented in the European Union. Moreover, its adoption is even discouraged by health activists. Without resorting to the patent linkage system, specific measures can be adopted to provide effective and cost efficient patent protection for originator companies, such as the streamlining of court procedures to ensure the speedy disposition of patent cases. In this regard, the Supreme Court, in 2011, approved the Rules of Procedure for Intellectual Property Rights Cases

(A.M. 10-3-10-SC), which if strictly followed will substantially reduce the duration of patent litigation. To avoid lengthy and costly patent litigation, IP courts and the litigants must ensure that the Rules must be strictly followed. Trial dates must also be scheduled as closely as possible.

### **C. RESOLUTION OF PATENT CASES**

Another issue raised by originator companies is the lengthy period it takes for the courts, including the IPOPHIL, to resolve patent infringement cases. They stated that the slow resolution of patent cases has enabled alleged patent infringers to engage in the strategy of resorting to patent cancellation counterclaims, in response to infringement actions, to thwart any request for injunction, as the issue of patent validity becomes a prejudicial question. This has allowed alleged infringers to sell their products in the long period it takes for the patent case to be resolved, resulting in considerable damage to originator companies.

It was suggested that to facilitate the resolution of patent cases, IPR trainings be provided to judges of IPR courts and that the IPOPHIL engage the services of more hearing officers to handle the IPR cases filed with the IPOPHIL. In this regard, the IPOPHIL has been active in providing IPR trainings to Judges of IPR Courts, prosecutors, and other adjudication officials.

For the speedy disposition of patent cases, it is recommended that the Rules of Procedure for Intellectual Property Rights Cases (A.M. 10-3-10-SC) be strictly applied by the IP courts. In the case of the IPOPHIL, the BLA must regularly review and and revise, as may be necessary, the IPC and IPV Rules. Trial dates must also be scheduled as closely as possible so that cases may be resolved at the soonest possible time.

### **D. SPECIAL COMPULSORY LICENSING**

As part of the study, the IPOPHIL Director General requested that pharmaceutical companies be consulted regarding Section 93-A of the IP Code, particularly as to their suggested procedures on how the provision should be implemented, considering the absence of specific guidelines in the Joint Administrative Order 2008-01 issued by the DoH, DTI, IPOPHIL and BFAD.

Section 93-A of the IP Code provides that, as an additional special alternative procedure to ensure access to quality affordable medicines, special compulsory licenses may be issued by the IPOPHIL upon the recommendation of the Secretary of

<sup>108</sup> Correa, C. “Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines,” South Centre Research Paper 62 (September 2015)

<sup>109</sup> UNITAID, “The Trans-Pacific Partnership Agreement: Implications for Access to Medicines and Public Health”

Health. The special compulsory license shall be an exception to Sections 100.4<sup>110</sup> and 100.6<sup>111</sup> of the IP Code and shall be immediately executory. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

The pharmaceutical companies responded that the grounds for the issuance of a special compulsory license should be the same as those for the issuance of a compulsory license under Section 93 of the IP Code<sup>112</sup>, which grounds must be more strictly applied, considering the special nature of the compulsory license. There must be due process and transparency in the issuance of a special compulsory license. Pharmaceutical companies must be given notice and the opportunity to contest

<sup>110</sup> 100.4. Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: Provided, That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive.

<sup>111</sup> 100.6. The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process, to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration.

<sup>112</sup> SEC. 93. Grounds for Compulsory Licensing

The Director of Legal Affairs 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:

93.1. National emergency or other circumstances of extreme urgency;

93.2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or

93.3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or

93.4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;

93.5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, that the importation of the patented article shall constitute working or using the patent.

<sup>113</sup> Beall, R., "Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access" (April 2016); [http://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_gc\\_ip\\_ge\\_16/wipo\\_gc\\_ip\\_ge\\_16\\_brief.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_brief.pdf) (last accessed, August 9, 2017)

<sup>114</sup> PHAP/IMS Consulting Group, "Partnering for Nation Building: The Contributions of the Philippine Pharmaceutical Industry to Health and Economy," (2015)

the issuance of a compulsory license, which must be issued only upon a showing that reasonable efforts have been exerted by the proposed licensee to negotiate a voluntary license. The issuance of the compulsory license must be upon reasonable grounds and not only because of disagreements as to pricing between the pharmaceutical company concerned and the DOH. The compulsory license must also be for a limited period and only for the duration that the ground for the issuance exists.

In granting compulsory license or special compulsory license, the IPOPHIL must keep in mind that 95% of the essential medicines listed the MLEM (18th Edition) are already off-patent.<sup>113</sup> The IPOPHIL must confirm that the drug involved is in fact covered by a patent, considering that accurate patent information is not readily available in most countries.

## VII. CONCLUSION AND RECOMMENDATIONS

Pharmaceutical companies in the Philippines undertake various activities in the course of their business operations, which require the use of IPR. As part of their worldwide R&D, originator companies are conducting clinical trials in the Philippines in an increasing number, such that the Philippines is now ranked third in South East Asia, next to Thailand and Singapore in terms of the number of pharmaceutical industry sponsored clinical trials. In 2013, the pharmaceutical industry has invested over Php1 billion in R&D in the Philippines. Due to its R&D investments, originator companies were able to introduce, in the last four (4) years, 76 molecules or combinations for the country's top non-communicable diseases. Originator companies also made available over the past five (5) years, 55 vaccines that prevent childhood mortality and combat communicable diseases, such as pneumonia and diarrhea.<sup>114</sup> The pharmaceutical industry invests a significant amount of time and resource in the development of new drugs and vaccines. In order to recover the huge investments required in the discovery, research and development, manufacturing and commercialization of new and more effective drugs and medicines, originator companies rely on the effective protection and enforcement of their patent rights.

As observed in this study, IPR is used by the various players in the pharmaceutical industry according to their particular perspectives:

- **Originator companies** use patents and the patent system for the purpose of avoiding infringement, acquiring patent rights, preventing acquisition of rights, research and development, technology transfer, business strategy and industry development.
- **Generic companies**, on the other hand, conduct patent searches to avoid patent infringement. Generic companies also use the patent system to innovate and improve on existing products or processes. With the passage of the QUAMA, generic companies are able to utilize the flexibilities allowed under the TRIPS Agreement, such as the Bolar provision, which allows the early working of patented drugs and medicines for the purpose of securing marketing licenses, so that generic companies are able to commercialize drug as soon as the patent expires.
- **Pharmaceutical companies** also utilize other IPR such as (a) trademarks, to protect their investment and to promote public health; (b) copyright to protect original works necessary in research and development, securing regulatory approval, pharmacovigilance and product and support; and (c) trade secrets to protect vital but un-patentable proprietary information such as clinical trial data, product formulations and manufacturing process.

