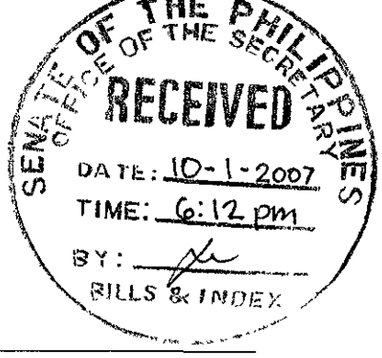
FOURTEENTH CONGRESS OF)
THE REPUBLIC OF THE PHILIPPINES)
First Regular Session)



S E N A T E

COMMITTEE REPORT NO. 6

Submitted jointly by the Committees on Trade and Commerce, Health and Demography, and, Finance on OCT 0 1 2007.

Re: S. No. 1658, prepared by the Committees.

Recommending approval in substitution of S. Nos. 90, 101, 755, 1404, 1420 and 1530, taking into consideration P.S. Resolution No. 49, with Senators Villar, Roxas, Trillanes IV, Pia Cayetano, Zubiri, Legarda, Lapid and Enrile as authors thereof.

Sponsors: Senator M A R Roxas, Senator Compañera Pia S. Cayetano, Senator Juan Ponce Enrile.

Mr. President:

The Committee on Trade and Commerce jointly with the Committees on Health and Demography, and, Finance to which were referred the following:

Senate Bill No. 90, introduced by Senator Manny Villar, entitled:

AN ACT
PROVIDING FOR CHEAPER MEDICINES
AND FOR OTHER PURPOSES

Senate Bill No. 101, 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 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

Senate Bill No. 755, introduced by Senator Antonio F. Trillanes IV, entitled:

AN ACT
PRESCRIBING SPECIAL MEASURES TO LOWER THE PRICE OF MEDICINES AND OTHER RELATED PURPOSES

Senate Bill No. 1404, introduced by Senator "Compañera" Pia S. Cayetano, 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, AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

Senate Bill No. 1420, introduced by Senator Juan Miguel F. Zubiri, entitled:

AN ACT
PROVIDING FOR CHEAPER MEDICINES AND FOR OTHER PURPOSES

Senate Bill No. 1530, introduced by Senator Loren B. Legarda, entitled:

AN ACT
TO FIX THE MAXIMUM RETAIL PRICE OF MEDICINES UNDER CERTAIN CONDITIONS AND INCREASE ACCESS TO CHEAPER MEDICINES BY CREATING A DRUG PRICES REGULATION BOARD AND BY AMENDING RELEVANT PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES, AND FOR OTHER PURPOSES

and taking into consideration, Philippine Senate Resolution No. 49, introduced by Senator Manuel M. Lapid, entitled:

RESOLUTION
DIRECTING THE SENATE COMMITTEE ON HEALTH AND DEMOGRAPHY, AND OTHER APPROPRIATE COMMITTEES IN THE SENATE TO CONDUCT AN INQUIRY, IN AID OF LEGISLATION, INTO THE DEMOGRAPHIC, SOCIO-ECONOMIC AND MARKET FACTORS WHICH MAKE THE PRICES OF ESSENTIAL DRUGS AND MEDICINES IN THE PHILIPPINES AMONG THE HIGHEST IN ASIA, WITH THE END IN VIEW OF PROVIDING A COMPREHENSIVE AND HOLISTIC HEALTH POLICY INTERVENTION THAT WOULD LOWER THE COST OF ESSENTIAL DRUGS AND MEDICINES IN THE COUNTRY

have considered the same and have conducted three (3) public hearings where the concerned government agencies and industry representatives of the affected sectors, including consumers, were represented and heard. These hearings were held on September 10, 12 and 17, 2007.

Further, all the records and position papers gathered in the 13th Congress during the deliberations for then Senate Bill No. 2139 filed by Senator MAR Roxas, which was unanimously passed by the Philippine Senate on third and final reading as Senate Bill No. 2263, have been adopted as part of the official records of the present committee hearings since it deals with the same subject matter. It is worth noting that then Senate Bill No. 2263 was finalized after taking into consideration the proposed amendments introduced by Senators Miriam Defensor-Santiago, Edgardo J. Angara and Ma. Consuelo Madrigal.

