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The Patent System and the Quest for Affordable Medicines

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This study examined how the patent system in the Philippines – as embodied by the Intellectual Property Code – affects the public's access to affordable medicines. It discussed the issue of patent protection vs. public health in the context of the Philippine pharmaceutical industry. The study discovered that Filipino-owned pharmaceutical companies find it difficult to compete with multinational corporations, and that this factor has raised the prices of medicines in the Philippines. The study then proposed solutions to the problem, which include the promotion of off-patent drugs and the amendment of the Intellectual Property Code.

Keywords: Patents, intellectual property, rights, health, medicines

A patent is a document issued by a government office, which describes an invention and creates a temporary monopoly in favor of the inventor, who has invested his time and resources, so that he can exclusively exploit the patented product or process. This exclusive right is given to the inventor not only to reward his creativity and ingenuity, but also to encourage him to continue his research and develop new inventions. As such, the patent system involves the interplay of two interests – the inventor on one hand and society on the other. This right is protected by no less than the 1987 Constitution of the Republic of the Philippines. Section 13, Article XIV, states:

> The State shall protect and secure the exclusive rights of scientists, inventors, artists and other gifted citizens to their intellectual property and creations, particularly when beneficial to the people, for such period as may be provided by law.

On the other hand, society has the right to benefit from the invention. While the inventor can enjoy the fruits of his labor, such enjoyment is for a limited period only. Ultimately, the goal of the patent system is not to reward the inventor, but to promote science and technology (Manzano vs. Court of Appeals, 1997). The constitutional provision quoted previously clearly provides that the protection is for a limited time only "for such period as may be provided by law."

The crucial role, then, of the patent system (through the Intellectual Property Office) is to strike a balance between these two apparently conflicting interests. A healthy patent system should satisfy both interests. Ultimately, however, the goal of the patent system is to benefit the public. In his book, *Intellectual Property Law* (2006), Aquino aptly described this relationship:

> Society profits by the creations of its men and women of letters and science. The State encourages the intellectual endeavors of men and women of talent by bestowing on them certain exclusive rights for limited periods so that there may be added motive for the creation of literary, artistic, scientific and technological works beneficial to society. Intellectual property protection is therefore merely a means toward the end of making society benefit from creations of its men and women of talent and genius.
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> The ethos of the intellectual property laws … explains why certain products of ingenuity that are concealed from the public are outside the pale of protection afforded by law. It also explains why the author or the creator enjoys no more rights than are consistent with public welfare.
>
> Put simply, the exclusive rights vested in authors and inventors entice others to write, create, produce and invent more for the benefit of society. (pp. 4-5)

PATENT PROTECTION VS. PUBLIC HEALTH

The promotion and protection of public health is of paramount importance to the State, as can be seen in the following constitutional provisions:

> Section 15, Article II. The State shall protect and promote the right to health of the people and instill health consciousness among them.
>
> Section 11, Article XIII. The state shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost. There shall be priority for the needs of the underprivileged sick, elderly, disabled, women and children. The state shall endeavor to provide free medical care to paupers.

On the other hand, the State is also mandated to protect intellectual property as quoted earlier (Section 13, Article XIV). Furthermore, Section 2 of the Intellectual Property Code of the Philippines (Republic Act No. 8293, 1998) provides that the State shall "protect and secure the exclusive rights of scientists, inventors, artists and other gifted citizens to their intellectual property, and creations, particularly when beneficial to the people…"

However, due to the Code's technical jargon and the lack of knowledge about the intricacies of the intellectual property system, it has been used by some pharmaceutical companies to defeat the very objectives of the law.

THE PROBLEM OF ACCESS TO AFFORDABLE MEDICINES

According to the UNDP Human Development Reports for 2003, only around 50 to 79 percent of the whole Philippine population has sustainable access to affordable essential drugs (United Nations Development Programme [UNDP], 2003). If there are around 80 million Filipinos living today, then around 24 million Filipinos have no access to affordable drugs. Even assuming that they do have access, their budget for health expenses is only around Php 2,000 per year, according to the Philippine National Health Accounts (National Statistics Coordination Board [NSCB], 2004).