In the course of the FGD and in response to the survey, originator companies have raised their concern regarding the effective protection and enforcement of their patent rights. They perceive that certain provisions of the QUAMA, such as the Bolar provision, have placed them at a disadvantage. With the Bolar provision and the abolition of the patent linkage system, originator companies state that unauthorized third parties are able to commercialize patented drugs and medicines, even before the patent has expired. This has necessitated originator companies to engage in resource intensive monitoring efforts.

Originator companies recommended the adoption of best practices in the implementation of the Bolar provision, such as defining the period for the early working of patented products. Originator companies also recommended the adoption of a patent linkage system that will preclude the issuance of CPR for products until the patent

expires, through the coordinated efforts of the FDA and the IPOPHIL.

Generic companies, argue, on the other hand, that the role of drug regulatory agencies is to protect public health, not to take part in private disputes about intellectual property protection. Patent linkage creates an additional burden on medicines regulators. Patent linkage also provides pharmaceutical patent holders an advantage not available to patent holders in other areas of technology, at the expense of the government. With regard to the Bolar provision, generic companies stated that the period allowed for early working must be such that will allow generic products to be commercially available as soon as the patent expires.

The authors recommend the establishment of specific and clear guidelines to implement the Bolar provision, adopting the best practices in other jurisdictions, which will ensure a balance between IPR protection and access to essential medicines. On the other hand, considering that patent linkage is not required under the TRIPS Agreement and is not implemented in the European Union, the authors do not recommend the establishment of a patent linkage system. Specific measures can be adopted to provide effective and cost efficient patent protection for originator companies, such as the streamlining of court procedures to ensure the speedy disposition of patent cases.

In the formulation and implementation of policies for protecting IPR and providing access to essential medicines, it is important to note that 95% of essential drugs listed in the MLEM are already off-patent.<sup>115</sup> As recommended by Beall in the 2016 WIPO study discussed above, a pragmatic approach to improve access to essential medicines is to target interventions, such as licensing agreements authorizing generic manufacturing and/or procurement, squarely upon the specific cases where patenting exists for essential medicines and poses a barrier to access. To take such an approach, the first policy intervention needed is *to increase the level of patent transparency on essential medicines*.<sup>116</sup> Accurate patent information on MLEM products is not readily available in most countries, which may act as a deterrent to potential manufacturers and exporters of essential

<sup>115</sup> Beall, R., "Patents and the WHO Model List of Essential Medicines (18th Edition): Clarifying the Debate on IP and Access" (April 2016); [http://www.wipo.int/edocs/mdocs/mdocs/en/wipo\\_gc\\_ip\\_ge\\_16/wipo\\_gc\\_ip\\_ge\\_16\\_brief.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_brief.pdf) (last accessed, August 9, 2017)

<sup>116</sup> Ibid, page 4.

medicines, who may erroneously believe there is patent protection where there is none.<sup>117</sup> The need for patent transparency extends to generic manufacturers, as they sometimes hold patents on products commonly believed to be patent-free.<sup>118</sup> The IPOPHIL can initiate patent transparency by publishing a list of patented drugs and off-patent drugs.

The importance of protecting the IPR of pharmaceutical companies cannot be over-emphasized. The pharmaceutical industry contributes to nation building by, among others, promoting greater access to healthcare among Filipinos, by providing a wide variety of essential medicines and vaccines. In addressing the concerns raised by the pharmaceutical companies, the government must adopt an integrated and holistic approach that seeks to strike a balance between IPR protection and access to medicines. IPR flexibilities must be maintained to ensure and increase access to essential drugs. Fair competition in the pharmaceutical industry must be promoted. Cooperation between government and industry must be strengthened with the view of establishing an environment that stimulates innovation, while ensuring widespread access to quality and affordable medicines. Seeking the right balance between the two concerns is not easy in practice, and strong and vocal advocacies on either side make it all the more a great policy challenge. The criterion of the greatest good for the greatest number, reckoned over the short to long term, should be the yardstick for good policy. In the end, informed public dialogue and consensus seeking should determine the right course of action to take, especially when future trade negotiations bring these opposing positions to the fore.

<sup>117</sup> Ibid.

<sup>118</sup> Ibid.

## ANNEX

### A. SURVEY ON INTELLECTUAL PROPERTY RIGHTS UTILIZATION BY PHARMACEUTICAL COMPANIES IN THE PHILIPPINES FOR ORIGINATOR COMPANIES

The Makati Business Club (MBC) is currently conducting a research focused on determining how pharmaceutical companies in the Philippines utilize Intellectual Property Rights (IPR). By providing a baseline assessment, the study seeks to identify how the current IP legal and regulatory framework impacts the operations of local and multinational pharmaceutical firms.

The study is expected to assist the pharmaceutical industry in responding to proposed legal and policy changes in the field of intellectual property, especially on matters that affect the industry, as the Philippines explore and enter into bilateral and regional economic agreements. This will be submitted to the Intellectual Property Office and the Department of Trade and Industry, and will also be made available to industry stakeholders and the general public.

In line with the aforementioned objectives, we are requesting 30 to 40 minutes of your time to answer this questionnaire. Your responses will be kept confidential and will be analyzed in aggregate.

Your participation is invaluable to the completion of this study. Thank you very much!

#### **Study authors:**

Atty. Maria Gladys Vilchez (Lead Researcher)

Mr. Ryan Joseph Dizon (Research Associate)

For completed questionnaires, please fax them to **(02) 750-7405 or (02) 750-7406**. You may also email them at **[makatibusinessclub@mbc.com.ph](mailto:makatibusinessclub@mbc.com.ph)**. We would appreciate getting your responses by 31 March 2017 (Friday).

Should you have any queries about the questionnaire or the research undertaking, please contact Mr. Ryan Dizon at **[ryandizonjoseph@gmail.com](mailto:ryandizonjoseph@gmail.com)** or **+63917-625-2182**.

