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

SENATE 2139

INTRODUCED BY HONORABLE MAR ROXAS

EXPLANATORY NOTE

This bill will 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 greater competition among drug companies and by providing the government with better policy tools to significantly influence the supply and demand of medicines.

It seeks to do so through the early working doctrine in the experimentation, production and registration of patented drugs or medicines and its appurtenant data prior to the expiration of patents. Industry data shows that it takes a local manufacturer around two years to study, experiment, register, manufacture and distribute in commercial quantities. This amendment will allow generics manufacturers to commence manufacturing, distribution and sale to the public immediately after patent expiration. This is based on the Bolar exception, which led to significant reductions in the prices of medicines upon adoption in the USA, Japan, Canada, Israel and Thailand.

Corollary to this, the bill also considers new uses, molecules or compounds of a patented invention like drugs or medicines as part of the original patent. Hence, new patents cannot be applied for previously patented drugs or processes to cover newly discovered benefits. This will prevent patented products or processes from doubling or prolonging its protected period or monopoly position in the market.

Further, this bill will also provide the government with better policy tools to protect public health by establishing a clear and legally secure framework for parallel importation and more liberal compulsory licensing procedures with regard to medicines. The changes will recognize the doctrine of international exhaustion as provided in Article 6 of the TRIPS Agreement so that patented drugs or medicines which the country needs may be imported. It will also establish an exception to the application of standard compulsory licensing requirements in the importation, including parallel importation, or manufacturing or sale or distribution by the government of medicines to protect public health based on a coordinated determination by the Secretaries of the DOH and DTI. Lastly, this bill will provide a limited exception in the use of tradenames and/or trademarks to protect public health for cases involving government procured medicines.

This bill also provides legal protection for government officials involved in parallel importations from all kinds of harassment suits. It also shields parallel importations from temporary restraining orders or injunctions. Lastly, this bill vests original and exclusive jurisdiction to the Intellectual Property Office (IPO) over cases involving parallel importation or issuance of compulsory licenses for drugs or medicines.

Various studies conducted by the Department of Trade and Industry, concerned non-governmental organizations (NGOs) and pharmaceutical groups have shown that drug spending in the Philippines is astonishingly among the highest in Southeast Asia.

Southeast Asia Pharmaceutical Market (in US$ Millions)					
Country	1997	1998	1999	2000	2001
Philippines	*1,247*	*1,012*	*1,183*	*1,118*	*1,062*
Indonesia	1,156	439	811	986	1,025
Thailand	923	586	743	772	780
Hong Kong	344	374	386	402	425
Malaysia	301	227	269	302	308
Singapore	208	185	217	243	241

Based on recent price surveys done by the Philippine International Trading Corporation (PITC), an agency originally attached to the Department of Trade and Industry but recently transferred to the Office of the President (OP), the savings generated through the *Presyong Tama* Program done through parallel importation is highlighted in the following comparative prices for major drugs:

Drug/Dosage	Generic Name	Domestic / Private Drug Store Price	PITC Maximum Retail Price (As of 6-Dec-04)	Savings
Bactrim Adult 400/80mg tab	Cotrimoxazole	P 15.60	P 7.00	P 8.60
Adalat Retard 20mg tab	Nifedipine	P 39.75	P 15.00	P 24.75
Lopid 300mg cap	Gemfibrozil	P 36.50	P 25.77	P 10.73
Ventorlin100mcg/200do.	Salbutamol	P 331.50	P 280.00	P 51.50
Dilantin 100mg cap	Phenytoin	P 22.50	P 12.00	P 10.50

Under the present state of our law, patent owners oppose parallel importation citing Sec. 71 of the Intellectual Property Code (IPC), which secures to the patentee the right to exclude anyone from making, using, selling or importing patented products. Aside from that, Section 95 of the IPC on compulsory licensing provides very restrictive rules on compulsory licensing. Furthermore, in Section 101 of the IPC, the patentee may move for the cancellation of the compulsory licenses upon showing of new facts and circumstances justifying such action. Lastly, patent owners argue that parallel importation violates the tradename and trademark protection clause in the IPC.