The obvious culprit is the high prices of medicines today. What has contributed to this problem? It is believed that the patent system is partly to blame.

THE PHILIPPINE PHARMACEUTICAL INDUSTRY

The Philippine pharmaceutical industry is dominated by multinational corporations. Based on the records (Pharmaceutical & Healthcare Association of the Philippines [PHAP], 2003),

around 60 percent of the market is controlled by multinational companies (MNCs). United Laboratories, Inc. (Unilab) and Pascual Laboratories are the only Filipino companies who can really compete with the MNCs. The rest of the market share is distributed among the more than 100 small- and medium-sized Filipino pharmaceutical companies. Indeed, MNCs get a lion-share of the Php 80 billion pharmaceutical industry.

In his position paper on Senate Bill 2139 (An Act to make the laws on patents, trademarks and tradenames more responsive to the health care needs of the Filipino People, 2005), Senator Mar Roxas quoted from the position paper of the Philippine Chamber of the Pharmaceutical Industry [PCPI] who claimed to have

> ... first-hand experience of how the Philippine IP system has been abused by a few multinational companies in defense of their narrow commercial interests. The balance between private and public interests has been jeopardized by multinational companies who try to create or preserve unjustifiable monopolies to the detriment of the public.

This imbalance has restricted competition, which, in turn, has resulted in the high prices of medicines. The Filipino pharmaceutical industry, however, believes that the local generic industry is in a position to offer more affordable, yet equally effective, medicines to the public, despite the smear campaign waged against it by some multinational companies.

The multinational companies claim that they have been able to dominate the Philippine pharmaceutical industry because of the good quality and the safety of their drugs. With this, they insinuate that Filipino drug companies do not ensure the same quality in their drugs, despite the fact that they have all passed the strict standards of the Bureau of Food and Drugs (BFAD).

As regards the high prices of their medicines, the MNCs argue that they have to recoup their research and development costs to secure their patent. Simply put, the multinational companies use the patent system to protect their profit margin. Wittingly or unwittingly, the patent system has protected the monopoly of the multinational companies since almost all of the pharmaceutical patents are owned by them.

ARE THE PRICES OF MEDICINES REALLY HIGH?

It is common knowledge that drug prices in the Philippines are among the highest in Asia, if not the world. This is supported by various studies made by the Department of Trade and Industry (DTI) and the stakeholders in the pharmaceutical industry.

For example, a 500-milligram unit of Ponstan (Mefenamic Acid) costs around Php 21.82 in the Philippines while the same costs only around Php 2.61 in India. In his Committee Report sponsoring Senate Bill No. 2263 in 2006, Senator Mar Roxas gave the following remarks:

> In every nook and corner of our archipelago, Mr. President, we have sick citizens who are sick not because there is no cure for their ailment, not because they haven't been able to see a doctor for diagnosis, they are sick because they cannot afford the medicine that has been prescribed for them and which will make them well.
>
> ...Norvasc, priced Php 44.75 in the Philippines, sells for equivalent of Php 5.00 in India ... Bactrim 400, priced at Php 17.75 per tablet in the Philippines, sells for the equivalent of Php 1.00 in Pakistan, Php 0.69 in India ... Ventolin, priced at Php 406 in the Philippines, sells for the equivalent of Php 231.00 in Thailand.
>
> Mr. President, what is so special about Thailand, India, Pakistan and other countries across and beyond our region, that these affordable medicines are available to their citizens while we Filipinos have to pay many more for the same medicines?

Many believe that the patent system itself may have contributed to the problem. The patent system has allowed itself to be used as a shield by patent owners to stave off competition, to the detriment of the interest of the general public as a whole. As in any industry, less competition means higher prices. Thus, there is a direct connection between patent protection, competition, and the prices of medicines.

