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THE REPUBLIC OF THE PHILIPPINES)
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SENATE

COMMITTEE REPORT NO. 79

Submitted jointly by the Committees on Trade and Commerce and Health and Demography on 07 JUN 2006.

Re: Senate Bill No. 2139, authored by Senator M A R Roxas

Recommending approval of its findings and recommendations on the issue of amending the Intellectual Property Code of the Philippines to achieve the objective of broadening the access and lowering the prices of drugs or medicines, and the attached substitute bill.

Sponsor: Senator M A R Roxas and Senator Pia Cayetano and the members of the Committees on Trade and Commerce and Health and Demography

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Mr. President:

The Committee on Trade and Commerce jointly with the Committee on Health and Demography to which were referred Senate Bill No. 2139, introduced by Senator MAR Roxas, entitled:

AN ACT
TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY ALLOWING THE IMPORTATION, EARLY DEVELOPMENT OF PATENTED MEDICINES AND EXCEPTIONS TO THE APPLICATION OF STANDARD COMPULSORY LICENSING REQUIREMENTS FOR DRUGS OR MEDICINES TO LOWER DRUG OR MEDICINE PRICES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

have considered the same and have conducted two (2) public hearings and three (3) technical working group meetings where the concerned government agencies and industry representatives of the affected sectors, including consumers, were represented.

After a careful scrutiny of Senate Bill No. 2139 and the evaluation of all testimonies and documents gathered during the hearings, the Committee on Trade and Commerce together with the Committee on Health and Demography provide herein the specific findings and its recommendation to address the issue of amending the Intellectual Property Code of the Philippines for the purpose of making it more responsive to the problem of expensive prices and lack of access of drugs and medicines.

I. Problem of Access to Affordable Drugs and Medicines

The problem of access to affordable drugs and medicines in the Philippines is clearly stated in the UNDP Human Development Reports for 2003 which stated that in *1999, of the whole Philippine population, only 50-79% had sustainable access to* affordable essential drugs.[1] For the year 2000 census of the National Statistical Coordination Board, the population of the Philippines was 76.5 million.[2] On the best scenario, this translates to 15.3 million Filipinos who have no access to essential drugs or medicines. On the worst case, 38.25 million or half of the Filipinos have no access to essential drugs or medicines. Based on the Philippine National Health Accounts, further aggravating this fact is that annual per capita health spending in 2003 at current prices was only P1,817 and for 2004 it was P1,979.[3] It should be noted that this per capita health spending is inclusive of all healthcare costs and not just limited to drugs and medicines.

In short, millions and millions of Filipinos have no access to affordable drugs and medicines and for those who have access, their budget for total health related expenses is a measly P2,000 per person per annum. A weak and ailing workforce will not do the economy any good since it will have a bearing on the nation's long-term stability. It is against this backdrop of facts that this piece of legislation to protect public health is being advocated.

II. Protection of Public Health and the Philippine Intellectual Property System

A. The Philippine Constitution

The protection of public health is of primordial importance especially as this echoes the constitutional mandate for the State to protect the health of the people.[4] Further, the Constitution mandates that the State must adopt an integrated and comprehensive approach to health development, which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost. Further, the State must prioritize the needs of the underprivileged, sick, elderly, disabled, women, and children.[5] On the basis of the foregoing, it is clear that the protection of public health with priorities over the interests of the underprivileged is a top State objective which is an overriding parameter to the manner by which the State, through Congress, regulates the acquisition, ownership, use, and disposition of property and its increments.[6]

In relation to intellectual property, the State is mandated to protect it particularly when it is beneficial to the people.[7] In incorporating this principle into the basic charter,

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[1] http://www.undp.org/hdr2003/indicator/cty_f_PHL.html
[2] http://www.nscb.gov.ph/secstat/d_popn.asp
[3] http://www/ncsb.gov.ph/stats/pnha/2004/healthexp.asp
[4] Sec. 15, Art. II Declaration of Principles and State Policies, 1987 Constitution: The State shall protect and promote the right to health of the people and instill health consciousness among them.
[5] Sec. 11, Art. XIII Social Justice and Human Rights, ibid: 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 the 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.
[6] Sec. 1, Art. XIII Social Justice and Human Rights, ibid: The Congress shall give highest priority to the enactment of measures that protect and enhance the right of all the people to human dignity, reduce social, economic, and political inequalities, and remove cultural inequities by equitably diffusing wealth and political power for the common good. To this end, the State shall regulate the acquisition, ownership, use, and disposition of property and its increments.
[7] Sec. 13, Art XIV Education, Science and Technology, Arts, Culture, and Sports, ibid: The State shall protect and secure the exclusive rights of scientists, inventors, artists, and other gifted citizens to their

the Philippines occupies a unique position in the global stage. It is perhaps the only country to acknowledge in its basic law the social function of intellectual property and to expressly recognize the intellectual property (IP) system as an instrument of government for use in advancing the welfare of its people. Unfortunately, because of its highly technical and abstruse nature, multinational companies and their lawyers have dominated the application of the intellectual property law in the Philippines.[8]

B. The Philippine Pharmaceutical Industry

The dominance of multinational corporations in the application of intellectual property law in the Philippines is visibly apparent in its pharmaceutical industry. In terms of market revenue share, this is clearly illustrated in the schedule below:[9]

Sales of Top 20 Corporate Groups (P Million)							
Corporation	1998	1999	2000	2001	2002		
					Rank	Sales	% Share
Total Market	P45,895	P51,496	P54,772	P60,451		P65,670	100%
United Lab	9,348	9,298	10,048	10,617	1	12,264	18.6%
Glaxo SK	4,799	5,203	5,763	6,429	2	6,618	10.1%
Pfizer Inc.	2,842	2,974	3,470	3,741	3	4,325	6.6%
Wyeth Phil	2,378	2,963	2,764	3,166	4	3,589	5.5%
AstraZeneca	1,900	2,338	2,754	2,780	5	3,125	4.8%
Bristol-Myers	2,153	2,709	2,763	2,971	6	3,059	4.7%
Novartis	1,656	1,830	1,784	2,021	7	2,279	3.5%
Abbot Lab	1,732	1,765	1,664	1,982	8	2,145	3.3%
Roche Phil	1,480	1,795	2,113	2,073	9	2,074	3.2%
Boe. Ingelheim	1,299	1,551	1,534	1,765	10	2,011	3.1%
Sanofi-Synth	806	961	1,130	1,426	11	1,744	2.7%
Pharmacia Phil	971	1,156	1,341	1,457	12	1,534	2.3%
Eli Lilly	722	1,033	1,173	1,329	13	1,304	2.0%
Merck	723	877	1,063	1,032	14	1,299	2.0%
Aventis Pharma	1,112	1,229	1,164	1,222	15	1,286	2.0%
Johnson	826	986	1,035	1,209	16	1,259	1.9%
Bayer Pharm	725	979	1,112	1,185	17	1,193	1.8%
Schering Plough	798	999	1,108	1,151	18	1,184	1.8%
Pascual Labs	468	782	858	810	19	1,051	1.6%
Zuellig Pharma	771	770	792	880	20	905	1.4%
SUB TOTAL	37,508	42,196	45,432	49,243		54,249	82.7%