Based on the foregoing and after a careful scrutiny of the aforementioned resolution and bills, together with 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, and, Finance provide herein the specific findings and its recommendation to address the issue of broadening access to quality affordable medicines for the benefit of all Filipinos.

I. Problem of Access to Quality 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. The

[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.

State must also 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, 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%

[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 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.

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 P100 to 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 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.

[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.

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

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:

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

Comparison of Select Branded Generic Drug or Medicine Prices (Philippines vs. India and Pakistan in Philippine Pesos)[13]								
Drug	Generic Name	Company	Philippine Price		India Price		Pakistan Price	
			2005	2004	**2005**	2004	**2005**	2004
Ponstan 500mg tab	Mefenamic Acid	Pfizer	**21.82**	20.98	**2.61**	2.80	**1.38**	1.46
Lopid 300mg cap	Gemfibrozil	Pfizer	**36.39**	34.66	**12.27**	13.17	**2.72**	2.89
Buscopan 10mg tab	Hyoscine-N-butylbromide	Boehringer	**9.61**	9.26	**2.28**	2.45	**0.57**	0.60
Bactrim 400/80mg tab	Co-trimoxazole	Roche	**15.55**	14.80	**0.69**	0.75	**1.03**	1.09
Adalat Retard 20mg tab	Nefedipine	Bayer	**37.56**	37.56	**1.40**	1.50	**3.63**	3.85
Lasix 40mg tab	Furosemide	Aventis	**8.99**	8.56	**0.49**	0.53	**1.21**	1.28
Plendil ER 5mg tab	Felodipine	AstraZeneca	**35.93**	35.94	**4.58**	5.95	**7.78**	8.25
Diamicron 80mg tab	Gliclazide	Servier	**11.46**	11.00	**7.05**	7.57	**4.71**	5.00
Ventolin 100mcg inh	Salbutamol	Glaxo	**315.00**	315.00	**123.31**	132.38	**62.10**	65.88
Voltaren 50mg tab	Diclofenac Na	Novartis	**17.98**	17.98	**0.86**	0.92	**3.70**	3.92
Isordil SL 50mg tab	Isosorbide Dinitrate	Wyeth	**10.29**	10.29	**0.24**	0.26	**0.22**	0.23
Imodium 2mg cap	Loperamide HCI	Janssen	**10.70**	10.70	**3.05**	3.27	**1.83**	1.94
Fortum 1g inj	Ceftadizime	Glaxo	**980.00**	980.00	**390.00**	418.72	**304.22**	322.75

Based on the foregoing table, it is very clear that prices for exactly the same drugs are much lower in India and Pakistan in both 2005 and 2004. Further, comparing the presented 2005 and 2004 prices, it is observable that prices for exactly the same medicines in India and Pakistan have gone down while several Philippine prices have either gone up or just stayed the same. 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 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

[13] Based on the Department of Health (DOH) Presentation to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing held on September 10, 2007 and on the Philippines International Trading Corporation (PITC) Presentation to the Senate Committee on Trade and Commerce Hearing held on November 24, 2005. Cited sources of the DOH and PITC presentations are MIMS 2005 and 2004, Philippines; IDR 2005 and 2004, India; Red Book 2005 and 2004, Pakistan, respectively.

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. *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 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)[14] and the Doha Declaration on the TRIPS Agreement and Public Health[15] of the World Trade Organization (WTO)[16]. 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

[14] 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

[15] 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

[16] 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.

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.

V. *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. On the extreme, allowing such could also open the floodgates to new patent registrations for what are already classified at present as generics or off-patent medicines.

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.

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.[17]

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)[18] and the Intellectual Property Office (IPO)[19] 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. Further, the WHO and IPO proposed that this amendment be patterned after Section 3(d) of the 2005 Amendments to the India Patents Law.

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[17] 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.

[18] 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.

[19] 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 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.