With the monopoly attached to the grant of the patent, the patent holders can freely fix the price of their patented drug. They have always argued that the high research and development costs of developing medicines justify the high prices. It is therefore just right, they claim, that the company recovers the investment made on the development of the product.

On the other hand, the public has been clamoring for more affordable medicines, as the majority of Filipinos cannot even make ends meet. It should be noted that unlike other patented products, medicines are socially sensitive as they are directly related to public health. While people can afford to forego eating at restaurants or loading up their cell phones, they cannot miss out on their antibiotics. Thus, the debate has pitted the interests of multinational drug companies against the interests of the public clamoring for lower prices. So far, the battle has been one-sided in favor of the patent holders, as the prices in the country remain astonishingly high compared to those of our Asian neighbors. In poor countries like the Philippines, patents on pharmaceuticals can become obstacles to public health, because patent holders can set prices that the majority of the people cannot afford.

EFFORTS TO ADDRESS THE PROBLEM

There have been efforts to address the problem of skyrocketing prices of medicines. The Generics Act of 1988 is one attempt to lower the prices by offering the public a generic equivalent of the patented product. However, due to lack of information and the public's suspicion of the efficacy of the generic drugs, the Generics Act did not really make a dent in the prices of medicines. Another attempt was the enactment of the Retail Trade Liberalization Act of 2000 which aimed to open the door to greater competition among drug and pharmaceutical companies. The effects of this law, however, have yet to be felt.

Recently, the government has been exerting efforts to bring down the prices of medicines through parallel importation, encouraging the manufacture and use of generic products, and establishing drugstores offering medicines at affordable prices, like *Botika ng Bayan* and *Botika ng Barangay*. The Philippine International Trade Center (PITC) has been at the forefront of these activities in an effort to provide consumers less expensive but equally effective medicines. However, even PITC is not immune from suits; it is now the subject of civil suits filed by multinational companies. When PITC made a parallel importation of the drug Norvasc, manufactured by Pfizer, Pfizer sued PITC for violation of the patent law. At present, Unilab is taking up the cudgels in the fight against the MNCs. Unilab is now not only manufacturing counterpart drugs, but also questioning the validity of the patents owned by the MNCs.

These major breakthroughs, however, are only band-aid antidotes to the problem. The real solution would come from the market forces themselves through increased competition. While it is true that the majority of drugs available in the market are already off-patent, there is lack of industry and consumer awareness on this matter. The patent holders may have contributed to this misinformation so that they can "extend" their warranties even after these have lapsed. In fact, only three percent of drug sales are "generic" generic; while "branded" generic medicines, although majority of these are already off-patent, account for 97 percent of medicine sales. This glaring statistic only points to the obvious: that the introduction of off-patent drugs in the pharmaceutical industry will spur competition and ultimately lower the prices of medicines. Of course, this is easier said than done, as the patent holders will do their best to stall

competition and maintain their monopoly. At any rate, the government must not waver in its commitment to lower the prices of medicines.

One of the measures that can spur competition and lower prices is the development of off-patent drugs. The next part of this study discusses the state of off-patent products and how the development of off-patent drugs can help lower the prices of medicines. To bring this about, the legal framework must support this new regime. Consequently, there is a need to look into the present law (i.e., the Intellectual Property Code) and make amendments thereto, so as to level the playing field for the benefit of local players in the industry.

PROPOSED SOLUTIONS

Promotion of Off-Patent Drugs

What are off-patent drugs? These are drugs whose patent protections have already expired; or drugs which, though patented abroad, are not patented in the Philippines.