### **SURVEY ON INTELLECTUAL PROPERTY RIGHTS UTILIZATION BY PHARMACEUTICAL COMPANIES IN THE PHILIPPINES**

#### **FOR ORIGINATOR COMPANIES**

Name of Company:

Start Date of Operations in the Philippines:

#### **I. Profile**

##### **1. Which of the following describes your company?**

*Please select only one answer.*

- ☐ Multinational Company subsidiary/branch/representative
- ☐ Filipino company

##### **2. What class of drugs does your company deal in/manufacture/sell?**

*Please select all that apply from the following WHO Anatomical Therapeutic Chemical (ATC) classification system main groups.*

- ☐ Alimentary tract and metabolism
- ☐ Blood and blood forming organs
- ☐ Cardiovascular system
- ☐ Dermatologicals
- ☐ Genito urinary system and sex hormones
- ☐ Systemic hormonal preparations, excl. Sex hormones and insulins
- ☐ Antiinfectives and immunomodulating agents
- ☐ Musculo-skeletal system
- ☐ Nervous system
- ☐ Antiparasitic products, insecticides and repellents
- ☐ Respiratory system
- ☐ Sensory organs
- ☐ Various

**II. Activities & IPR****A. RESEARCH & DEVELOPMENT****3. Which of the following R&D activities does your company (including your parent company) carry out in the Philippines? Identify the intellectual property right/s (IPR) utilized by your company in such activities.**

*Please tick all activities (as defined in Annex A of this questionnaire) and the corresponding IPR that apply.*

**A. Basic Research**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**B. Discovery**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**C. Formulation, delivery, packaging development**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**D. Pharmacokinetics and drug disposition**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**E. Preclinical toxicology testing and IND application**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**F. Clinical Trial (Phase I)**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/>            | <input type="checkbox"/>               |
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**G. Clinical Trial (Phase II)**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**H. Clinical Trial (Phase III)**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**I. Clinical Trial (Phase IV)**

- |                                     |  |
|-------------------------------------|--|
| <input type="checkbox"/> Patents    | <input type="checkbox"/> Trade Secrets |
| <input type="checkbox"/> Trademarks | <input type="checkbox"/> Copyright     |

**3.a. How is/are the identified IPR utilized by your company in such activities as noted in the above table, conducted in the Philippines?**

*Please refer to above number/letter code for your responses.*

*Example: 1.A. (Use of patent/s in basic research) – “At the level of basic research, patent search is conducted to determine the state of the art and to avoid duplication of R&D efforts and spending.”*

**4. Based on the total number of basic research undertaken worldwide by your company (including parent company), how many have been conducted in the Philippines in the last 5 years (from 2012-2017)?**

*If none, write “0” and skip to question number 5.*

**4.a. Of basic research conducted in the Philippines, how many are now ongoing?****5. Does your company have its drugs manufactured in the Philippines?**

*Please select only one answer.*

- ☐ Yes ☐ No (Skip to question 10)

**6. What percentage of drugs manufactured in the Philippines are sold locally?**

*Please select only one answer.*

- |                                     |                                      |
|-------------------------------------|--------------------------------------|
| <input type="checkbox"/> 0%         | <input type="checkbox"/> 51% to 75%  |
| <input type="checkbox"/> 1% to 25%  | <input type="checkbox"/> 76% to 100% |
| <input type="checkbox"/> 26% to 50% |                                      |

**7. What percentage of drugs manufactured in the Philippines are exported?**

*Please select only one answer.*

- |                                     |                                      |
|-------------------------------------|--------------------------------------|
| <input type="checkbox"/> 0%         | <input type="checkbox"/> 51% to 75%  |
| <input type="checkbox"/> 1% to 25%  | <input type="checkbox"/> 76% to 100% |
| <input type="checkbox"/> 26% to 50% |                                      |

**8. Who manufactures the drugs in the Philippines?**

*Please select only one answer.*

- ☐ Company's own manufacturing facility in the Philippines
- ☐ Toll manufacturer
- ☐ Both

9. If your company manufactures drugs in the Philippines, either at its own manufacturing facility, through a toll manufacturer or both, please state how the following IPR is/are used by your company in the manufacture of drugs. Choose all applicable IPR and provide a summary statement in the appropriate box/es. Example: If your company manufactures drugs through a toll manufacturer and trade secrets are involved in the arrangement, the following answer may be written in the second column (2. Toll Manufacturer) and 3rd row (C. Trade Secrets): Trade secrets relating to the detailed process for drug manufacture are divulged to the toll manufacturer and are covered by a non-disclosure agreement.

IPR	MANUFACTURER	
	1. Own Manufacturing Facility	2. Toll Manufacturer
A. Patents		
B. Trademarks		
C. Trade Secrets		
D. Copyright		

10. Does your company import drugs to be sold locally?

Please select only one answer.

☐ Yes ☐ No (Skip to question 11)

- 10.a. If your company imports drugs to be sold locally, provide a summary statement on how the following applicable IPR is/are used by your company in the importation of drugs.

Please write answer in appropriate box for all applicable IPR used.

IPR	IMPORTATION
A. Patents	
B. Trademarks	
C. Trade Secrets	
D. Copyright	

11. Does your company market/distribute/sell drugs in the Philippines?

Please select only one answer.

☐ Yes ☐ No (Skip to question 12)

- 11.a. If your company markets/distributes/sells drugs in the Philippines, provide a summary statement on how for the following IPR is/are used by your company in the marketing/ distribution/ sale of drugs in the Philippines.

Please write answer in appropriate box for all applicable IPR used.

IPR	IMPORTATION
A. Patents	
B. Trademarks	
C. Trade Secrets	
D. Copyright	

12. Under what business agreement/s does your company manufacture/market/distribute/sell drugs in the Philippines? Identify the IPR used in such agreement/s.

Please tick all business agreements and IPR that apply. For the definition of each business agreement, please refer to Annex B. Please specify other agreement if column 4 (Others) is checked.

IPR	BUSINESS AGREEMENT TYPE			
	1. Licensing Agreements	2. Co-Marketing Agreements	3. Co-Promotion Agreements	4. Other:
A. Patents				
B. Trademarks				
C. Trade Secrets				
D. Copyright				

- 12.a. Provide a summary statement on how the identified IPR is/are used by your company in such agreements as marked in the above table.

Please refer to above number/letter code for your responses.

13. Based on your company's total drug portfolio worldwide, what is the percentage of drugs that are sold in the Philippines?

Please select only one answer.