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. As it has been agreed upon during the interpellations of Senator Edgardo J. Angara in the 13th Congress, the substance of this amendment has been introduced under Section 26 on Inventive Step 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 of exactly the same product, without the consent of the patent holder, of a patented product that is marketed in another country by the same patent owner. Parallel importation allows one to 'shop around' for a good price.[20] 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[21] 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*

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[20] 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."*

[21] 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.

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 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.[22] The IPO unequivocally supported this proposed amendment without any modifications.

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.[23] Argentina, Cambodia, Thailand and Vietnam permit parallel importation, with clearly worded legislation.[24]

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.[25] 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 three years after patent expiry.[26] Again, this will facilitate generic competition through

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[22] 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.
[23] Japan Supreme Court, DECISION on Case No. Heisei 7(wo) 1988 delivered on July 1, 1997.
[24] 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.
[25] PHAP vs. Secretary of Health, et.al., Civil Case No. 00-1374, Makati Regional Trial Court
[26] 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.

the immediate entry in the Philippine pharmaceutical market of more affordable or lower priced drugs or medicines.

The IPO supports[27] the proposed amendments which allows the early working doctrine because such is consistent with the TRIPS Agreement.

As an exception to rights conferred on patent owners and in compliance with the TRIPS Agreement[28], the first proposed amendment broadens the purposes of experimental use of inventions to include scientific or educational purposes and such other activities directly related to such scientific or educational experimental use.

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.

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.[29]

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 is also worth noting that the current proposed amendment in the substitute bill on early working also integrates the recommendation of Senator Miriam Defensor-Santiago which recognizes the protection of data under Article 39.3 of the TRIPS Agreement and which further specifically requires the Intellectual Property Office to issue the appropriate rules and regulations regarding the execution of the doctrine of early working.

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[27] 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.

[28] 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."*

[29] 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."*

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.[30]

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"[31].

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 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.[32]

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 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.

As proposed by Senator Edgardo J. Angara in the 13th Congress, it is worth noting that the proposed amendment in the substitute bill grants to the President of the Republic of the Philippines the power to make a 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

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[30] 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.

[31] 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.

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

for the implementing agencies and its officers, which shall implement the said action. This legal cover is the grant of an exemption from temporary restraining orders and preliminary injunctions of such government actions, except if issued by the Supreme Court.

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.[33]

As proposed by Senator Edgardo J. Angara in the 13th Congress, this proposed amendment is introduced once again as an amendment to Section 159 of the Intellectual Proeprty Code of the Philippines.

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.

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

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

[33] 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.

(AGAP), (17) Philippine Healthwatch Initiatives, Inc., (18) Health Alliance for Democracy (HEAD), and, various NGOs for the poor, sick and elderly.

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

Notwithstanding the aforementioned, the Committees noted that there are other issues that contribute to the continued high cost of drugs and medicines, including off-patent drugs. These are, among others:[34]

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 strengthen, enact and enforce regulatory and supervisory laws and regulations to ensure the safety and efficacy of drugs, particularly the charter of the Bureau of Food and 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.

VII. Other Options to Improve Access to Quality, Affordable Medicines

Aside from discussions on the proposed amendments to the Intellectual Property Code, the various senate bills filed as well as the discussions in the committee hearings also introduced several other legislative proposals that seek to ensure better access to quality, affordable medicines.

A. Strengthening the Bureau of Food and Drugs (BFAD)

It has been stated during the hearings that another avenue to ensure broader access to quality, affordable medicines is to strengthen the capability of BFAD. The DOH proposed that these should involve the following[35]:

1. Expansion of the research and regulatory capability of BFAD in the regions. Specifically, this will mean more laboratory facilities with appropriate equipment and personnel.

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

[35] Based on the Department of Health (DOH) Presentation to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing held on September 10, 2007 and on the Bureau of Food and Drugs Presentation to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 17, 2007.

2. Creation of a more flexible structure for BFAD that will consider the corporitization of BFAD, exempt BFAD from the Salary Standardization Law, allow its use and retention of its income, give it authority to hire additional personnel, among others.

3. Imposition of a mandatory electronic submission of essential regulatory information on the pharmaceutical industry inputs and outputs.

4. Imposition of the mandatory disclosure of drug prices and inventory of drugs sold in other foreign markets by importer-applicants and linking of entry price as a regulatory requirement.