At present, there are around 3,200 to 3,500 drugs moving in the shelves of drugstores throughout the Philippines. Of this number, only 647 are considered essential, that is, they can cure 90 percent of the illnesses of patients. Of the 647 essential drugs, only around 40 have live patents. This means that around 607 drugs are already off-patent. Of the 607 drugs, however, only around 150 are manufactured and/or distributed by local companies. This means that around 457 drugs are still virtually patented, although technically they are already off-patent. These 457 off-patent drugs are left untouched by local companies, thereby effectively reverting them to the patented regime. This is the reason prices of medicines are still high despite the number of off-patent drugs.

Why have local companies not yet tapped these 457 off-patent drugs? Two reasons come to mind: (1) the lack of technology, and (2) a small market.

Most of these off-patent drugs, which include vaccines and antivirals, are used for the treatment of cancer and ailments of the heart and other major organs. At present, we still do not have the technology to research and develop the majority of these off-patent drugs. It takes around two to three years before a company can manufacture an off-patent drug, and without the technology to help us, it may take even longer.

Another reason is the small market of some of these off-patent drugs. Local companies, due to their limited resources, find it more practical to invest in higher yielding products. Of course, this is not a valid reason to ignore these drugs. Simply put, Filipino companies still do not have the capability to give the original patent holders of the off-patent drugs effective competition, even after the patents have already lapsed.

In one of his public appearances, Atty. Adrian S. Cristobal Jr., Director-General of the Intellectual Property Office (IPO), urged local pharmaceutical companies to increase production of off-patent drugs to help lower the prices of medicines. Since these drugs are off-patent, everyone is free to manufacture and produce them without fear of an infringement suit. Fortunately, most of the drugs sold in the market today are off-patent. According to the data from the IPO, the patents of 10,266 drugs registered from 1947 to 1988 have already expired, while only 6,142 drugs registered from 1989 to March 2005 still have pending patents.

Cristobal has encouraged the production of off-patent drugs because "the essence of the intellectual property regime is the diffusion of knowledge and information for national development and progress."

To prove that introduction of off-patent drugs can help lower the prices of medicines, we can look at the case of Lipitor and Soccor. In the past, when there was no competition from local companies, the price of each tablet ranged from Php 70 to Php 80. When Unilab introduced its own version of the off-patent drug, it sold the same for only Php 28. This forced the makers of Lipitor and Soccor to lower their prices to around Php 35 to Php 40. This only proves that competition works!

Another example to illustrate this point is Unilab's production of Oseltamvir, the generic equivalent of Tamiflu, owned by Roche, which is an antiviral medicine used against bird flu. In his comment, Undersecretary Alexander Padilla of the Department of Health (DOH) said that "Unilab is doing the right thing. It's challenging the multinational companies' use of patents to keep prices high and delay competition." Unilab knew much earlier that Tamiflu was not patented in the Philippines, for which reason it proceeded to manufacture Oseltamvir under the name of DOH to reduce the risk of litigation. Later, Roche agreed to help Unilab make the generic version of the drug by supplying the active pharmaceutical ingredient. By insisting on manufacturing the off-patent drug, Unilab reduced its price by half.

Amending the Intellectual Property Code

While there is no doubt that the development of off-patent drugs can help reduce the prices of medicines, the Intellectual Property Code, as it is right now, does not fully support this thrust. For instance, the flexibility of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) – of which the Philippines is a signatory – relating to patents has not been incorporated into the law. Thus, there is a need to re-examine the provisions of the Intellectual Property Code to level the playing field.

During the 13th Congress, Senate Trade and Commerce Committee Chairman Mar Roxas filed Senate Bill No. 2139 (2005), which aimed to lower drug prices by amending certain provisions of the Intellectual Property Code. In the bill's explanatory note, Roxas stated that the aim of the bill was "to protect public health by creating an environment that will lower the prices of medicines through greater competition among drug companies and by providing the government with better policy tools to significantly influence the supply and demand of medicines." Many local industry players, including PCPI, supported the bill. However, the Pharmaceutical & Healthcare Association of the Philippines (PHAP), an organization dominated by multinational companies, opposed the bill arguing that it violated due process and the equal protection clause, and that it was an undue delegation of legislative power.