Based on the schedule, at least 60% of the market is controlled by the multinational companies. This clearly establishes the marketing and distribution power of the multinationals in the Philippines. Only United Laboratories and Pascual Laboratories are owned by Filipinos. The rest of the market revenues share of around 17% were earned by various small and medium sized pharmaceutical companies some of which are still foreign owned but which may not be classified as multinational companies.

At present, rough industry estimates pegged the Philippine pharmaceutical industry market at around P85 billion with the market revenue sharing still the same as the trends of the previous years which shows a clear dominance by the multinationals. It

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intellectual property and creations, particularly when beneficial to the people, for such period as may be provided by law.

[8] Paragraphs 1 and 2, Position Paper of the Philippine Chamber of Pharmaceutical Industry on Senate Bill No. 2139, as Introduced by Hon. Mar Roxas; submitted to the Senate Committee on Trade and Commerce on January 26, 2006.

[9] Page 67, Philippine Pharmaceutical Industry Fact Book, 6th Edition, July 2003, PHAP.

is also worth noting that the division between Filipino and multinational companies is also manifested by its two umbrella organizations: (1) Philippine Chamber of Pharmaceutical Industry, Inc. (PCPI)[10],and,(2) Pharmaceutical and Healthcare Association of the Philippines (PHAP)[11]. Majority of Filipino-owned corporations are members of PCPI while all multinationals are members of PHAP. Each association has its own advocacies and projects.

The multinational companies justify their dominance of the Philippine pharmaceutical market on the ground that the drugs or medicines that they produce are of good quality with its efficacy and safety assured. Hence, the consumers patronize it more. In relation to the alleged high prices that they impose, they justify such because of the quality and the need to recoup their research and development costs in relation to each successful patent which is given exclusive rights by the intellectual property law of the Philippines. In other words, the strength of the multinationals lies in the patents of the drugs or medicines.

On the other hand, Filipino pharmaceutical companies, a significant majority of which are small and medium sized corporations, contend that there are a lot of barriers to a level playing field in the Philippine pharmaceutical market. As much as they acknowledge that they do not have that much capital, they especially note that, unlike the intellectual property laws of other countries, the intellectual property laws of the Philippines are designed in favor of heavily protecting the patents of the multinationals. Thus, granting more marketing monopoly in favor of the multinationals. It was manifested by the representative of the local pharmaceutical companies that every time they consider coming up with a generic drug or medicine, a significant risk they consider is the possibility and costs of a lawsuit that may be filed by a multinational. Also, they noted that their resources are limited in terms of checking which patents filed by the multinationals are truly innovative or actually frivolous.

This monopoly in pharmaceutical patents by the multinationals may be clearly seen in the following schedules:[12]

Number of Published Pharmaceutical Patents Filed From 2001 to 2004			
Year Published	Number of Foreign Pharmaceutical Patent Applications Filed	Number of Local Pharmaceutical Patent Applications Filed	Total Number of Pharmaceutical Patent Applications Filed
2001	1	9	10
2002	100	12	112
2003	54	1	55
2004	15	0	14
2005	0	0	0

Number of Pharmaceutical Patents Issued from 2002 - 2005			
Year	Number of Foreign Pharmaceutical Patent Applications Issued	Number of Local Pharmaceutical Patent Applications Issued	Total Number of Pharmaceutical Patent Applications Issued
2001	448	1	449
2002	363	0	363
2003	351	0	351
2004	531	0	531
2005 *(As of December 2, 2005)*	404	0	404

[10] PCPI is composed of 122 member companies, majority of which are Filipino owned, which was formed by the merger of four industry associations; namely: Association of Drug Industry of the Philippines, Inc. (ADIP), Association of Philippine Pharmaceutical Manufacturers, Inc. (APPMAN), Chamber of Philippine Pharmaceutical Manufacturers and Distributors, Inc. (CFDMD) and Filipino Drug Association (FIDA).

[11] PHAP is composed of 65 member companies and all multinational companies are part of it.

[12] Letter of Intellectual Property Office dated March 13, 2006 submitted to the Senate Committee on Trade and Commerce on March 13, 2006.

Number of Approved Pharmaceutical Patents to Expire from 2006 - 2015	
Foreign Patents	3,113
Local Patents	5
Total	3,118

As may be seen from the abovestated information, the strict intellectual property laws of the Philippines are largely protecting the monopolies of the multinationals or foreign owners since almost all of the pharmaceutical patents are foreign owned and all by multinationals from the developed world. It is posited that as a general rule for developing countries, the fewer patents granted on medicines, the better, so that monopolies are limited and generic versions can be introduced without delay.

III. Comparative Access and Affordability of Drugs and Medicines

To understand further the impact of the monopoly of the multinationals over the Philippine pharmaceutical industry, a comparison of drugs and medicine prices, particularly those sold by the same multinational companies, in other countries must be made. This may be understood better in the following illustrative tables:

Comparison of Select Branded Generic Drug or Medicine Prices (Philippines vs. India in Philippine Pesos)[13]

Drug	Generic Name	Company	Philippine Price	India Price	Pakistan Price
Ponstan 500mg tab	Mefenamic Acid	Pfizer	P20.98	P2.80	P1.46
Lopid 300mg cap	Gemfibrozil	Pfizer	34.66	13.17	2.89
Buscopan 10mg tab	Hyoscine-N-butylbromide	Boehringer	9.26	2.45	0.60
Bactrim 400/80mg tab	Co-trimoxazole	Roche	14.80	0.75	1.09
Adalat Retard 20mg tab	Nefedipine	Bayer	37.56	1.50	3.85
Lasix 40mg tab	Furosemide	Aventis	8.56	0.53	1.28
Plendil ER 5mg tab	Felodipine	AstraZeneca	35.94	5.95	8.25
Diamicron 80mg tab	Gliclazide	Servier	11.00	7.57	5.00
Ventolin 100mcg inh	Salbutamol	Glaxo	315.00	132.38	65.88
Voltaren 50mg tab	Diclofenac Na	Novartis	17.98	0.92	3.92
Isordil SL 50mg tab	Isosorbide Dinitrate	Wyeth	10.29	0.26	0.23
Imodium 2mg cap	Loperamide HCl	Janssen	10.70	3.27	1.94
Fortum 1g inj	Ceftadizime	Glaxo	980.00	418.72	322.75