☐ 1% to 25% ☐ 51% to 75%  
☐ 26% to 50% ☐ 76% to 100%

**14. Based on the total number of drugs manufactured/ imported/ commercialized by your company in the Philippines, what is the percentage of drugs is protected by Philippine trademark registration/s?**

*Please select only one answer. If 0%, please tick the box below and skip to question number 18.*

- ☐ 0%                      ☐ 51% to 75%  
☐ 1% to 25%           ☐ 76% to 100%  
☐ 26% to 50%

**14.a. Based on the total number of drugs manufactured/imported/commercialized by your company in the Philippines, what is the total number of drugs protected by Philippine trademark registration/s?**

**14.b. In whose name are the Philippine trademarks registered?**

- ☐ Parent company  
☐ Philippine subsidiary/branch  
☐ Both

**15. Based on the total number of trademarks registered in the Philippines by your company (including parent company), how many trademarks have been infringed in the last 5 years to the present (from 2012-2017)?**

*If none, write "0" and skip to question number 18.*

**16. What and how many action/s has your company taken to address such infringement, if any?**

*Please tick all types of actions taken then list the number of times you have taken that particular action to the right.*

Action taken	Number of times
<input type="checkbox"/> Search and seizure	
<input type="checkbox"/> File administrative case in the IPO	
<input type="checkbox"/> File civil case in court	
<input type="checkbox"/> Other - Please specify below	

Other action not listed:

**17. What is/are the result/s of the cases filed before the IPO/courts?**

*Please tick all types of results then list the number of cases for which you have received that particular result to the right.*

Result	Number of cases
<input type="checkbox"/> Case is still pending in court/IPO	
<input type="checkbox"/> Case finally resolved in favor of your company	
<input type="checkbox"/> Case finally resolved in favor of the other party	
<input type="checkbox"/> Case amicably settled between parties	
<input type="checkbox"/> Other - Please specify below	

Other result not listed:

**17a. How many cases do you currently have pending with the IPO/courts?**

**18. What kind of drugs does your company manufacture/import/commercialize in the Philippines?**

*Please select all that apply.*

- ☐ Drugs with patent registration in the Philippines  
☐ Drugs without patent registration in the Philippines  
☐ Drugs originally patented in the Philippines but which has become off-patent (expired patent)

**19. Based on the total number of drugs that your company manufactures/imports/ commercializes in the Philippines, what is the percentage of drugs covered by an existing Philippine patent?**

*Please select the corresponding cell to note percentage of drugs covered by patent type in the table below.*

EXISTING PH PATENT TYPE	PERCENTAGE OF DRUGS COVERED				
	0%	1% – 25%	26% – 50%	51% – 75%	76% – 100%
A. Product Patent					
B. Process Patent					
C. Formulation Patent					
D. Method of Use Patent					

**19a. Based on the total number of drugs that your company manufactures/imports/commercializes in the Philippines, what is the *number* of drugs covered by the following Philippine patent types?**

- A. Product Patent:
- B. Process Patent:
- C. Formulation Patent:
- D. Method of Use Patent:

**20. For drugs patented in the Philippines, in whose name are the patents registered?**

*Please select only one answer.*

- ☐ Parent company
- ☐ Philippine subsidiary/branch
- ☐ Both

**21. What percentage of drugs manufactured/imported/commercialized by your company in the Philippines, have Philippine patents been applied for in the past 5 years (from 2012 to 2017)?**

*If 0% is selected for all patent types, skip to question number 27.*

PH PATENT TYPE	PERCENTAGE APPLIED IN THE LAST 5 YEARS				
	0%	1% – 25%	26% – 50%	51% – 75%	76% – 100%
A. Product Patent					
B. Process Patent					
C. Formulation Patent					
D. Method of Use Patent					

**22. What percentage of drugs manufactured/imported/commercialized by your company in the Philippines will come off-patent in the next 5 years (2017 to 2022)?**

PH PATENT TYPE	PERCENTAGE OFF-PATENT IN THE NEXT 5 YEARS				
	0%	1% – 25%	26% – 50%	51% – 75%	76% – 100%
A. Product Patent					
B. Process Patent					
C. Formulation Patent					
D. Method of Use Patent					

**23. Of the total number of drugs patented by your company in the Philippines (including parent company), how many patents have been infringed in the last 5 years (2012 to 2017)?**

*If none, write "0" for all and skip to question number 27.*

- A. Product Patent:
- B. Process Patent:
- C. Formulation Patent:
- D. Method of Use Patent:

**24. What and how many action/s has your company taken to address such infringement, if any?**

*Please tick all types of actions taken then list the number of times you have taken that particular action to the right.*

Action taken	Number of times
<input type="checkbox"/> Search and seizure	
<input type="checkbox"/> File administrative case in the IPO	
<input type="checkbox"/> File civil case in court	
<input type="checkbox"/> Other - Please specify below	

Other action not listed:

**25. What is/are the result/s of the cases filed before the IPO/courts?**

*Please tick all types of results then list the number of cases for which you have received that particular result to the right.*

Result	Number of cases
<input type="checkbox"/> Case is still pending in court/IPO	
<input type="checkbox"/> Case finally resolved in favor of your company	
<input type="checkbox"/> Case finally resolved in favor of the other party	
<input type="checkbox"/> Case amicably settled between parties	
<input type="checkbox"/> Other - Please specify below	

Other result not listed:

**26. How many cases do you currently have pending with the IPO/courts?**

### III. General IP Questions

27. What challenge/s does your company face in the current Philippine Intellectual Property (IP) legal/regulatory framework, if any?
28. What are your suggestions to improve the Philippine IP legal/ regulatory framework for the Philippine pharmaceutical industry, if any?
29. Under what conditions do you think the Department of Health (DOH) can recommend the issuance of a special compulsory license under Section 93-A of the IP Code, as amended by the Cheaper Medicines Act? Please refer to Annex "B" for Section 93-A.
30. In what circumstances would you consider it justifiable for the IPO Director General to issue a special compulsory license under Section 93-A of the IP Code?
- 30a. What procedure would you expect to be followed in the issuance of a special compulsory license under section 93-A of the IP Code?
- 30b. How would you respond to the issuance of a special compulsory licensing involving one of your products?
- 30c. What conditions would prevent you from supplying a particular drug in the Philippines?