The present Senate has approved its version of the bill through Senate Bill No. 1658 submitted by the joint committees on Trade and Commerce, Health and Demography, and Finance on 1 October 2007. It was during the 14th Congress when the bill was finally passed into a law. On 6 June 2008, the Universally Accessible Cheaper and Quality Medicines Act of 2008 was passed; it amended not only the Intellectual Property Code but also the Generics Act of 1988 and the Pharmacy Law. The following were the amendments made on the Intellectual Property Code:

Prohibiting the grant of "frivolous" inventions.

The intention is to prevent the "evergreening of patents," i.e., pharmaceutical companies extending their patents by seeking new uses for old patents. This was perceived as a way to lengthen the term of protection by making trivial improvements on the product. Under the new law, "new uses or molecules or compounds of a patented invention shall be deemed as included in the original patent and shall not be allowed to be covered by a new and separate patent." The law amended section 22.1 of the Intellectual Property Code by disallowing the issuance of another patent for new uses of an existing substance that has already been patented. This will enable pharmaceutical companies to research and market their own versions of the patented product without threat of infringement. Through this amendment, other pharmaceutical companies can offer their generic versions sooner, thereby increasing competition and consequently lowering the prices of medicines.

Adoption of the principle of international exhaustion.

The original law (Section 72.1 of the Intellectual Property Code) provided for the domestic exhaustion principle, where there is no infringement only if the product has already been "put on the market in the Philippines by the owner or with his

express consent." With the amendment under the new law, once a product has been introduced or used anywhere in the world by the patent owner, it becomes free for all to use and the product can be resold in the Philippines without risk of infringement (international exhaustion). As aptly put by Senator Roxas in his Committee Report (2006), this means that the prices in the Philippines will be influenced by the prices of the medicines in other countries. This will allow the country to buy medicine from other countries at lower prices, thereby legalizing parallel importation of drugs. This is in accordance with the TRIPS agreement (see Footnote 6 to Article 28) and subsequently reiterated in the Doha Declaration (2001): "The effect of the provisions in the TRIPS agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge…"

Parallel importation.

The new law allows the importation by the Philippines of less expensive patented medicines from another country, an action prohibited under the original Section 71 of the Intellectual Property Code. By allowing parallel importation, the state can "shop around" for drugs to get the lowest possible prices and resell these in the Philippines for prices lower than prevailing domestic prices. On this point, PCPI believes that national interest is best served if government sources pharmaceutical products from local companies instead of obtaining them from foreign sources, as this will help the local pharmaceutical industry.

Bolar provision or the early working exemption.

The new law now allows local generic companies to start studying and testing generic equivalents of patented drugs before the expiration of the patent. This will also allow pharmaceutical companies to get ready to start the production and sale of a generic drug shortly after the patent expires. Under the original law, this preparation can only be done after the patent has expired. The whole process may take three years, further delaying the introduction of off-patent drugs. This is based on the Bolar exception, which led to significant reductions in the prices of medicines upon its adoption in the U.S., Japan, Canada, Israel, and Thailand.

Government use.

The law amended Section 74 of the Intellectual Property Code by removing the requirement of government to undergo the long and difficult process of compulsory licensing. Instead of going through the normal compulsory licensing process, the government can now authorize the manufacture of patented drugs when public health so requires, as in the case of outbreaks or epidemics. At present, compulsory licensing applications take years to process.

Immunity of government officials.

Government officials engaged in parallel importation need immunity to prevent harassment suits or temporary restraining orders. With the new law in place, the government officials can concentrate on finding ways to increase competition and thereby lower the prices of medicines.