The selling price differences as presented above are observable in other drugs and medicines sold by multinational pharmaceutical companies. Multinationals contend, however, that there are cheaper generic medicines available in the Philippines which are priced the same as Indian and Pakistan prices. Other participants in the hearing noted

[13] Based on the Philippine International Trading Corporation (PITC) Presentation to the Senate Committee on Trade and Commerce Hearing held on November 24, 2005. Cited sources of the PITC presentation are MIMS 2004, Philippines; IDR 2004, India; Red Book 2004, Pakistan.

though that the distribution and marketing reach of the generic drugs manufactured by local generic companies are very limited. It is also argued by the multinationals that economies-of-scale and recovery of research and development costs justify the differences in pricing strategy in the Philippines and in India. On this aspect, other participants in the hearing noted that what determines the pricing strategy of pharmaceutical companies is the maximum capability of the market to absorb the highest possible price.

Regardless of the arguments presented, it still does not answer the situation that the high Philippine prices have deprived at least half of the Filipinos access to medicines and, further, limited access for those Filipinos who have some money to purchase the same.

In the course of the proceedings of the Senate Committee on Trade and Commerce, it has been determined that the protection given by the Intellectual Property Code of the Philippines in favor of the inventors has resulted in a significant imbalance between supply and demand of drugs and medicines. Specifically, it was also posited by most of the participants that the market dominance of the multinational companies has caused artificial barriers to the fair trade of drugs and medicines which consequently led to the high prices and lack of access of drugs and medicines to the detriment of millions and millions of Filipinos.

IV. Other Causes for the High Prices of Drugs and Medicines

Notwithstanding the aforementioned, the Committee notes that there are other issues that contribute to the continued high cost of drugs and medicines, including off-patent drugs. These are, among others:[14]

1. The need to increase the national budget for health to help ease the out-of-pocket expenses of patients;
2. The need to improve the negative investor outlook at the local pharmaceutical market and the purchasing power of the Philippine peso;
3. The need to strengthen the local pharmaceutical industry to enable it to compete with multinational companies. This can be through increased government support in the form of tax exemptions for active substance drugs, technical assistance, loans, parallel importation, discounts or exemptions from regulatory fees;
4. The need to strengthen public confidence in the local generic industry;
5. The need to enact and enforce regulatory and supervisory laws and regulations to ensure the safety and efficacy of drugs;
6. The need to promote research and development in public health.
7. The need to develop the local generics industry's capability to manufacture more complex drugs (i.e. higher generation antibiotics, cardiovascular drugs, cancer chemotherapy drugs, or hyperalimentation);
8. The need to develop the local pharmaceutical industry's capability to develop drugs from endogeneous or local sources; and
9. The need to identify and develop sources of raw materials to lessen dependence on importation.

V. *Framework for Amending the Intellectual Property Code of the Philippines in light of the Constitutional Mandate of Protecting Public Health*

Based on the foregoing, there is a need to revisit the framework of the Intellectual Property Code of the Philippines so that the protection given to the intellectual property

[14] Based on the Letter of the Philippine Medical Association submitted to the Senate Committee on Trade and Commerce on 24 November 2005.

owners will be balanced with the greater public health interest of providing a more sustainable access to quality affordable medicines for the benefit of the greater populace. Aside from addressing the primary concern of ensuring better access to affordable drugs and medicines, the proposed Intellectual Property Code amendments should also be flexible enough to remedy various possible challenges to Philippine public health like biological and/or chemical terror attacks and global pandemics like bird flu or SARS.

There are basically three focus points by which these goals may be achieved. These are the following: (1) improvement of the supply of drugs and medicines to meet the large demand, (2) establishment of greater support for Filipino pharmaceutical generic companies, and, (3) rationalization and strengthening of government use options.

It should be noted though that the overarching parameter for these interventions implies that there should be no arbitrary taking of private property and that such interventions should be one oriented towards developing a more competitive and responsive Philippine pharmaceutical industry.

Further, amendments to the Intellectual Property Code of the Philippines must be introduced in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[15] and the Doha Declaration on the TRIPS Agreement and Public Health[16] of the World Trade Organization (WTO)[17]. As provided in the position paper of the Intellectual Property Office, the proposed amendments, as stated in the substitute bill, are in exercise of the flexibilities allowed to developing countries under the TRIPS Agreement and the Doha Declaration. The TRIPS flexibilities were envisioned "to balance the protection of intellectual property owners with economic and social welfare, as well as with technological development." The Doha Declaration was a recognition by Member Countries "of the gravity of the public health problems affecting many developing and least-developed countries." It also emphasized "the need for the TRIPS Agreement to be part of the wider action to address these problems," and an acknowledgment that intellectual property protection had an effect on the price of medicines, even as it is important for pharmaceutical research and development.

VI. *Areas for Amendments and Rationale for Each*

A. Non-Patentable Inventions: New Use of Existing Substances

The protection periods of patents eventually expire. However, it has been observed that patent owners have engaged in the practice of filing new patents for each demonstrable "new use" of a previously patented product or process. This method of "new use" is perceived as a way to prolong the monopoly companies enjoy through the patents over their medicines. This means that companies will be able to charge artificially high prices for double (or more) the length of time they have already been granted for the same patented product or process.

Based on the Intellectual Property Code of the Philippines and the TRIPS Agreement, countries have an obligation to grant patents on pharmaceutical products and processes. However, these same countries are not obliged to grant patents on new uses of existing substances. In fact, no provision in the TRIPS Agreement or in the Intellectual Property Code of the Philippines requires the grant of patents for such.

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[15] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement which established the WTO. http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

[16] DOHA Declaration on the TRIPS Agreement and Public Health was unanimously adopted by WTO member States, including the Philippines, on November 14, 2001 in the Fourth Session of the Ministerial Conference at Doha, Qatar. http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[17] The Agreement establishing the WTO was ratified by the Senate of the Philippines on December 14, 1994. Records of the Senate, page 500, Vol. III, No. 48.