Further, in the committee hearings, it was presented by BFAD that there is a nationwide ratio of one food and drug regulatory officer for every two hundred and two establishments. At present, there are only 220 officers monitoring 44,333 BFAD registered establishments. It was also further noted that out-migration of highly trained BFAD personnel is going on in favor of better pay and facilities particularly in food and drug regulatory agencies of other countries. Lastly, inspection processes take a significant amount of time due to limited facilities and equipment. Hence, there is clearly a need to augment the operations budget of BFAD from internally generated income sources.

The abovestated recommendations and facts have been taken into consideration by the committees and it was agreed that there is a need to strengthen the Bureau of Food and Drugs by allowing it at the minimum to retain its income for use in improving/upgrading its facilities, expanding its organizational capability and training its personnel, among others.

B. Re-examination of the Generics Act of 1988 and the Pharmacy Law

It has also been noted during the hearings that there is also a need to amend Section 6 of the Generics Law (R.A. No. 6675) by strictly requiring that only generic names of drugs be written in medical prescriptions by doctors. In the same light, it has been proposed that drug outlets should also be required to inform all buyers of medicines of all other drug products having the same generic name so that buyers may decide which product to buy. Corollary to this, it has also been discussed in the committee hearings that there is a need to revisit the mandatory requirement in the Pharmacy Law (P.D. No. 1363) which mandates that registered pharmacists should supervise all pharmaceutical drug sales. For both proposed amendments to the Generics Act and the Pharmacy Law, higher penalties have also been proposed. Considering that these proposals have a major impact in the professional practice of doctors and pharmacists, these comments have been noted by the committees and will be subject to further discussions through technical working group meetings under the primary control of the Committee on Health and Demography.

C. Creation of a Congressional Oversight Committee

The committees also took note of the need to establish a congressional oversight committee that will monitor the whole pharmaceutical policy of the government. Considering that the proposed amendments in the attached substitute bill will have significant impacts in national drug policy, the committees agree that there must indeed be a congressional oversight committee to monitor the implementation of the proposed law once enacted.

D. Imposition of a Non-Discriminatory Clause

The committees also took note of the need to impose a non-discriminatory clause or "mandatory carry" system. Some participants in the hearing have expressed reservations to the imposition to the same. Foremost among these is the position of the Drug Stores Association of the Philippines (DSAP). Specifically, DSAP contends that such a provision creates safety risks and in another aspect, lead to a weakening of the economic viability of small drugstores. For DSAP, requiring all drugstores to carry parallel imports without a clear set up of accrediting such by the proper authorities could be "used as a shield for those selling unregistered imported medicines."[36] Further, it was highlighted that most drugstores in the country with limited capital would prefer to carry on their shelves only saleable items. For DSAP, forcing them to shell out capital for none movable items means waste of valuable capital in non-moving stock inventory. Another is the position of Mercury Drug Corporation[37], which hinges its opposition on the right to property of individuals and on the guarantees for the quality of medicines sold. On the latter, Mercury cites Section 29 of the Pharmacy Law which provides that, "In cases of drugs, pharmaceuticals or poisons sold in their original packaging, the seal of which has not been broken or tampered with, the liability rests upon the manufacturer or in his absence upon the importer, the distributor, representative or dealer who was responsible for their distribution for sale." Another health organization, Philippine Healthwatch Initiatives, Inc., raised questions on the practicality of a "must carry" provision since the medication needs, on the basis of morbidity rates, vary across the nation. Hence, implementing it will entail a complex system that differs per regions health needs. The same organization contends that this may even result in unnecessary costs and could even increase the prices of medicines.

Considering that the impact of a non-discriminatory clause relative to lowering of medicine prices cannot be assured at present, the committees have opted to have this matter studied further through technical working group meetings under the supervision of the committees.

