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

SENATE

S. B. No. 1404

Introduced by **SENATOR COMPAÑERA PIA S. CAYETANO**

EXPLANATORY NOTE

In the Philippines, the problem of access to medicines has become very alarming through the years. Drugs and medicines used for the treatment of just about any ailment cost more in the Philippines than elsewhere.

Without legislation, the pharmaceutical industry has shown that on its own, it does not have sufficient mechanisms for ensuring their affordability. It will simply charge as much as it can, and it has done so.

The multinational companies justify their dominance of the Philippine pharmaceutical market on the ground that the medicines that they produce are of good quality with their efficacy and safety assured. 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, the smaller Filipino pharmaceutical companies contend that there are a lot of barriers to a level playing field in the local pharmaceutical market. As much as they acknowledge that they do not have that much capital, they especially note that, unlike in other countries, local intellectual property laws are designed in favor of heavily protecting the patents of the multinationals, thus granting more marketing monopoly in favor of the multinationals.

Not surprisingly then, multinationals have gained a monopoly in pharmaceutical patents. Based on data from the Intellectual Property Office, of the 191 pharmaceutical patents filed from 2001 to 2004, at least 89% were foreign patents while only 11% were local. Of the number of pharmaceutical patents issued from 2002 to 2005, only one local patent was issued compared to 448 foreign patents issued in 2001, 363 in 2002, 351 in 2003, 531 in 2004 and 404 in 2005. The country now has a total of 3,113 foreign patents on medicines but only 5 local patents due to expire from 2006 to 2015.

Surely, the arguments that the cost of manufacturing and local taxes result in higher prices cannot justify the exorbitant high prices of medicines here as compared to our Asian neighbors. Thus, this bill seeks to address this problem. It posits that things should not be so – that access to medicines is a question of life or death, and medicines cannot be treated as mere commodities.

In this regard, this bill lays down four cornerstones that will make quality medicines cheaper and more accessible to our people. Specifically, it shall make patents and trademark laws more responsive to the health care needs of our people by amending the Intellectual Property Code of the Philippines to allow the

following –

- ***One***, the parallel importation of medicines;
- ***Two***, the early development of patented medicines;
- ***Three***, exemption of government importation, manufacture, sale or distribution of medicines from the standard compulsory licensing requirements; and
- ***Four***, disallowing new uses or derivatives of patented drugs to be covered by a separate or new patent.

It should be emphasized that all these proposed amendments comply with the basic covenants under the Agreement on Trade-Related Aspects of Intellectual Properly Rights or TRIPS and the Doha Declaration on the TRIPS Agreement and Public Health of the World Trade Organization (WTO). Furthermore, these amendments are within the allowable flexibilities given 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 recognized "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 included an acknowledgment that intellectual property protection has an effect on the price of medicines, even as it is important for pharmaceutical research and development.

Everywhere around the world, governments are exercising the function to define the proper role of intellectual property protection in relation to balancing the private rights of innovators against the broader interest of the public.

The need to help our citizens gain access to affordable and quality medicines is surely a great move to solve the problem of expensive drugs and medicines in the country. The passage of this bill will somehow, unburden or, at least, lessen this heavy load on our people, especially to those living in poverty.

Thus, approval of this Bill is urgently sought.

COMPAÑERA PIA S. CAYETANO
Senator

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S. B. No. 1404

Introduced by **SENATOR COMPAÑERA PIA S. CAYETANO**

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 House of Representatives of the Philippines in Congress assembled:

SEC. 1. Section 26 of Republic Act No. 8293 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. 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."

SEC. 2. Section 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 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)"

SEC. 3. Section 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) 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."

SEC. 4. Section 159 of Republic Act No. 8293 is hereby amended to read as follows:

"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: *PROVIDED*, THAT SAID DRUGS OR MEDICINES BEAR THE REGISTERED MARKS THAT HAVE NOT BEEN TAMPERED, MODIFIED, OR INFRINGED UPON AS DEFINED UNDER SECTION 155 OF THIS CODE."

SEC. 5. *Implementing Rules and Regulations*. – Unless otherwise provided herein, the Intellectual Property Office shall issue the necessary implementing

rules and regulations within one hundred twenty (120) days after enactment of this law.

SEC. 6. *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. 7. *Repealing Clause.* – All laws, decrees, executive orders, proclamations and administrative regulations, or parts thereof inconsistent herewith are hereby repealed or modified accordingly.

SEC. 8. *Effectivity Clause.* – This Act shall take effect fifteen (15) days after its publication in at least two national papers of general circulation.

Approved,