It is contended by the multinationals in their position paper that proscribing new use from patentability runs counter to the general mandate of patentability which provides three (3) basic requirements for patents; namely, novelty, inventive step and industrial application. Further, in the same position paper it was cited that under American law that the broader concept applied is "utility" so that an invention only needs to be operable and capable of satisfying some function of benefit to humanity (i.e., to be useful). Hence, it ultimately reasons out that there is no reason to believe that the new use, molecules or compounds of a patented product could not meet the requirement of industrial applicability, provided that it can be applied for practical purposes.[18]

On the other hand, all the other participants in the hearing support the policy prescription of this particular amendment in line with the support and specific recommendations of the World Health Organization (WHO)[19] and the Intellectual Property Office (IPO)[20] of the Philippines. Both the WHO and the IPO noted that this proposed amendment would effectively limit the possibility of several patents being issued for what is essentially the same invention. Hence, it hinders access to generic versions of the medicine. Further, the WHO and IPO proposed that this amendment be patterned after Section 3(d) of the 2005 Amendments to the India Patents Law.

For reference, the WHO and IPO proposed amendment to Section 72.1 of the Intellectual Property Code of the Philippines, with the proposed amendments capitalized, is as follows:

> *"Sec.22. Non-Patentable Inventions. – The following shall be excluded from patent protection:*
>
> *22.1. THE MERE DISCOVERY OF A NEW FORM OF A KNOWN SUBSTANCE WHICH DOES NOT RESULT IN THE ENHANCEMENT OF THE KNOWN EFFICACY OF THAT SUBSTANCE OR THE MERE DISCOVERY OF ANY NEW PROPERTY OR NEW USE FOR A KNOWN SUBSTANCE OR THE MERE USE OF A KNOWN PROCESS UNLESS SUCH KNOWN PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT.*
>
> *FOR THE PURPOSES OF THIS CLAUSE, SALTS, ESTERS, ETHERS, POLYMORPHS, METABOLITES, PURE FORM, PARTICLE SIZE, ISOMERS, MIXTURES OF ISOMERS, COMPLEXES, COMBINATIONS AND OTHER DERIVATIVES OF KNOWN SUBSTANCE SHALL BE CONSIDERED TO BE THE SAME SUBSTANCE, UNLESS THEY DIFFER SIGNIFICANTLY IN PROPERTIES WITH REGARD TO EFFICACY. XXX."*

The IPO recommended, further, that this proposed amendment be introduced as among the enumerations in Section 22 of the Intellectual Property Code on Non-Patentable Inventions. This is instead of placing this clarification on Section 21 of the Intellectual Property Code because it may lead to a misinterpretation of the definition of patentability as prescribed in the TRIPS Agreement.

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[18] Position Paper of the Pharmaceutical and Healthcare Association of the Philippines (PHAP) on Senate Bill No. 2139, page 16, dated 11 January 2006, filed before the Senate Committee on Trade and Commerce.

[19] Position Paper of the World Health Organization (WHO) on Senate Bill No. 2139, dated 21 November 2005, filed before the Senate Committee on Trade and Commerce. To wit: *"It is a good bill, in brief, which seeks to implement some of the strategies to increase access to medicines that WHO has been advocating."* Cover Letter signed by Dr. Jean-Marc Olive, WHO Representative, WHO Philippine Office.

[20] Position Paper of the Intellectual Property Office of the Philippines on Senate Bill No. 2139, dated 24 January 2006, filed before the Senate Committee on Trade and Commerce.

The Committees on Trade and Commerce, and, Health and Demography agree with the WHO and the IPO that this particular amendment will prevent the filing of frivolous patents especially for new uses of existing substances. Hence, by introducing this amendment, greater access to cheaper medicines will be achieved because generic versions of off patent medicines will be introduced into the market sooner for the benefit of all Filipinos especially the underprivileged. The Committees also agree with the WHO and IPO proposed restructuring of the proposed amendment by adopting the similar amendment to the India Patent Law and integrating such in Section 22 on Non-Patentable Inventions of the Intellectual Property Code of the Philippines.

B. Parallel Importation and International Exhaustion of Intellectual Property Rights for Patents

Parallel importation refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price.[21] Competition in the supply of drugs or medicines is thus enhanced because of the importation of much lower priced identical drugs, which again redounds to the benefit of all Filipinos.

Under the present state of the Intellectual Property Code of the Philippines, parallel importation, as defined in the prior paragraph, is not allowed because of the adoption of the domestic exhaustion principle of intellectual property rights as stated in Sec. 72.1 of the same law. The current provision effectively grants exclusive rights in the Philippines, including authority to import, on patented products in favor of the patent owner only. There is, thus, a need to amend this particular provision to allow for the doctrine of international exhaustion of intellectual property rights in drugs and medicines instead of the current domestic exhaustion of intellectual property right.

The right of a country to adopt an international exhaustion regime is one of the "flexibilities" recognized under the TRIPS Agreement[22] and subsequently reiterated in the Declaration on TRIPS and Public Health, otherwise known as the Doha Declaration. Clause 5(d) of the Doha Declaration provides:

> *"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, subject to the MFN and national treatment provisions of Articles 3 and 4." (emphasis supplied)*

In support of this amendment, the IPO also noted in its position paper that nothing in the TRIPS Agreement prohibits the adoption of the doctrine of international exhaustion of intellectual property rights. It also reasoned that this proposed amendment is very important because it allows the supply of the product to be increased and prices to be moderated through competition, or, in other words, by improving accessibility through

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[21] Position Paper of the World Health Organization (WHO) on Senate Bill No. 2139, dated 21 November 2005, filed before the Senate Committee on Trade and Commerce, page 3, to wit: *"Parallel importation refers to importation, without the consent of the patent holder, of a patented product that is marketed in another country. Parallel importation allows one to 'shop around' for a good price. For example, if a company sells drug X in country A at a price of $10, while the same company sells the same drug X in country B for $1, then someone may import drug X from country B and sell it in country A, charging for example $3. As a result, in this example, country A would save $7 on product X. In other words, parallel importation also enables competition, but in a different way."*

[22] Footnote 6 to Article 28 of the TRIPS Agreement subjects the exclusive rights of the patent holder to Article 6, which in turn provides that *"nothing in the [TRIPS] Agreement shall be used to address the issue of the exhaustion of intellectual property rights."* By implication, there is nothing in the TRIPS Agreement requiring a State Party to adopt a particular form of exhaustion principle.

importation of drugs priced cheaply abroad than their counterparts in the Philippines. The implication of adopting an international exhaustion of rights regime is that once a drug or medicine is sold or marketed anywhere in the world, the Philippines can immediately benefit from the price differences for the same drug or medicine in a different market.[23] The IPO unequivocally supported this proposed amendment under Senate Bill No. 2139 without any modifications.