E. Creation of a Drug Prices Regulation Board

Unlike the previous issues, this matter has been subject to a lot of reservations by most of the participants during the committee hearings. The DTI notes that the creation of a drug price regulation board is redundant since the similar powers have already been granted to the National Price Coordinating Council and the President of the Philippines as provided in Sections 7 and 10 of the Price Act (R.A. No. 7581). The DOH, through Undersecretary Alexander Padilla,[38] also categorically stated that they are against the inclusion of drug price control provisions in the same law which introduces the TRIPS flexibilities. The DOH representative further advised that the same should be studied further considering that the implementation of such is too complex and far-reaching. In the hearings, it was also noted that the large composition of a price regulation board could lead to delays in agreeing on decisions tom impose price controls considering that the parties include representatives from the industries to be regulated on the one hand and the consuming public Aside from that, the WHO[39] presented its comparative studies of the impact of drug price regulation noting that the creation of such has no bearing on

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[36] Position paper submitted by the Drug Stores Association of the Philippines to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 17, 2007.
[37] Position paper submitted by Mercury Drug Corporation to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 12, 2007.
[38] Based on the testimony of DOH Undersecretary Alexander Padilla during the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 10, 2007.
[39] Based on the WHO Presentation during the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 17, 2007.

prices. In fact, it highlighted that in Japan, which has a very complicated drug price regulation scheme, the prices remain to be very high.

The dangers of price control or regulation have also been noted in the position papers submitted by several noted economists and business professors[40] which includes the following: Dr. Felipe M. Medalla of the U.P. Diliman, School of Economics; Dr. Cielito F. Habito of the Ateneo de Manila University, Department of Economics; Dr. Fernando T. Aldaba, Chairperson of the Ateneo de Manila University, Department of Economics, and, Dr. Cid L. Terosa, University of Asia and the Pacific, School of Economics. Dr. Rene B. Azurin[41] of the U.P. Diliman Graduate School of Business also testified to the same concerns by the economists. Basically, the concerns are that price controls are at risk of regulatory capture especially in countries where the governance structure is weak and prone to corruption. It was also noted that there is no clear study that says such have been effective. Others highlighted that price controls may also result to unavailability or delay in the availability of drugs. Medalla and Habito emphasized also that more competition is the best approach to ensuring access to quality affordable medicines. Corollary to this, they also noted that imposing a price control mechanism might actually be incompatible with competition enhancing policies.

Conversely, the Philippine Nursing Association (PNA)[42] and the Health Alliance for Democracy (HEAD)[43] submitted position papers in support of the imposition of drug price controls. It is worth noting that the position of HEAD with regard to the creation of a drug price regulatory board is subject to a three to five year life span, and, it further required that the board should have more patient and consumer groups represented therein. On another front, the Drug Stores Association of the Philippines (DSAP) agrees that price regulation has its role in reducing the prices of medicines. DSAP specifically recommends that the same be imposed on the manufacturers and distributors end. It also contends that price referencing is a better alternative compared to imposing price ceiling. Lastly, DSAP suggests that locally manufactured generic products be exempted from price regulation since the same are already low priced.

Based on the foregoing reservations, oppositions, or limited support on the creation of a drug price regulatory board, the committees have decided to propose a system of medicine price regulation patterned after the provisions of Republic Act No. 7581, otherwise known as the Price Act. Basically, the proposed provision gives the power to impose price ceilings on any drug to the President of the Republic of the Philippines upon joint recommendation of the Secretaries of Health and Trade and Industry provided that certain conditions with public health impacts exist. These conditions, patterned after the Price Act, are as follows:

1. The impendency, existence, or effects of a calamity that affects public health;
2. The threat, existence, or effect of a public health emergency officially recognized by the Department of Health or by official Department of Health recognized non-governmental organizations;
3. The prevalence of widespread acts of illegal price manipulation of any drug or medicine;

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[40] Position papers and letters have been submitted by Dr. Felipe M. Medalla, Dr. Cielito F. Habito, Fernando T. Aldaba, and, Dr. Cid L. Terosa to the Senate Committee on Trade and Commerce.
[41] Dr. Rene B. Azurin testified on the merits of drug price regulation during the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearing on September 17, 2007
[42] Position paper submitted on September 7, 2007 by the Philippine Nursing Association (PNA) to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearings.
[43] Position paper submitted on September 17, 2007 by the Health Alliance for Democracy (HEAD) to the Senate Committees on Trade and Commerce, Health and Demography, and, Finance Hearings.