### ANNEX "A"

#### Stages of Drug Development<sup>1</sup>

**Basic Research** – This first phase of the drug development. During this phase researchers try to understand the underlying mechanism or cause of a certain disease. Researchers look for new chemical or molecular entities that display promising activity against a particular biological target thought to be important for the disease. Other properties (including safety, toxicity, etc) and metabolic effects of the identified entities in humans are not focused on at this stage.<sup>2</sup>

**Discovery** - Discovery often begins with target identification – choosing a biochemical mechanism involved in a disease condition. Drug candidates, discovered in academic and pharmaceutical/biotech research labs, are tested for their interaction with the drug target. Up to 5,000 to 10,000 molecules for each potential drug candidate are subjected to a rigorous screening process which can include functional genomics and/or proteomics as well as other screening methods. Once scientists confirm interaction with the drug target, they typically validate that target by checking for activity versus the disease condition for which the drug is being developed. After careful review, one or more lead compounds are chosen.

**Product Characterization** - When the candidate molecule shows promise as a therapeutic, it must be characterized—the molecule's size, shape, strengths and weaknesses, preferred conditions for maintaining function, toxicity, bioactivity, and bioavailability must be determined. Characterization studies will undergo analytical method development and validation. Early stage pharmacology studies help to characterize the underlying mechanism of action of the compound.

#### Formulation, Delivery, Packaging Development

- Drug developers must devise a formulation that ensures the proper drug delivery parameters. It is critical to begin looking ahead to clinical trials at this phase of the drug development process. Drug formulation and delivery may be refined continuously until, and even after, the drug's final approval. Scientists determine the drug's stability—in the formulation itself, and for all the parameters involved with storage and shipment, such as heat, light, and time. The formulation must remain potent and sterile; and it must also remain safe (nontoxic). It may also be necessary to perform leachables and extractables studies on containers or packaging.

<sup>1</sup> Pacific BioLabs, "Stages of Drug Development: Stages of Drug Development", [http://www.pacificbiolabs.com/drug\\_stages.asp#discovery](http://www.pacificbiolabs.com/drug_stages.asp#discovery)

<sup>2</sup> Peira, "The Drug Discovery Process", <http://www.peira.be/drug-discovery-process>

### **Pharmacokinetics and Drug Disposition -**

Pharmacokinetic (PK) and ADME (Absorption/ Distribution/Metabolism/Excretion) studies provide useful feedback for formulation scientists. PK studies yield parameters such as AUC (area under the curve), Cmax (maximum concentration of the drug in blood), and Tmax (time at which Cmax is reached). Later on, this data from animal PK studies is compared to data from early stage clinical trials to check the predictive power of animal models.

### **Preclinical Toxicology Testing and IND Application**

- Preclinical testing analyzes the bioactivity, safety, and efficacy of the formulated drug product. This testing is critical to a drug's eventual success and, as such, is scrutinized by many regulatory entities. During the preclinical stage of the development process, plans for clinical trials and an Investigative New Drug (IND) application are prepared. Studies taking place during the preclinical stage should be designed to support the clinical studies that will follow.

**Clinical Trials** - Clinical studies are grouped according to their objective into three types or phases:

#### **Phase I Clinical Development (Human Pharmacology)**

- Thirty days after a biopharmaceutical company has filed its IND, it may begin a small-scale Phase I clinical trial unless the FDA places a hold on the study. Phase I studies are used to evaluate pharmacokinetic parameters and tolerance, generally in healthy volunteers. These studies include initial single-dose studies, dose escalation and short-term repeated-dose studies.

#### **Phase II Clinical Development (Therapeutic Exploratory)**

- Phase II clinical studies are small-scale trials to evaluate a drug's preliminary efficacy and side-effect profile in 100 to 250 patients. Additional safety and clinical pharmacology studies are also included in this category.

#### **Phase III Clinical Development (Therapeutic Confirmatory)**

- Phase III studies are large-scale clinical trials for safety and efficacy in large patient populations. While phase III studies are in progress, preparations are made for submitting the Biologics License Application (BLA) or the New Drug Application (NDA). BLAs are currently reviewed by the FDA's Center for Biologics Evaluation and Research (CBER). NDAs are reviewed by the Center for Drug Evaluation and Research (CDER).

### **Phase IV Clinical Development (Post-Marketing Studies)**

- conducted after regulatory approval and are critical to informing the ongoing use of the therapy. Through such trials, researchers collect additional information about longer-term risks, benefits and optimal use.<sup>3</sup>

## **ANNEX "B"**

### **Manufacturing/ Commercialization Arrangements<sup>4</sup>**

**Licensing agreement** - An agreement where the patent holder grants a licensee the right to produce and sell goods, apply a brand name or trademark, or use patented technology

**Co-marketing agreement** - Calls for the sale and marketing of a certain product conducted independently and under different trademarks by each party. The company that agrees to co-market the patented drug pays a certain amount as royalty or agrees to source its supply of such drug from the patentee.

**Co-promotion agreement** - A co-promotion agreement is a straight-forward licensing arrangement whereby the patent holder allows the licensee to promote and sell the patented product bearing the patent owner's mark, provided that the licensee pays the patent holder royalty fees or sources its supply from the patent holder.

<sup>3</sup> Pfizer, "What Are Clinical Trials?", [http://www.pfizer.com/research/clinical\\_trials/phases\\_of\\_development](http://www.pfizer.com/research/clinical_trials/phases_of_development)

<sup>4</sup> Lucenarío, Dina, "IP Utilization of Innovative Drug Companies", lecture given during the November 16, 2016 IPAA Seminar entitled "Technology Protection and IPR in Healthcare", held at the Dusit Thani (Manila)

**ANNEX “C”****Republic Act No. 9502****AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES**

**SEC. 11.** A new Section 93-A is hereby inserted after Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to read as follows:

“SEC. 93-A. Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.

- 93-A.1. The Director General of the Intellectual Property Office, upon the 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. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

“The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory.

“No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

**B. SURVEY ON INTELLECTUAL PROPERTY RIGHTS UTILIZATION BY PHARMACEUTICAL COMPANIES IN THE PHILIPPINES FOR GENERIC DRUG COMPANIES**

The Makati Business Club (MBC) is currently conducting a research focused on determining how pharmaceutical companies in the Philippines utilize Intellectual Property Rights (IPR). By providing a baseline assessment, the study seeks to identify how the current IP legal and regulatory framework impacts the operations of local and multinational pharmaceutical firms.