For reference, the proposed amendment to Section 72.1 of the Intellectual Property Code of the Philippines, with the proposed amendments capitalized, is as follows:

> *"72.1. 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 OR MEDICINES, THE LIMITATION ON PATENT RIGHTS SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE INVENTION."*

Parallel importation is permitted in several countries. The European Union permits parallel importation between European countries. In Japan, the courts have held that the parallel importing of patented products sold in one country into Japan does not violate the patents granted in Japan.[24] Argentina, Cambodia, Thailand and Vietnam permit parallel importation, with clearly worded legislation.[25]

It should be noted that the Philippines, at present, imports off-patent lower priced drugs or medicines from India through the Philippine International Trading Corporation (PITC). Though this involves the importation of drugs or medicines, this is not parallel importation as legally defined which, as stated earlier, involves the importation of patented drugs even without the consent of the patent owner. Nevertheless, the multinational corporations, represented by PHAP, have filed cases against the relevant government officials led by the Secretary of Health, Director of the Bureau of Food and Drugs and the PITC contending that these actions of importing cheaper off-patent branded medicines by the government on the ground that such constitutes infringement of its patent, trademark and tradename rights in violation of the basic right that no person shall be deprived of property without due process of law.[26] The case is for prohibition of the importation with an application for a temporary restraining order and preliminary injunction.

C. Early Working

Early working refers to the process by which generic companies are allowed to experiment and test for regulatory approval of generic versions of a drug or medicine before its patent expires. This will allow generic producers to get ready, so that they can start the production and sale of a generic drug as soon as its patent expires.

As explained by the WHO, in the absence of such provision, generic manufacturers can only start the time-consuming process of testing and registration after the expiry of the patent. This easily delays the marketing of generic drugs for two to

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[23] Position Paper of the Intellectual Property Office of the Philippines on Senate Bill No. 2139, dated 24 January 2006, filed before the Senate Committee on Trade and Commerce.
[24] Japan Supreme Court, DECISION on Case No. Heisei 7(wo) 1988 delivered on July 1, 1997.
[25] Position Paper of the Intellectual Property Office of the Philippines on Senate Bill No. 2139, dated 24 January 2006, filed before the Senate Committee on Trade and Commerce.
[26] PHAP vs. Secretary of Health, et.al., Civil Case No. 00-1374, Makati Regional Trial Court

three years after patent expiry.[27] Again, this will facilitate generic competition through the immediate entry in the Philippine pharmaceutical market of more affordable or lower priced drugs or medicines.

The IPO supports[28], without any corrections or modifications, the two proposed amendments of Senate Bill No. 2139 which allows the early working doctrine because both amendments are consistent with TRIPS Agreement.

For reference, the proposed amendment to Section 72.3 and 72.4 of the Intellectual Property Code of the Philippines, with the proposed amendments capitalized, is as follows:

> *"72.3. Where the act consists of making or using exclusively for EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR FOR COMMERCIAL PURPOSES THAT DO NOT UNREASONABLY CONFLICT WITH A NORMAL EXPLOITATION OF THE PATENT AND THAT DO NOT UNREASONABLY PREJUDICE THE LEGITIMATE INTERESTS OF THE PATENT OWNER, TAKING INTO ACCOUNT THE LEGITIMATE INTERESTS OF SUCH THIRD PARTIES.*
>
> *72.4 WHERE THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION REQUIRED UNDER ANY LAW OF THE PHILIPPINES OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT."*

As an exception to rights conferred on patent owners and in compliance with the TRIPS Agreement[29], the first proposed amendment broadens the purposes of experimental use of inventions to include commercial purposes aside from scientific purposes; provided, that it does not unreasonably conflict with a normal exploitation of the patent and that it does not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of such third parties.

The second proposed amendment introduces into the Intellectual Property Code of the Philippines the doctrine of early working by creating an exception to the exclusive right of the patent holder to the use of the invention by allowing a third party to use and test the patented invention including any data related thereto. The same proposal, however, clearly limits this exception solely for purposes reasonably related to the development and submission of information required under any law of the Philippines or of another country. In short, this will allow generic companies to engage in any activity that will facilitate the registration of a generic version of a drug before the Bureau of Food and Drugs or any other drug regulatory authority before the patent expires. For the protection of the patent holder, it may be inferred from the amendment in relation to the existing 20-year patent period that the actual act of manufacturing in commercial quantities, stockpiling, marketing, distribution and selling to the public may only be done after expiration of the patent.

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[27] Position Paper of the World Health Organization (WHO) on Senate Bill No. 2139, dated 21 November 2005, filed before the Senate Committee on Trade and Commerce.

[28] Position Paper of the Intellectual Property Office of the Philippines on Senate Bill No. 2139, dated 24 January 2006, filed before the Senate Committee on Trade and Commerce.

[29] Article 30 of the TRIPS Agreement, to wit: *"Exceptions to Rights Conferred: Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."*

It is worth noting that this amendment is similarly provided in many other jurisdictions, i.e., Canada, Argentina, Thailand, Malaysia and Indonesia. In the United States, a similar provision is stated in the US Code.[30]

As stated earlier, these proposed amendments will make the Philippine pharmaceutical industry more competitive because it will increase the supply of medicines by allowing the early entry of generic versions within a short period of a few months after patent expiration. For the Filipino consumer, this will effectively result to an increase in the supply of cheaper generic medicines as alternatives to the branded off-patent drugs.

It should also be noted that the second proposed amendment also allows generic companies to perform early working for purposes of registration in other countries. This also broadens the market of the generic Philippine companies by giving them the right to compete and export to areas beyond our national boundaries as long as the importing country allows the same in their domestic laws. For the Philippines, this could translate to more internal tax revenues. For the Filipino consumer, again this will ensure high quality generic medicines made by Filipino pharmaceutical companies and sold at cheaper prices.

D. Government Use and Legal Cover for Government Use

Provisions for the governmental use of patented medicines or processes for their manufacture constitutes an important tool to protect public health. Unlike the case of compulsory licenses, there is no need for an application by a private or public party, but the government can, in exercising its authority, decide ex officio to use a patented invention. In addition, the government can allow a subcontractor or authorized representative to use the invention on its behalf.[31]

The US Government has made an extensive application of government use provisions: "the US has always relied heavily on the non-voluntary licensing of patented inventions to facilitate public, non-commercial uses by the government and its agents... The bulk of the non-voluntary licenses issued for government use pertain to national defense. Nevertheless, the US has also used this same legal tool to reduce the costs of certain medicines and to advance both environmental and economic development goals, including major projects to dam river and generate electricity"[32].