4. The impendency, existence, or effect of any event that causes artificial and unreasonable increase in the prices of any drug or medicine.
5. Whenever the prevailing price of any drug or medicine has risen to unreasonable levels.

This process of imposing price regulation is deemed most effective and efficient because the decision making process is limited to a few people who have the best knowledge of the public health situation of the Philippines at any point in time. Further, it is consistent with existing laws. As an additional feature, the proposed provision likewise allows the Secretary of the Department of Health to impose administrative fines for those who violate the order of the President. As a safeguard on the exercise of this power, only the Supreme Court of the Philippines shall be allowed to restrain through any appropriate order the actions of the President invoked under any of the abovestated conditions. Considering that most, if not all, are agreed that the imposition of price controls are extreme measures that should be use as a last resort, the proposed set-up which gives the power to the President of the Republic of the Philippines is deemed best and will be most efficient in the conditions contemplated.

VIII. *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.B. No. 1658, prepared by the Committees, entitled:

AN ACT
TO PROVIDE FOR QUALITY AFFORDABLE MEDICINES

be approved in substitution of the pertinent proposals as embodied in Senate Bill Nos. 90, 101, 755, 1404, 1420 and 1530, taking into consideration P.S. Res. No. 49 with Senators Villar, Roxas, Trillanes IV, Cayetano, P., Zubiri, Legarda, Lapid and Enrile as authors thereof.

Respectfully submitted:

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Member, Committee on Health and Demography
Member, Committee on Finance

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Senate President
Senate of the Philippines
Pasay City

FOURTEENTH CONGRESS OF THE)
REPUBLIC OF THE PHILIPPINES)
First Regular Session)

SENATE
S. No. 1658

(In substitution of S.B. Nos. 90, 101, 755, 1404, 1420, 1530 and P.S. Resolution No. 49)

Prepared by the Committees with Senators Villar, Roxas, Trillanes IV, Cayetano, P., Zubiri, Legarda, Lapid and Enrile as authors thereof

AN ACT
TO PROVIDE FOR QUALITY AFFORDABLE MEDICINES

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

SECTION 1. *Short Title.* – This Act shall be known as the *"Quality Affordable Medicines Act of 2007."*

SECTION 2. *Declaration of Policy.* – The State recognizes as a priority national policy the protection and promotion of the right to health of the people. In protecting public health, it shall always endeavor to ensure broad access to quality affordable medicines for the benefit of the people.

SECTION 3. *Construction in Favor of Protection of Public Health.* - All doubts in the implementation and interpretation of the provisions of this Act, including its implementing rules and regulations, shall be resolved in favor of protecting public health.

SECTION 4. Section 26 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 26. *Inventive Step.* – 26.1. An invention involves an inventive step if, having regard to prior art, it is not obvious to a person skilled in the art at the time of the filing date or priority date of the application claiming the invention.

"26.2. IN THE CASE OF DRUGS OR MEDICINES, THERE IS NO INVENTIVE STEP IF THE INVENTION RESULTS FROM THE MERE DISCOVERY OF A NEW FORM OR NEW PROPERTY OF A KNOWN SUBSTANCE WHICH DOES NOT RESULT IN THE ENHANCEMENT OF THE KNOWN EFFICACY OF THAT SUBSTANCE, OR, THE MERE DISCOVERY OF ANY NEW USE FOR A KNOWN SUBSTANCE OR A KNOWN PROCESS UNLESS SUCH KNOWN PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT LEAST ONE NEW REACTANT."

SECTION 5. Section 72 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, 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 TO THE USE, SALE, OFFERING FOR SALE OR IMPORTATION OF THE PRODUCT 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 EDUCATIONAL PURPOSES AND SUCH OTHER ACTIVITIES DIRECTLY RELATED TO SUCH SCIENTIFIC OR EDUCATIONAL EXPERIMENTAL USE.