The study is expected to assist the pharmaceutical industry in responding to proposed legal and policy changes in the field of intellectual property, especially on matters that affect the industry, as the Philippines explore and enter into bilateral and regional economic agreements. This will be submitted to the Intellectual Property Office and the Department of Trade and Industry, and will also be made available to industry stakeholders and the general public.

In line with the aforementioned objectives, we are requesting 30 to 40 minutes of your time to answer this questionnaire. Your responses will be kept confidential and will be analyzed in aggregate.

Your participation is invaluable to the completion of this study. Thank you very much!

**Study authors:**

Atty. Maria Gladys Vilchez (Lead Researcher)  
Mr. Ryan Joseph Dizon (Research Associate)

For completed questionnaires, please fax them to **(02) 750-7405 or (02) 750-7406**. You may also email them at [makatibusinessclub@mbc.com.ph](mailto:makatibusinessclub@mbc.com.ph). We would appreciate getting your responses by **31 March 2017 (Friday)**.

Should you have any queries about the questionnaire or the research undertaking, please contact Mr. Ryan Dizon at [ryandizonjoseph@gmail.com](mailto:ryandizonjoseph@gmail.com) or **+63917-625-2182**.

**SURVEY ON INTELLECTUAL PROPERTY RIGHTS UTILIZATION BY PHARMACEUTICAL COMPANIES IN THE PHILIPPINES**

**FOR GENERIC DRUG COMPANIES**

Name of Company:

Start Date of Operations in the Philippines:

**I. Profile**

**1. Which of the following describes your company?**

*Please select only one answer.*

- ☐ Multinational Company subsidiary/branch/representative
- ☐ Filipino company

**2. What class of drugs does your company deal in/manufacture/sell?**

*Please select all that apply from the following WHO Anatomical Therapeutic Chemical (ATC) classification system main groups.*

- ☐ Alimentary tract and metabolism
- ☐ Blood and blood forming organs
- ☐ Cardiovascular system
- ☐ Dermatologicals
- ☐ Genito urinary system and sex hormones
- ☐ Systemic hormonal preparations, excl. Sex hormones and insulins
- ☐ Antiinfectives and immunomodulating agents
- ☐ Musculo-skeletal system
- ☐ Nervous system
- ☐ Antiparasitic products, insecticides and repellents
- ☐ Respiratory system
- ☐ Sensory organs
- ☐ Various

## II. ACTIVITIES & IPR

### A. INNOVATION & PATENTS

3. Does your company engage in R&D activities for the innovation/improvement of generic or unpatented drugs in the Philippines?

Please select only one answer.

☐ Yes ☐ No (Skip to question 13)

4. Please list the top three innovations/ improvements on generic or unpatented drugs, in terms of impact on business, that have been undertaken by your company in the past 5 years (2012- 2017). Please explain how these innovations/improvements have impacted your business.

*Example: Innovation on paracetamol - The liquid pharmaceutical composition of paracetamol for children was modified to improve its taste. The innovation has increased the company's income.*

5. Have you secured patent protection for such innovations/ improvements in the Philippines?

Please select only one answer.

☐ Yes ☐ No (Skip to question 13)

6. How many Philippine patents have you secured in total?

7. Of the total number of Philippine patents, how many have been applied for in the last 5 years (2012 to 2017)?

8. Of the total number of Philippine patents, how many will expire in the next 5 years (2017 to 2022)?

9. How many of your Philippine patents have been infringed in the last five years (2012-2017)?

If none, write "0" and skip to question number 13.

10. What and how many action/s has your company taken to address such infringement, if any?

Please tick all types of actions taken then list the number of times you have taken that particular action to the right.

Action taken	Number of times
<input type="checkbox"/> Search and seizure	
<input type="checkbox"/> File administrative case in the IPO	
<input type="checkbox"/> File civil case in court	
<input type="checkbox"/> Other - Please specify below	

Other action not listed:

11. What is/are the result/s of the cases filed before the IPO/courts?

Please tick all types of results then list the number of cases for which you have received that particular result to the right.

Result	Number of cases
<input type="checkbox"/> Case is still pending in court/IPO	
<input type="checkbox"/> Case finally resolved in favor of your company	
<input type="checkbox"/> Case finally resolved in favor of the other party	
<input type="checkbox"/> Case amicably settled between parties	
<input type="checkbox"/> Other - Please specify below	

Other result not listed:

12. How many cases do you currently have pending with the IPO/courts?

13. Based on the total number of generic or unpatented drugs manufactured/ imported/ commercialized by your company in the Philippines, what percentage of drugs are protected by Philippine trademark registration/s?

Please select only one answer. If 0%, please tick the box below and skip to question number 19.

<input type="checkbox"/> 0%	<input type="checkbox"/> 51% to 75%
<input type="checkbox"/> 1% to 25%	<input type="checkbox"/> 76% to 100%
<input type="checkbox"/> 26% to 50%	

- 13a. Based on the total number of generic or unpatented drugs manufactured/ imported/ commercialized by your company in the Philippines, what are the total number of drugs protected by Philippine trademark registration/s?

#### 14. In whose name are the trademarks registered?

Please select only one answer.

- ☐ Parent company  
☐ Philippine subsidiary/branch  
☐ Both  
☐ Other: Specify

#### 15. Based on the total number of trademarks registered in the Philippines by your company (including parent company), how many trademarks have been infringed in the last 5 years (from 2012-2017)?

If none, write "0" and skip to question number 19.

#### 16. What and how many action/s has your company taken to address such infringement, if any?

Please tick all types of actions taken then list the number of times you have taken that particular action to the right.

Action taken	Number of times
<input type="checkbox"/> Search and seizure	
<input type="checkbox"/> File administrative case in the IPO	
<input type="checkbox"/> File civil case in court	
<input type="checkbox"/> Other - Please specify below	

Other action not listed:

#### 17. What is/are the result/s of the cases filed before the IPO/courts?

Please tick all types of results then list the number of cases for which you have received that particular result to the right.

Result	Number of cases
<input type="checkbox"/> Case is still pending in court/IPO	
<input type="checkbox"/> Case finally resolved in favor of your company	
<input type="checkbox"/> Case finally resolved in favor of the other party	
<input type="checkbox"/> Case amicably settled between parties	
<input type="checkbox"/> Other - Please specify below	

Other result not listed:

#### 18. How many cases do you currently have pending with the IPO/courts?

#### 19. Does your company manufacture/import/commercialize drugs covered by the following kind of patents owned by another pharmaceutical company in the Philippines?