The TRIPS Agreement does not limit the right of member states to make the determination of the reasons, including public health, which may justify the government use of a patented invention. Under the Intellectual Property Code of the Philippines, the government has broad room to decide the use of patented inventions. However, the same law subjects the government, *mutatis mutandis*, to the same conditions applicable to

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[30] 35 U.S.C. 271 (e)(1); to wit: *"It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product [as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913] which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products."*

[31] Carlos M. Correa, Use of TRIPS Flexibilities under the Patent Law of the Republic of the Philippines, November 2005. Note: Carlos M. Correa is a world renowned expert in intellectual property rights and public health and was guest speaker in the first Philippine Intellectual Property Rights and Public Health Forum held last October 20 and 21, 2005 at the Intercontinental Hotel of Manila, Makati City.

[32] Reichman, J. and Hasenzahl, C. (2002), Non-Voluntary Licensing of Patented Inventions: Historical perspective, Legal framework under TRIPS, and an Overview of the Practice in Canada and the United States of America, UNCTAD/ICTSD, Geneva, as cited in Carlos M. Correa, Use of TRIPS Flexibilities under the Patent Law of the Republic of the Philippines, November 2005.

compulsory licenses. It is this present requirement of following compulsory licensing rules, which has unduly impeded the exercise of the government use option by the appropriate agency.

Present Philippine jurisprudential experience in compulsory licensing shows that it takes a long period of time to get approval because of procedural delays caused by appeals filed by the patent owners. The only compulsory license petition granted, after the new Philippine Intellectual Property Code took effect on January 1, 1998, was a compulsory license petition filed on December 8, 1991 when the old Patent law was still in effect. This petition was finally granted on December 19, 2001 – that is after a period of ten years.[33]

In relation to the proposed amendments to the government use provisions, all parties in the hearing agreed that the proposal of the IPO, which supports the policy approach of the amendments of Senate Bill No. 2139 but restructures this particular proposed amendment, is acceptable to all the parties. The IPO proposal clarifies the whole government use option and effectively removed the process for the exercise of such from the *mutatis mutandis* application of compulsory licensing rules. This is expected to make the process more efficient and timely particularly in handling emergency situations.

It is worth noting that the IPO proposal retained part of the proposed amendment of Senate Bill No. 2139 which grants to the Secretaries of the Departments of Health, and, Trade and Industry the power to make a joint determination on the immediately executory use or other exploitation by the government or its authorized representatives of drugs or medicines to protect public health. It also retained the proposals to provide legal cover for the implementing agencies and its officers, which shall implement the said action. This legal cover includes the following: (1) exemption from temporary restraining orders and preliminary injunctions of the act, and, (2) the non-filing of any suit against the relevant public officials in relation to the act.

For reference, the proposed amendment to Section 74.1 of the Intellectual Property Code of the Philippines, with the proposed amendments capitalized, is as follows:

> *"Sec. 74. Use of Invention by Government. – 74.1. A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:*
>
> *(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or*
>
> *(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his license, is anti-competitive; OR*
>
> *(C) THERE IS PUBLIC NON-COMMERCIAL USE OF THE PATENT BY THE PATENTEE, WITHOUT SATISFACTORY REASON.*
>
> *"74.2. UNLESS OTHERWISE PROVIDED HEREIN, the use by the Government, or third person authorized by the Government shall be subject TO THE FOLLOWING PROVISIONS:*

[33] Carlos M. Correa, Use of TRIPS Flexibilities under the Patent Law of the Republic of the Philippines, November 2005.

(A) IN SITUATIONS OF NATIONAL EMERGENCY OR OTHER CIRCUMSTANCES OF EXTREME URGENCY, THE RIGHT HOLDER SHALL BE NOTIFIED AS SOON AS REASONABLY PRACTICABLE;

(B) IN THE CASE OF PUBLIC NON-COMMERCIAL USE, WHERE THE GOVERNMENT OR CONTRACTOR, WITHOUT MAKING A PATENT SEARCH, KNOWS OR HAS DEMONSTRABLE GROUNDS TO KNOW THAT A VALID PATENT IS OR WILL BE USED BY OR FOR THE GOVERNMENT, THE RIGHT HOLDER SHALL BE INFORMED PROMPTLY;

(C) THE SCOPE AND DURATION OF SUCH USE SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS AUTHORIZED, AND IN THE CASE OF SEMI-CONDUCTOR TECHNOLOGY, SHALL ONLY BE FOR PUBLIC NON-COMMERCIAL USE OR TO REMEDY A PRACTICE DETERMINED AFTER JUDICIAL OR ADMINISTRATIVE PROCESS TO BE ANTI-COMPETITIVE;

(D) SUCH USE SHALL BE NON-EXCLUSIVE;

(E) THE RIGHT HOLDER SHALL BE PAID ADEQUATE REMUNERATION IN THE CIRCUMSTANCES OF EACH CASE, TAKING INTO ACCOUNT THE ECONOMIC VALUE OF THE AUTHORIZATION;

(F) THE LEGAL VALIDITY OF ANY DECISION RELATING TO THE AUTHORIZATION OF SUCH USE SHALL BE SUBJECT TO JUDICIAL REVIEW; AND

(G) SUBJECT TO THE CONTROL, SUPERVISION AND DETERMINATION OF THE RESPECTIVE SECRETARIES OF THE DEPARTMENT OF HEALTH AND DEPARTMENT OF TRADE AND INDUSTRY, THE USE OR OTHER EXPLOITATION BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL BE IMMEDIATELY EXECUTORY AND SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION OR SUCH OTHER PROVISIONAL REMEDIES THAT WILL PREVENT ITS IMPLEMENTATION. NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER AUTHORIZED PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY. ALL CASES ARISING FROM THE IMPLEMENTATION OF THIS PROVISION SHALL BE COGNIZABLE BY COURTS WITH APPROPRIATE JURISDICTION PROVIDED BY LAW."

The Department of Health representative, however, noted that since paragraph G of the proposed amendment to Section 74.2. of the Intellectual Property Code of the Philippines deals with the protection of public health, the primary responsibility for the determination should be done by the Secretary of the Department of Health since it is within the latter's field of expertise. On the other hand, proponents for a joint determination posit that for purposes of checks and balances, the coordinating decision of the Secretary of Trade and Industry and the Secretary of Health would be better.

The restructuring of the government use provision is expected to create an environment whereby the government will now be able to act promptly and decisively on matters that involve public interest. On the matter of protecting public health, this proposed amendment to government use would also give the government the ability to act immediately on issues like the avian influenza and SARS without fear of possible lawsuits from patent owners.