"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 AND ISSUANCE OF APPROVALS BY GOVERNMENT REGULATORY AGENCIES REQUIRED UNDER ANY LAW OF THE PHILIPPINES THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT: *PROVIDED,* THAT IN ORDER TO PROTECT THE DATA SUBMITTED BY THE ORIGINAL PATENT HOLDER FROM UNFAIR COMMERCIAL USE PROVIDED IN ARTICLE 39.3 OF THE TRIPS AGREEMENT, THE INTELLECTUAL PROPERTY OFFICE (IPO), IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE RULES AND REGULATIONS NECESSARY THEREIN NOT LATER THAN ONE HUNDRED TWENTY (120) DAYS AFTER ENACTMENT OF THIS LAW.

"[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)"

SECTION 6. Section 74 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, 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) THE USE OR OTHER EXPLOITATION BY THE GOVERNMENT OR THIRD PERSON AUTHORIZED BY THE GOVERNMENT OF DRUGS OR MEDICINES UNDER THIS SECTION SHALL BE SUBJECT TO THE EXCLUSIVE DETERMINATION OF THE PRESIDENT OF THE REPUBLIC OF THE PHILIPPINES AND SHALL BE IMMEDIATELY EXECUTORY: *PROVIDED,* THAT NO COURT, EXCEPT THE SUPREME COURT OF THE PHILIPPINES, SHALL ISSUE ANY TEMPORARY RESTRAINING ORDER OR PRELIMINARY INJUNCTION OR PRELIMINARY MANDATORY INJUNCTION THAT WILL PREVENT ITS IMMEDIATE EXECUTION. THE OFFICE OF THE PRESIDENT, IN CONSULTATION WITH THE APPROPRIATE GOVERNMENT AGENCIES, SHALL ISSUE THE APPROPRIATE IMPLEMENTING RULES AND REGULATIONS FOR THE EXERCISE OF THIS AUTHORITY WITHIN ONE HUNDRED TWENTY (120) DAYS AFTER ENACTMENT OF THIS LAW. ALL CASES ARISING FROM

THE IMPLEMENTATION OF THIS PROVISION SHALL BE COGNIZABLE BY COURTS WITH APPROPRIATE JURISDICTION PROVIDED BY LAW."

SECTION 7. Section 159 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"Section 159. x x x

"x x x

"x x x

"x x x

"159.4 THERE SHALL BE NO INFRINGEMENT OF TRADEMARKS OR TRADENAMES OF IMPORTED OR SOLD DRUGS OR MEDICINES ALLOWED UNDER SECTION 72.1 OF THIS ACT, AS WELL AS, IMPORTED OR SOLD OFF-PATENT DRUGS OR MEDICINES: PROVIDED, THAT SAID DRUGS OR MEDICINES BEAR THE REGISTERED MARKS THAT HAVE NOT BEEN TAMPERED, UNLAWFULLY MODIFIED, OR INFRINGED UPON AS DEFINED UNDER SECTION 155 OF THIS CODE."

SECTION 8. *Implementing Rules and Regulations on Amendments to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines.* – Unless otherwise provided herein, the Intellectual Property Office, in coordination with the Department of Health and the Bureau of Food and Drugs, shall issue the necessary implementing rules and regulations for all amendments to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, within one hundred twenty (120) days after enactment of this law.

SECTION 9. *Strengthening of the Bureau of Food and Drugs (BFAD).* – (a) For a more effective and expeditious implementation of this Act, the Director or head of the Bureau of Food and Drugs shall be authorized to retain, without need of a separate approval from any government agency, and subject only to the existing accounting and auditing rules and regulations, all the fees, fines, royalties and other charges, collected by the Bureau of Food and Drugs under this Act and other laws that it is mandated to administer based on the immediately prior year of operations, for use in its operations, like upgrading of its facilities, equipment outlay, human resource development and expansion, and the acquisition of the appropriate office space, among others, to improve the delivery of its services to the public. This amount, which shall be in addition to the Bureau of Food and Drugs' annual budget, shall be deposited and maintained in a separate account or fund, which may be used or disbursed directly by the Director or head.

