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

SENATE

S. No. 101

INTRODUCED BY THE HONORABLE MAR ROXAS

EXPLANATORY NOTE

This bill seeks to amend Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, to protect public health by creating an environment that will lower the prices of medicines through increased competition among drug companies and by providing the government with better policy tools to significantly influence the supply and demand of medicines.

In its report, the 13th Congress' Senate joint committees on trade and commerce and health and demography had noted Filipinos' insufficient annual per capita health spending, of P1,979 as of 2004. A major part of this problem is the lack of access to affordable drugs and medicines.

It was also found that the present intellectual property system has been used to great advantage by pharmaceutical industries in maximizing their profits, with 60% of the market dominated by multinationals. Such dominance however is due to present laws that prevent a level playing field and that largely protect multinationals, who are holding practically all patents on pharmaceutical products as of 2005.

As a general rule for developing countries, the fewer patents granted on medicines, the better, so that large businesses' control over the industry is limited and generic versions can be introduced without delay.

To further illustrate the lack of competitive prices in the country, we can compare local prices of branded medicines to their counterparts from abroad, specifically, from India and Pakistan.

Norvasc, priced at P44.75 in the Philippines, sells for the equivalent of P5.00 in India. *Bactrim* 400, priced at P17.75 per tablet in the Philippines, sells for the equivalent of P1 in Pakistan, and P0.69 in India.

The flaws of the present Intellectual Property Code of the Philippines have resulted in a significant imbalance between supply and demand of drugs and medicines. More specifically, the market dominance of multinationals has caused artificial barriers to the fair trade of drugs and medicines which has led to high prices and lack of access to drugs and medicines to the detriment of millions of Filipinos.

This bill is in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the *Doha Declaration on the TRIPS Agreement and Public Health* of the World Trade Organization. It provides the flexibilities allowed to developing countries under the two accords.

The proposed amendments to the Intellectual Property Code will allow generic drug manufacturers to begin experimentation, production and registration on patented drugs or medicines even prior to the expiration of the patents. As per industry estimates and experience, under the present law, generic drug makers take roughly three years after a patent expires in order to study the patented drug. This results in a virtual patent extension of three years, a period wherein patent holders can continue to charge high prices for their medicines.

Through the early working doctrine, generics companies will be able to make available their products immediately after expiration of the drug patent, thus preventing a continued monopoly on prices by the patent holder. This doctrine has already led to a significant reduction of prices in the USA, Japan, Canada, Israel and Thailand.

Furthermore, the proposed measure will bar patent owners from extending patents on the basis of a "new use" for existing substances. The practice of extending patents on such grounds has allowed patent owners to continue a hold on the patent, even when the new use does not result in a new product or could even be deemed an "obvious" use.

The bill will also provide a legal mechanism for the importation of drugs whose patents have not expired locally. Parallel importation, as it is called, is already in practice among European Union nations, as well as in Japan, Argentina, Cambodia, Thailand and Vietnam. The changes to the law will also provide for the use of local trademarks of patented drugs in an importation scheme.

Lastly, the bill grants the government discretion in use of patents when public health is at stake, and provides a framework for ample compensation to the patent holder.

The bill has been discussed extensively in the 13th Congress, but was not passed, to the dismay of stakeholders and the general public in need of more affordable medicines. It is high time that Congress enacts this bill into law during the 14th Congress.

In view of the foregoing, approval of this bill is earnestly requested.

MAR ROXAS
Senator

FOURTEENTH CONGRESS OF THE)
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S. No. 101

INTRODUCED BY THE HONORABLE MAR ROXAS

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:

SECTION 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,