It should be noted that the exercise of the patentee's exclusive rights is subject to and must be correlated with the public interest exceptions under Section 74 in favor of the Government or any third person authorized by the Government in the circumstances enumerated thereunder. The public interest consideration under Section 74, particularly as the same relates to public health, is of primordial importance especially as this echoes the constitutional mandate for the State to protect the health of the people *(Sec. 15, Art. II, 1987 Constitution)* and to 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 *(Sec. 11, Art. XIII, ibid.)*.

It is a sad state of affairs that the exorbitant cost of medicines puts them beyond the reach of the marginalized Filipino despite the major advances in pharmaceutical research and development. Clearly, it is not the lack of cure or medicines but the unaffordability thereof that causes one to succumb to death due to illness. The passage of this bill will correct this situation.

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

M A R ROXAS
Senator

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

5 OCT 13

SENATE

RECEIVED BY:

S. No. 2139

INTRODUCED BY 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 ALLOWING THE IMPORTATION, EARLY DEVELOPMENT OF PATENTED MEDICINES AND EXCEPTIONS TO THE APPLICATION OF STANDARD COMPULSORY LICENSING REQUIREMENTS FOR DRUGS OR MEDICINES TO LOWER DRUG OR MEDICINE PRICES BY AMENDING FOR THIS PURPOSE CERTAIN PROVISIONS OF REPUBLIC ACT NO. 8293 OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

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

Section 1. Sec.21 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec.21. Patentable Inventions. – Any technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable shall be patentable. It may be, or may relate to, a product, or process, or an improvement of any of the foregoing. NEW USES OR MOLECULES OR COMPOUNDS OF A PATENTED INVENTION SHALL BE DEEMED AS INCLUDED IN THE ORIGINAL PATENT AND SHALL NOT BE ALLOWED TO BE COVERED BY A NEW AND SEPARATE PATENT."

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

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

72.1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market; PROVIDED THAT, WITH REGARD TO DRUGS OR MEDICINES, THE LIMITATION ON PATENT RIGHTS SHALL APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED ANYWHERE IN THE WORLD BY THE PATENT OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE INVENTION.

72.2. Where the act is done privately and on a non-commercial 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 EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR FOR COMMERCIAL PURPOSES THAT DO NOT UNREASONABLY CONFLICT WITH A NORMAL EXPLOITATION OF THE PATENT AND THAT DO NOT UNREASONABLY PREJUDICE THE LEGITIMATE INTERESTS OF THE PATENT OWNER, TAKING INTO ACCOUNT THE LEGITIMATE INTERESTS OF SUCH THIRD PARTIES.

72.4 WHERE THE ACT INCLUDES TESTING, USING, MAKING OR SELLING THE INVENTION INCLUDING ANY DATA RELATED THERETO, SOLELY FOR PURPOSES REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION REQUIRED UNDER ANY LAW OF THE PHILIPPINES OR OF ANOTHER COUNTRY THAT REGULATES THE MANUFACTURE, CONSTRUCTION, USE OR SALE OF ANY PRODUCT.

72.5 [72.4]. 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;

72.6 [72.5]. Where the invention is used in any ship, vessel, aircraft, or land vehicles 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."

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

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

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

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

74.2. Unless otherwise provided herein, 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.

74.3. SUBJECT TO THE CONTROL, SUPERVISION AND DETERMINATION OF THE RESPECTIVE SECRETARIES OF THE DEPARTMENT OF HEALTH AND DEPARTMENT OF TRADE AND INDUSTRY, THE IMPORTATION, INCLUDING PARALLEL IMPORTATION, OR MANUFACTURING OR SALE OR DISTRIBUTION BY THE GOVERNMENT OR ANY OF ITS