(b) After five (5) years from the coming into force of this Act, the Director or head of the Bureau of Food and Drugs shall, subject to the approval of the Secretary of the Department of Health, determine if the fees and charges mentioned in subsection (a) hereof that the Bureau of Food and Drugs shall collect are sufficient to meet its budgetary requirements. If so, it shall retain all the fees and charges it shall collect under the same conditions indicated in said subsection (a) but shall forthwith, cease to receive any funds from the annual budget of the National Government; if not, the provisions of subsection (a) shall continue to apply until such time when the Director or head of the Bureau of Food and Drugs, subject to the approval of the Secretary of Health, certifies that the abovestated fees and charges the Bureau of Food and Drugs shall collect are enough to fund its operations.

(c) The Bureau of Food and Drugs shall submit a yearly performance report to the Quality Affordable Medicines Oversight Committee, as provided in Section 11 of this Act. The report shall itemize the use of such retained funds in the past year up to the present and the budgeted use of the same in the succeeding periods.

SECTION 10. *Drug or Medicine Price Regulation by the President of the Philippines.* -

(a) Without prejudice to the provisions in Republic Act No. 7581, otherwise known as the Price Act, the President of the Philippines shall have the power to impose price ceilings over any or all drugs or medicines, upon joint recommendation of the Secretaries of the Department of Health and Trade and Industry, if any of the following conditions so warrant:

(1) The impendency, existence, or effects of a calamity that affects public health;

(2) The threat, existence, or effect of a public health emergency officially recognized by the Department of Health or by official Department of Health recognized non-governmental organizations;

(3) The prevalence of widespread acts of illegal price manipulation of any drug or medicine;

(4) The impendency, existence, or effect of any event that causes artificial and unreasonable increase in the prices of any drug or medicine.

(5) Whenever the prevailing price of any drug or medicine has risen to unreasonable levels.

(b) The power of the President of the Philippines to impose price ceilings shall be exercised within such period of time that the President shall deem necessary. The effectivity of this power of the President of the Philippines to impose price ceilings on drugs or medicines maybe revoked by the President of the Philippines by Executive Order. No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or preliminary mandatory injunction that will prevent the immediate execution of the exercise of this power of the President of the Republic of the Philippines.

(c) Any person who refuses to comply with the order of the President of the Philippines as provided herein shall be punished with an administrative fine of not less than One Hundred Thousand Pesos (Php100,000.00) but not more than Five Hundred Thousand pesos (Php500,000.00) at the discretion of the Secretary of the Department of Health for the first offense. For each of the succeeding offenses, the administrative fine shall not be less

than Five Hundred Thousand Pesos (Php500,000.00) but not more than One Million Pesos (Php1,000,000.00) at the discretion of the Secretary of the Department of Health plus the cancellation of the license to operate by the Bureau of Food and Drugs and/or such other appropriate government authorities.

(d) The Secretary of the Department of Health (DOH) shall issue the necessary implementing rules and regulations for the enforcement of the exercise of this power by the President of the Philippines. The implementing rules and regulations shall be issued by the Department of Health (DOH) within sixty (60) days from the promulgation of the order of the President of the Philippines.

SECTION 11. *Congressional Oversight Committee.* – (a) For the effective implementation of this Act, there shall be created a Congressional Oversight Committee, here-in-after to be referred to as the Quality Affordable Medicines Oversight Committee to be composed of five (5) members from the Senate, which shall include the Chairpersons of the Senate Committees on Trade and Commerce and Health and Demography, and, five (5) members from the House of Representatives, which shall include the Chairpersons of the House of Representatives Committees on Trade and Commerce and Health and Demography. The Chair of the Quality Affordable Medicines Oversight Committee shall be the Chairperson of the Senate Committee on Trade and Commerce, and, the Vice-Chair of the oversight committee shall be the Chairperson of the House of Representatives Committee on Health and Demography.

(b) The Quality Affordable Medicines Oversight Committee shall oversee the full implementation of the provisions of this Act.

SECTION 12. *Appropriations.* – For the initial implementation of this Act, the amount of Twenty Five Million Pesos (Php25,000,000.00) shall be provided for purposes of this Act in the current General Appropriations Act as addition to the annual budget of the Department of Health. Thereafter, such sum as may be necessary for its continued implementation shall be included in the annual general Appropriations Act.

SECTION 13. *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.

SECTION 14. *Repealing Clause.* – All laws, decrees, executive orders, proclamations and administrative regulations, or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

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

Approved,