Please mark each type of drug by activity in the corresponding cell in the following table. If none, skip to question number 20.

TYPE OF DRUGS PATENTED BY OTHERS	ACTIVITY		
	1. Manufacture	2. Import	3. Marketing/ Distribution/ Sale
A. Drugs with product patent			
B. Drugs without product patent but with process patent			
C. Drugs without product patent but with formulation patent			
D. Drugs without product patent but with method of use patent			

#### 19a. Under what kind of arrangements do you manufacture/import/commercialize the drugs with such patent protections?

Please refer to above number/letter code for your responses.

Examples: 1.B (Manufacture of drugs without product patent but with process patent) Drug is manufactured in the Philippines through the use of another non-infringing process.

2.A. (Importation of drugs with product patent) – Drugs with product patent are imported into the Philippines pursuant to a license agreement with the product patent owner.

#### 20. Does your company manufacture any generic drugs or unpatented drugs in the Philippines?

Please select only one answer.

- ☐ Yes ☐ No (Skip to question 21)

#### 20a. What percentage of all drugs that your company manufactures in the Philippines are generic/unpatented drugs?

Please select only one answer. If 0%, please tick the box below and skip to question number 21.

- ☐ 0% ☐ 51% to 75%  
☐ 1% to 25% ☐ 76% to 100%  
☐ 26% to 50%

**20b. How many kinds of generic/unpatented drugs do you currently manufacture in the Philippines in total?**

**21. If your company manufactures drugs, whether patented or generic/unpatented, who does the manufacturing?**

*Please select only one answer.*

- ☐ Company's own manufacturing facility in the Philippines
- ☐ Toll manufacturer
- ☐ Both

**21a. If your company manufactures any drugs in the Philippines (whether patented or generic/unpatented) provide a summary statement on how the following IPR is used in the manufacture of drugs by your own manufacturing facility or by the toll manufacturer.**

*Please write answer in the appropriate corresponding cell in the table below.*

*Example: If your company manufactures drugs through a toll manufacturer and trade secrets are involved in the arrangement, the following answer may be written in the second column (2. Toll Manufacturer) and 3rd row (C. Trade Secrets): "Trade secrets relating to the detailed process for drug manufacture are divulged to the toll manufacturer and are covered by a non-disclosure agreement."*

IPR	MANUFACTURER	
	1. Own Manufacturing Facility	2. Toll Manufacturer
A. Patents		
B. Trademarks		
C. Trade Secrets		
D. Copyright		

**21b. What percentage of drugs manufactured by your company in the Philippines are sold locally or are exported?**

**SOLD LOCALLY:**

*Please select only one answer.*

- ☐ 0% ☐ 51% to 75%
- ☐ 1% to 25% ☐ 76% to 100%
- ☐ 26% to 50%

**EXPORTED:**

*Please select only one answer.*

- ☐ 0% ☐ 51% to 75%
- ☐ 1% to 25% ☐ 76% to 100%
- ☐ 26% to 50%

**22. Does your company import drugs to be sold locally?**

*Please select only one answer.*

- ☐ Yes ☐ No (Skip to question 23)

**22a. For the drugs your company imports to be sold locally, provide a summary statement on how the following IPR is used.**

*Please write answer in the appropriate box.*

IPR	IMPORTATION
A. Patents	
B. Trademarks	
C. Trade Secrets	
D. Copyright	

**23. Does your company market/distribute/sell drugs to be sold locally?**

*Please select only one answer.*

- Yes No (Skip to question 24)

**22a. If your company markets/distributes/sells drugs in the Philippines, provide a summary statement on how the following IPR is used.**

*Please write answer in the appropriate box.*

IPR	MARKETING/DISTRIBUTION/SALE OF DRUGS IN PH
A. Patents	
B. Trademarks	
C. Trade Secrets	
D. Copyright	

**24. Under what business agreement/s does your company manufacture/market/distribute/sell drugs in the Philippines? Identify the IPR used in such agreement/s?**

*Please tick all business agreements and IPR that apply. For the definition of each business agreement, please refer to Annex B. Please specify other agreement if column 4 (Other) is checked.*

IPR	BUSINESS AGREEMENT TYPE			
	1. Licensing Agreements	2. Co-Marketing Agreements	3. Co-Promotion Agreements	4. Other:
A. Patents				
B. Trademarks				
C. Trade Secrets				
D. Copyright				

24a. Provide a summary statement on how the identified IPR is/are used by your company in such agreements as marked in the above table.

*Please refer to above number/letter code for your responses.*

### III. General IP Questions

25. What challenge/s does your company face in the current Philippine Intellectual Property (IP) legal/regulatory framework, if any?

26. What are your suggestions to improve the Philippine IP legal/ regulatory framework for the Philippine pharmaceutical industry, if any?

27. Under what conditions do you think the Department of Health (DOH) can recommend the issuance of a special compulsory license under Section 93-A of the IP Code, as amended by the Cheaper Medicines Act? *Please refer to Annex "B" for Section 93-A.*

28. In what circumstances would you consider it justifiable for the IPO Director General to issue a special compulsory license under Section 93-A of the IP Code?

28a. What procedure would you expect to be followed in the issuance of a special compulsory license under section 93-A of the IP Code?

28b. How would you respond to the issuance of a special compulsory licensing involving one of your products?

28c. What conditions would prevent you from supplying a particular drug in the Philippines?

## ANNEX "A"

### Stages of Drug Development<sup>1</sup>

**Basic Research** – This first phase of the drug development. During this phase researchers try to understand the underlying mechanism or cause of a certain disease. Researchers look for new chemical or molecular entities that display promising activity against a particular biological target thought to be important for the disease. Other properties (including safety, toxicity, etc) and metabolic effects of the identified entities in humans are not focused on at this stage.<sup>2</sup>

**Discovery** - Discovery often begins with target identification – choosing a biochemical mechanism involved in a disease condition. Drug candidates, discovered in academic and pharmaceutical/biotech research labs, are tested for their interaction with the drug target. Up to 5,000 to 10,000 molecules for each potential drug candidate are subjected to a rigorous screening process which can include functional genomics and/or proteomics as well as other screening methods. Once scientists confirm interaction with the drug target, they typically validate that target by checking for activity versus the disease condition for which the drug is being developed. After careful review, one or more lead compounds are chosen.