AUTHORIZED REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL BE IMMEDIATELY EXECUTORY ONLY UPON FILING OF AN EX PARTE NOTICE BEFORE THE INTELLECTUAL PROPERTY OFFICE (IPO). THIS PROCEDURE SHALL BE AN EXCEPTION TO THE APPLICATION OF THE STANDARD REQUIREMENTS OF COMPULSORY LICENSING. ANY DRUG OR MEDICINE PROCURED, AS PROVIDED HEREIN, SHALL BE EVALUATED AND APPROVED FOR PUBLIC CONSUMPTION BY THE BUREAU OF FOOD AND DRUGS (BFAD) AFTER PROPER LABORATORY TESTING FOR SAFETY, EFFICACY AND QUALITY. IT IS PROVIDED FURTHER, THAT THE SALE AND DISTRIBUTION OF SUCH DRUGS OR MEDICINES SHALL ONLY BE MADE BY PERSONS WHO ARE DULY LICENSED BY BOTH THE DEPARTMENT OF HEALTH TO ENGAGE IN THE SALE AND DISTRIBUTION OF DRUGS OR MEDICINES AND AUTHORIZED BY THE DEPARTMENT OF TRADE AND INDUSTRY TO BE OFFICIAL DISTRIBUTORS OR RETAILERS OF THE DRUGS OR MEDICINES SUBJECT OF THE SAID PROCUREMENT.

ALL IMPORTATIONS, MANUFACTURING, SALE OR DISTRIBUTION OF DRUGS OR MEDICINES SHALL BE UNDERTAKEN BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENATIVES THROUGH THE COORDINATED REGULATORY EFFORTS AND SUBJECT TO THE APPROVAL OF THE DEPARTMENTS OF HEALTH AND TRADE AND INDUSTRY.

THE IMPORTATION, MANUFACTURING, SALE OR DISTRIBUTION OF DRUGS OR MEDICINES UNDER THIS PROVISION SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR INJUNCTION AND NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR ANYTHING WHICH IS IN GOOD FAITH DONE OR INTENDED TO BE DONE IN THE EXECUTION OR PURPORTED EXECUTION OF THIS PROVISION.

THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY SHALL ACCORDINGLY INDEMNIFY ITS MEMBERS AND OTHER OFFICIALS, INCLUDING PERSONNEL OF THE DEPARTMENTS PERFORMING ANY FUNCTION OR SERVICE RELATED TO THIS PROVISION AGAINST ALL COSTS AND EXPENSES REASONABLY INCURRED BY SUCH PERSONS IN CONNECTION WITH ANY CIVIL OR CRIMINAL ACTION, SUIT OR PROCEEDINGS TO WHICH HE MAY BE, OR IS MADE A PARTY BY REASON OF THE PERFORMANCE OF HIS FUNCTIONS OR DUTIES, UNLESS HE IS FINALLY ADJUDGED IN SUCH ACTION OR PROCEEDING TO BE LIABLE FOR NEGLIGENCE OR MISCONDUCT.

THE INTELLECTUAL PROPERTY OFFICE (IPO) SHALL HAVE ORIGINAL AND EXCLUSIVE JURISDICTION OF ALL CASES FOR THE IMPORTATION OR ISSUANCE OF

COMPULSORY LICENSES OF DRUGS OR MEDICINES AS DESCRIBED HEREIN. ALL CASES DECIDED UPON BY THE INTELLECTUAL PROPERTY OFFICE (IPO) WITH FINALITY SHALL BE APPEALABLE TO THE COURT OF APPEALS. THE INTELLECTUAL PROPERTY OFFICE SHALL ALLOW ONLY ONE *MOTION FOR RECONSIDERATION OF ITS DECISION.*

PARALLEL IMPORTATION SHALL REFER TO THE IMPORTATION AND RESALE OF DRUGS OR MEDICINES IN THE PHILIPPINES, WHETHER PATENTED OR NOT AND WITHOUT THE CONSENT OF THE PATENT HOLDER, BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES BASED UPON THE JOINT DETERMINATION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR THE PURPOSE OF PROTECTING PUBLIC HEALTH. DRUGS AND MEDICINES APPROVED AND IMPORTED FOR THIS PURPOSE SHALL NOT BE CONSIDERED AS COUNTERFEIT DRUGS AS DEFINED BY APPLICABLE LAWS."