E. Exception to Trademarks and Tradenames Rights

Under the Intellectual Property Code of the Philippines and the TRIPS Agreement, which establishes the basic rights of trademark owners, it should be noted that the protection in favor of trademark holders is against the use of their marks where there is a likelihood of confusion.

Under this legal framework, it is also possible for multinational pharmaceutical companies who own the tradenames or trademarks to restrict access to drugs and medicines by asserting that parallel importers may not use local trademarks for drugs imported pursuant to Section 72.1 of the Intellectual Property Code of the Philippines even if these drugs or medicines have been put on the market by the trademark holders in other markets. Imposing restrictions on trademarks in addition to conditions involved in the importation, sale or distribution of drugs or medicines imported pursuant to Section 72.1 create an additional barrier to the entry of said drugs or medicines in the market.[34]

To avoid violating this legal obligation, the following proposed amendment to Section 147 of the Intellectual Property Code of the Philippines, which has been proposed by the IPO and with the changes capitalized, is as follows:

> *"Sec. 147. Rights Conferred. – 147.1. EXCEPT IN CASES OF IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1, t[T]he 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. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.*
>
> *147.2 The exclusive right of the owner of a wellknown mark defined in Subsection 123.1(e) which is registered in the Philippines, shall extend to goods and services which are not similar to those in respect of which the mark is registered: Provided, That use of that mark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered mark: Provided, further, That the interests of the owner of the registered mark are likely to be damaged by such use."*

This proposed amendment will complement the adoption of the international exhaustion of intellectual property rights as explained earlier. Further, this will also support the contention that in cases of parallel importation, the drugs or medicines bear the trademark of the same patent owner, hence, there is no likelihood of confusion. In short, this amendment is meant to create a competitive business environment for parallel importation.

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[34] Position Paper of the Intellectual Property Office of the Philippines on Senate Bill No. 2139, dated 24 January 2006, filed before the Senate Committee on Trade and Commerce.

F. *Closing Points on the Proposed Amendments*

Several factors contribute to the high cost of essential medicines in the Philippines but the absence of effective competition in the pharmaceutical industry is a significant contributor. The lack of effective competition is in turn attributable to several factors. Foremost of which is an intellectual property system on patents in the Philippines that is skewed in favor of the patent holder to the detriment of the general public, which at present is heavily suffering from the lack of access to quality affordable medicines. This proposed legislation seeks to remedy this situation by introducing a few but major amendments to the Intellectual Property Code of the Philippines which, as explained earlier, are TRIPS compliant, and, will promote greater competition in the Philippine pharmaceutical industry. Ultimately, the effects of this proposed legislation would be more access to quality affordable drugs or medicines for all Filipinos.

G. Support for the Proposed Amendments to the Intellectual Property Code of the Philippines

Except for PHAP, which represented the interest of the multinationals, all participants in the hearings of the Senate Committee on Trade and Commerce for Senate Bill No. 2139 supported all the proposed amendments espoused in the said bill, as restructured by the IPO, because it will effectively improve the access to low priced drugs or medicines for the benefit of millions and millions of Filipinos.

The parties in favor and supportive of these proposed amendments are the following: (1) Department of Health (DOH), (2) Department of Trade and Industry (DTI), (3) Intellectual Property Office (IPO), (4) Bureau of Food and Drugs (BFAD), (5) Philippine International Trading Corporation (PITC), (6) National Institutes of Health (NIH), (7) World Health Organization (WHO), (8) Philippine Medical Association (PMA), (9) Philippine Nurses Association (PNA), (10) Integrated Midwives Association of the Philippines (IMAP), (12) Philippine Chamber of the Pharmaceutical Industry (PCPI), (13) Third World Network (TWN), (14) Cut the Cost, Cut the Pain Network (3CPNet), (15) OXFAM Philippines, (16) Ayos na Gamot sa Abot Kayang Presyo (AGAP), and, various NGOs for the poor, sick and elderly.

VII. ***Recommendation***

After a careful review of all the proposals, including submitted documents and pertinent records, the Committees have the honor to report them back to the Senate with the recommendation that the attached substitute bill, S. No. 2263, prepared by the Committees, entitled:

AN ACT

TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY CLARIFYING NON-PATENTABLE INVENTIONS, ALLOWING THE IMPORTATION AND EARLY DEVELOPMENT OF PATENTED MEDICINES, AND MODIFYING GOVERNMENT USE PROVISIONS FOR DRUGS OR MEDICINES, TO LOWER PRICES AND INCREASE ACCESS TO AND SUPPLY OF QUALITY DRUGS OR MEDICINES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES.

be approved in substitution of S. No. 2139 with Senator MAR Roxas and Senator Pia Cayetano as authors thereof.

Respectfully submitted:

MAR ROXAS
Chairman, Committee on Trade & Commerce
Member, Committee on Health and Demography

"COMPAÑERA" PIA S. CAYETANO
Chairperson, Committee on Health and Demography
Member, Committee on Trade and Commerce

RICHARD J. GORDON
Vice-Chairman, Committee on Trade and Commerce
Member, Committee on Health and Demography

MEMBERS:

RAMON "BONG" REVILLA, JR.
Committee on Trade and Commerce

SERGIO R. OSMEÑA III
Committee on Trade and Commerce

Subject to amendments

EDGARDO J. ANGARA
Committee on Trade and Commerce
Committee on Health and Demography

RALPH G. RECTO
Committee on Trade and Commerce
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M.A. MADRIGAL
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RODOLFO G. BIAZON
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Majority Leader

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Minority Leader

HON. FRANKLIN M. DRILON
Senate President
Senate of the Philippines
Pasay City

THIRTEENTH CONGRESS OF)
THE REPUBLIC OF THE PHILIPPINES)
Second Regular Session)

6 JUN -7 A8:48

RECEIVED BY:

SENATE

S. No. 2263

(In substitution of Senate Bill No. 2139)

Prepared by the Committees on Trade and Commerce and Health and Demography with Senator MAR Roxas and Senator Pia Cayetano as authors thereof

---

AN ACT
TO MAKE THE LAWS ON PATENTS, TRADENAMES AND TRADEMARKS MORE RESPONSIVE TO THE HEALTH CARE NEEDS OF THE FILIPINO PEOPLE BY CLARIFYING NON-PATENTABLE INVENTIONS, ALLOWING THE IMPORTATION AND EARLY DEVELOPMENT OF PATENTED MEDICINES, AND MODIFYING GOVERNMENT USE PROVISIONS FOR DRUGS OR MEDICINES, TO LOWER PRICES AND INCREASE ACCESS TO AND SUPPLY OF QUALITY DRUGS OR MEDICINES, AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES.