RECOMMENDATIONS

As a result of this study, the following observations and recommendations are made:

1. The local pharmaceutical industry must be made aware of the high number of off-patent drugs that can now be exploited. Educating the market will compel pharmaceutical companies to reasonably price their medicines. Furthermore, it is admitted that at present we do not have the resources to do research and development for new medicines. Hence, our best chance to compete, in the meantime, is in the manufacture of off-patent drugs Filipino drug companies can be most competitive in this area.

2. Allow market forces to bring down the price of medicines. One of the best ways to lower the prices of medicines is to create competition. Records have shown that competition has lowered the prices of medicines, especially if there is active participation from the Philippine pharmaceutical industry. True competition, however, is possible only when there is a level playing field
3. There is a need to take advantage of the new law amending the Intellectual Property Code to level the playing field and to make competition fairer to the Filipino pharmaceutical company;
4. The government must continue to exercise its police power to help Filipino drug companies level the playing field. Amending the law is just part of the solution. Implementation is the more difficult part.
5. Price control through the creation of a price control board may lower the prices of medicine in the short term, but it is not a long-term solution. The price control board is prone to abuse and will only result in additional costs for the pharmaceutical industry.
6. There should be consumer empowerment. Consumers must be encouraged to ask their doctors and pharmacists about the prices of medicines so that they can choose wisely. Through this, consumers will learn that there are medicines that are just as effective as those of the innovator company, but with a much lower price.
7. Support the local Filipino pharmaceutical industry. The government should give incentives to local companies to encourage local investment. Records will show that countries like India and Thailand, which have a strong local pharmaceutical industry, have lower medicine prices. In the long term, it is the Filipino who will save his fellow Filipino.

CONCLUSION

The best solution to the skyrocketing prices of medicines in the Philippines is to encourage competition. Since the Philippine pharmaceutical industry cannot compete with the patented products of the multinational companies, the best way to compete is in the generic sector, either with "branded generic" or "generic generic."

As regards the patent system, Congress already did its job by amending the Intellectual Property Code. These amendments will help level the playing field. It is good that the proposals to create a price control board for medicines did not fly as this, to my mind, is anti-competition and should be used only as a last resort.

Hank McKinnell, Chairman and CEO of Pfizer, argued in 2005 that

> It's a fallacy to suggest that the pharmaceutical industry prices a product to recapture the R & D budget spent in development. Business doesn't work like that. Those are sunk costs. In other words, pharmaceutical firms spent the money and it cannot be recovered no matter what they decide to do with pricing.

It sounds strange that this statement came from the head of one of the leading multinational pharmaceutical companies in the world. We just hope that the other multinational pharmaceutical companies are listening.

In the meantime, we must do our best to help the Philippine pharmaceutical industry avoid high prices caused by lack of competition and an inadequate legal infrastructure. Slowly but surely, local pharmaceutical companies like Pascual Laboratories, Lloyds Laboratories and United Laboratories are venturing into the research and development of these patented and off-patent drugs. We should realize that the best way to lower prices is to focus on what we can do for the moment – developing off-patent generic or branded drugs to create competition and, thus, make these more affordable to Filipinos.

The government must do its part in supporting the local pharmaceutical industry by leveling the playing field. While amendments to the Intellectual Property Code will, by no small measure, help the industry to remove the roadblocks to free competition, its implementation and impact is yet to be seen. It is now, more than ever, when the people should be vigilant in fighting barriers to free competition.

It should be stressed that the message is not that the multinational companies are the "big bad wolves." In fact, we need these multinational companies as Filipino companies cannot, as of the moment, supply the demand of the Philippine market. Multinational companies and Filipino companies should work hand in hand to lower the prices of medicines. However, this can only be done if there is a level playing field. This is the challenge facing Filipino pharmaceutical companies. The amendments to the Intellectual Property Code is a step towards the right direction, but there is still a long way to go before we can say that the Filipino pharmaceutical industry is capable of giving the multinational companies a run for their money. With these challenges, let us brace ourselves for exciting times ahead in the pharmaceutical industry.

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