Section 4. Sec.166 of Republic Act No. 8293 is hereby amended to read as follows:

"Sec. 166. Goods Bearing Infringing Marks or Tradenames. – 166.1. UNLESS OTHERWISE PROVIDED, no article of imported merchandise which shall copy or simulate the name of any domestic product, or *manufacturer, or dealer, or which shall copy or simulate a* mark registered in accordance with the provisions of this Act, or shall bear a mark or trade name calculated to induce the public to believe that the article is manufactured in the Philippines, or that it is manufactured in any foreign country or locality other than the country or locality where it is in *fact manufactured, shall* be admitted to entry at any customhouse of the Philippines.

166.2. THE IMPORTATION, MANUFACTURING, SALE OR DISTRIBUTION BY THE GOVERNMENT OF DRUGS OR MEDICINES WITH TRADEMARKS AND TRADENAMES FOR THE PROTECTION OF PUBLIC HEALTH AS PROVIDED IN SECTION 74.3 OF THIS ACT SHALL BE A LIMITED EXCEPTION TO THE RIGHTS CONFERRED BY TRADEMARKS AND/OR TRADENAMES; PROVIDED FURTHER, THAT SUCH DRUGS OR MEDICINES PROCURED BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED REPRESENTATIVES UNDER THIS PROVISION SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING ORDER OR INJUNCTION AND NO SUIT OF ANY KIND RELATED TO SUCH MAY BE FILED AGAINST THE RELEVANT PUBLIC OFFICIALS OR OTHER PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY FOR ANYTHING WHICH IS IN GOOD FAITH DONE OR INTENDED TO BE DONE IN THE EXECUTION OR PURPORTED EXECUTION OF THIS PROVISION.

THE DEPARTMENT OF HEALTH AND THE DEPARTMENT OF TRADE AND INDUSTRY SHALL ACCORDINGLY INDEMNIFY ITS MEMBERS AND OTHER OFFICIALS, INCLUDING

PERSONNEL OF THE DEPARTMENTS PERFORMING ANY FUNCTION OR SERVICE RELATED TO THIS PROVISION AGAINST ALL COSTS AND EXPENSES REASONABLY INCURRED BY SUCH PERSONS IN CONNECTION WITH ANY CIVIL OR CRIMINAL ACTION, SUIT OR PROCEEDINGS TO WHICH HE MAY BE, OR IS MADE A PARTY BY REASON OF THE PERFORMANCE OF HIS FUNCTIONS OR DUTIES, UNLESS HE IS FINALLY ADJUDGED IN SUCH ACTION OR PROCEEDING TO BE LIABLE FOR NEGLIGENCE OR MISCONDUCT.

THE INTELLECTUAL PROPERTY OFFICE (IPO) SHALL HAVE ORIGINAL AND EXCLUSIVE JURISDICTION OF ALL TRADEMARK AND TRADENAMES CASES INVOLVING THE IMPORTATION OR ISSUANCE OF COMPULSORY LICENSES OF DRUGS OR MEDICINES AS DESCRIBED HEREIN. ALL CASES DECIDED UPON BY THE INTELLECTUAL PROPERTY OFFICE (IPO) WITH FINALITY SHALL BE APPEALABLE TO THE COURT OF APPEALS. THE INTELLECTUAL PROPERTY OFFICE SHALL ALLOW ONLY ONE MOTION FOR RECONSIDERATION OF ITS DECISION."

166.3. In order to aide the officers of the customs service in enforcing this prohibition, any person who is entitled to the benefits of this Act, may require that his name and residence, and the name of the locality in which his goods are manufactured, a copy of the certificate of registration of his mark or trade name, to be recorded in books which shall be kept for this purpose in the Bureau of Customs, under such regulations as the Collector of Customs with the approval of the Secretary of Finance shall prescribe, and may furnish to the said Bureau facsimiles of his name, the name of the locality in which his goods are manufactured, or his registered mark or trade name, and thereupon the Collector of Customs shall cause one (1) or more copies of the same to be transmitted to each collector or to other proper officers of the Bureau of Customs."

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

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

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

Approved.