Be it enacted by the Senate and the House of Representatives of the Philippines in Congress assembled:

SECTION 1. Sec. 22 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 22. *Non-Patentable Inventions.*– The following shall be excluded from patent protection:

"22.1. THE MERE DISCOVERY OF A NEW FORM OF A KNOWN SUBSTANCE WHICH DOES NOT RESULT IN THE ENHANCEMENT OF THE KNOWN EFFICACY OF THAT *SUBSTANCE OR THE MERE DISCOVERY OF ANY NEW* PROPERTY OR NEW USE FOR A KNOWN SUBSTANCE OR THE MERE USE OF A KNOWN PROCESS UNLESS SUCH KNOWN PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT.

FOR THE PURPOSES 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.

"[22.1.] 22.2. Discoveries, scientific theories and mathematical methods;

"[22.2.] 22.3. Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;

"[22.3.] 22.4. Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and composition for use in any of these methods.

"[22.4.] 22.5. Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.

Provisions under this subsection shall not preclude Congress to consider the enactment of a law providing *sui generis* of plant varieties and animal breeds and a system of community intellectual rights protection;

"[22.5.] 22.6. Aesthetic creations; and

"[22.6.] 22.7. Anything which is contrary to public order or morality. (Sec. 8, R.A. No. 165a)"

SEC. 2. Sec. 72 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 72. *Limitations of Patent Rights.* – The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

"72.1. 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 OR MEDICINES, THE LIMITATION ON PATENT RIGHTS SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE INVENTION.

"72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: *Provided,* That it does not significantly prejudice the economic interests of the owner of the patent;

"72.3. Where the act consists of making or using exclusively for [the purpose of experiments that relate to the subject matter of the patented invention;] EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR FOR COMMERCIAL PURPOSES THAT DO NOT UNREASONABLY CONFLICT WITH A NORMAL EXPLOITATION OF THE PATENT AND THAT DO NOT UNREASONABLY PREJUDICE THE LEGITIMATE INTERESTS OF THE PATENT OWNER, TAKING INTO ACCOUNT THE LEGITIMATE INTERESTS OF SUCH THIRD PARTIES;

"72.4 WHERE THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION REQUIRED UNDER ANY LAW OF THE

PHILIPPINES OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT.

"[72.4] 72.5. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

"[72.5] 72.6. Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: *Provided*, That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines. (Secs. 38 and 39, R.A. No. 165a)"

SEC. 3. Sec. 74 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 74. *Use of Invention by Government.* – 74.1. A Government agency or third person authorized by the Government may exploit the invention even without agreement of the patent owner where:

(a) The public interest, in particular, national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or

(b) A judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his license, is anti-competitive; OR

(C) THERE IS PUBLIC NON-COMMERCIAL USE OF THE PATENT BY THE PATENTEE, WITHOUT SATISFACTORY REASON.

"74.2. UNLESS OTHERWISE PROVIDED HEREIN, [T]the use by the Government, or third person authorized by the Government shall be subject, [*mutatis mutandis*, to the conditions set forth in Sections 95 to 97

and *100 to 102.* (Sec. 41, R.A. No. 165a)] TO THE FOLLOWING PROVISIONS:

(A) IN SITUATIONS OF NATIONAL EMERGENCY OR OTHER CIRCUMSTANCES OF EXTREME URGENCY, THE RIGHT HOLDER SHALL BE NOTIFIED AS SOON AS REASONABLY PRACTICABLE;

(B) IN THE CASE OF PUBLIC NON-COMMERCIAL USE, WHERE THE GOVERNMENT OR CONTRACTOR, WITHOUT MAKING A PATENT SEARCH, KNOWS OR HAS DEMONSTRABLE GROUNDS TO KNOW THAT A VALID PATENT IS OR WILL BE USED BY OR FOR THE GOVERNMENT, THE RIGHT HOLDER SHALL BE INFORMED PROMPTLY;

(C) THE SCOPE AND DURATION OF SUCH USE SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS AUTHORIZED, AND IN THE CASE OF SEMI-CONDUCTOR TECHNOLOGY, SHALL ONLY BE FOR PUBLIC NON-COMMERCIAL USE OR TO REMEDY A PRACTICE DETERMINED AFTER JUDICIAL OR ADMINISTRATIVE PROCESS TO BE ANTI-COMPETITIVE;

(D) SUCH USE SHALL BE NON-EXCLUSIVE;

(E) *THE RIGHT HOLDER SHALL BE PAID ADEQUATE* REMUNERATION IN THE CIRCUMSTANCES OF EACH CASE, TAKING INTO ACCOUNT *THE ECONOMIC* VALUE OF THE AUTHORIZATION;

(F) THE LEGAL VALIDITY OF ANY DECISION RELATING TO THE AUTHORIZATION OF SUCH USE SHALL BE *SUBJECT TO JUDICIAL REVIEW*; AND

(G) SUBJECT TO THE CONTROL, SUPERVISION AND DETERMINATION OF THE RESPECTIVE SECRETARIES OF THE DEPARTMENT OF HEALTH AND DEPARTMENT OF TRADE AND INDUSTRY, THE USE OR OTHER EXPLOITATION BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL BE IMMEDIATELY EXECUTORY AND SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION OR SUCH OTHER PROVISIONAL REMEDIES THAT WILL PREVENT ITS IMPLEMENTATION. NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER AUTHORIZED PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY. ALL CASES ARISING FROM THE IMPLEMENTATION OF THIS PROVISION SHALL BE COGNIZABLE BY COURTS WITH APPROPRIATE JURISDICTION PROVIDED BY LAW."

SEC. 4. Sec. 147 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 147. *Rights Conferred.* – 147.1. EXCEPT IN CASES OF IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1, [T]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. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

"147.2 The exclusive right of the owner of a well known mark defined in Subsection 123.1(e) which is registered in the Philippines, shall extend to goods and services which are not similar to those in respect of which the mark is registered: *Provided,* That use of that mark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered mark: *Provided, further*, That the interests of the owner of the registered mark are likely to be damaged by such use.(n)"

SEC. 5. *Separability Clause.* – Any portion or provisions of this Act that may be declared unconstitutional or invalid shall not have the effect of nullifying other portions and provisions hereof as long as such remaining portion or provision can still subsist and be given effect in their entirety.

SEC. 6. *Repealing Clause.* – All laws, decrees, executive orders, proclamations and administrative regulations, or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SEC. 7. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation.

Approved,