**Product Characterization** - When the candidate molecule shows promise as a therapeutic, it must be characterized—the molecule's size, shape, strengths and weaknesses, preferred conditions for maintaining function, toxicity, bioactivity, and bioavailability must be determined. Characterization studies will undergo analytical method development and validation. Early stage pharmacology studies help to characterize the underlying mechanism of action of the compound.

### Formulation, Delivery, Packaging Development

- Drug developers must devise a formulation that ensures the proper drug delivery parameters. It is critical to begin looking ahead to clinical trials at this phase of the drug development process. Drug formulation and delivery may be refined continuously until, and even after, the drug's final approval. Scientists determine the drug's stability—in the formulation itself, and for all the parameters involved with storage and shipment, such as heat, light, and time. The formulation must remain potent and sterile; and it must also remain safe (nontoxic). It may also be necessary to perform leachables and extractables studies on containers or packaging.

**Pharmacokinetics and Drug Disposition -**

Pharmacokinetic (PK) and ADME (Absorption/Distribution/Metabolism/Excretion) studies provide useful feedback for formulation scientists. PK studies yield parameters such as AUC (area under the curve), C<sub>max</sub> (maximum concentration of the drug in blood), and T<sub>max</sub> (time at which C<sub>max</sub> is reached). Later on, this data from animal PK studies is compared to data from early stage clinical trials to check the predictive power of animal models.

**Preclinical Toxicology Testing and IND Application**

- Preclinical testing analyzes the bioactivity, safety, and efficacy of the formulated drug product. This testing is critical to a drug's eventual success and, as such, is scrutinized by many regulatory entities. During the preclinical stage of the development process, plans for clinical trials and an Investigative New Drug (IND) application are prepared. Studies taking place during the preclinical stage should be designed to support the clinical studies that will follow.

**Clinical Trials** - Clinical studies are grouped according to their objective into three types or phases:

**Phase I Clinical Development (Human Pharmacology)**

- Thirty days after a biopharmaceutical company has filed its IND, it may begin a small-scale Phase I clinical trial unless the FDA places a hold on the study. Phase I studies are used to evaluate pharmacokinetic parameters and tolerance, generally in healthy volunteers. These studies include initial single-dose studies, dose escalation and short-term repeated-dose studies.

**Phase II Clinical Development (Therapeutic Exploratory)**

- Phase II clinical studies are small-scale trials to evaluate a drug's preliminary efficacy and side-effect profile in 100 to 250 patients. Additional safety and clinical pharmacology studies are also included in this category.

**Phase III Clinical Development (Therapeutic Confirmatory)**

- Phase III studies are large-scale clinical trials for safety and efficacy in large patient populations. While phase III studies are in progress, preparations are made for submitting the Biologics License Application (BLA) or the New Drug Application (NDA). BLAs are currently reviewed by the FDA's Center for Biologics Evaluation and Research (CBER). NDAs are reviewed by the Center for Drug Evaluation and Research (CDER).

**Phase IV Clinical Development (Post-Marketing Studies)**

- conducted after regulatory approval and are critical to informing the ongoing use of the therapy. Through such trials, researchers collect additional information about longer-term risks, benefits and optimal use.<sup>3</sup>

**ANNEX "B"****Manufacturing/ Commercialization Arrangements<sup>4</sup>**

**Licensing agreement** - An agreement where the patent holder grants a licensee the right to produce and sell goods, apply a brand name or trademark, or use patented technology

**Co-marketing agreement** - Calls for the sale and marketing of a certain product conducted independently and under different trademarks by each party. The company that agrees to co-market the patented drug pays a certain amount as royalty or agrees to source its supply of such drug from the patentee.

**Co-promotion agreement** - A co-promotion agreement is a straight-forward licensing arrangement whereby the patent holder allows the licensee to promote and sell the patented product bearing the patent owner's mark, provided that the licensee pays the patent holder royalty fees or sources its supply from the patent holder.

**ANNEX “C”****Republic Act No. 9502****AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES**

**SEC. 11.** A new Section 93-A is hereby inserted after Section 93 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to read as follows:

“SEC. 93-A. Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.  
- 93-A.1. The Director General of the Intellectual Property Office, upon the 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. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the products imported under this provision.

“The grant of a special compulsory license under this provision shall be an exception to Sections 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory.

“No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

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## GLOSSARY OF ACRONYMS

<b>BFAD</b>	Bureau of Food and Drugs
<b>BLA</b>	Bureau of Legal Affairs
<b>DOH</b>	Department of Health
<b>FDA</b>	Food and Drug Administration
<b>FGDs</b>	Focus Group Discussions
<b>IP Code</b>	Intellectual Property Code
<b>IPAA</b>	Intellectual Property Alumni Association
<b>IPOPHIL</b>	Intellectual Property Office of the Philippines
<b>IPR</b>	Intellectual Property Rights
<b>IRR</b>	Implementing Rules and Regulations
<b>MLEM</b>	Model List of Essential Medicines
<b>PHAP</b>	Pharmaceutical and Healthcare Association of the Philippines
<b>PITC</b>	Philippine International Trading Corporation
<b>QUAMA</b>	Universally Accessible Cheaper and Quality Medicines Act
<b>TRIPS</b>	Trade-Related Aspects of Intellectual Property Rights
<b>WHO</b>	World Health Organization
<b>WIPO</b>	World Intellectual Property Organization

The study was undertaken for the Makati Business Club, as part of its efforts to assist government regulators in understanding the intricacies of the different Philippine industries for policy making purposes, to achieve the country's development goals. The study will be submitted to the Intellectual Property Office of the Philippines (IPOPHIL), the Department of Trade & Industry (DTI), the Food and Drug Administration (FDA) and the Department of Health (DOH), and will be made available to stakeholders and the general public.

## ABOUT THE AUTHOR

**Maria Gladys C. Vilchez** is a partner at Hechanova Bugay Vilchez & Andaya-Racadio, a top-tier IP law firm in the Philippines. She is an accredited arbitrator and mediator of the Intellectual Property Office Philippines (IPOPHIL) and an accredited mediator of the World Intellectual Property Organization (WIPO). She is currently an IP Consultant of the Technology Application and Promotion Institute (TAPI) of the Department of Science and Technology (DOST). She teaches IP Law at the Far Eastern University (FEU) Law Institute. She is a member of the Board of Trustees of the Intellectual Property Alumni Association (IPAA).

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# MBC

**MAKATI BUSINESS CLUB**  
THE FORUM FOR CONSTRUCTIVE IDEAS

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