THIRTEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES Second Regular Session

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SENATE

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s. No. <u>2263</u>

(In substitution of Senate Bill No. 2139)

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

AN ACT

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

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

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

2 follows:

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"Sec. 22. Non-Patentable Inventions .- The following shall be

4 excluded from patent protection:

"22.1. THE MERE DISCOVERY OF A NEW FORM OF A 5 KNOWN SUBSTANCE WHICH DOES NOT RESULT IN THE 6 THE KNOWN EFFICACY OF 7 ENHANCEMENT OF THAT SUBSTANCE OR THE MERE DISCOVERY OF ANY NEW 8 PROPERTY OR NEW USE FOR A KNOWN SUBSTANCE OR THE 9 MERE USE OF A KNOWN PROCESS UNLESS SUCH KNOWN 10 PROCESS RESULTS IN A NEW PRODUCT THAT EMPLOYS AT 11 LEAST ONE NEW REACTANT. 12

1 FOR THE PURPOSES OF THIS CLAUSE, SALTS, ESTERS, 2 ETHERS, POLYMORPHS, METABOLITES, PURE FORM, PARTICLE 3 ISOMERS, MIXTURES OF ISOMERS, SIZE, COMPLEXES, 4 COMBINATIONS AND OTHER DERIVATIVES OF A KNOWN 5 SUBSTANCE SHALL BE CONSIDERED TO BE THE SAME SUBSTANCE, UNLESS THEY DIFFER SIGNIFICANTLY 6 IN PROPERTIES WITH REGARD TO EFFICACY. 7

8 "[22.1.] 22.2. Discoveries, scientific theories and mathematical
9 methods;

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

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

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

20 Provisions under this subsection shall not preclude Congress to 21 consider the enactment of a law providing *sui generis* of plant varieties 22 and animal breeds and a system of community intellectual rights 23 protection;

24 "[22.5.] 22.6. Aesthetic creations; and
25 "[22.6.] 22.7. Anything which is contrary to public order or
26 morality. (Sec. 8, R.A. No. 165a)"

1 "Sec. 72. *Limitations of Patent Rights.* – The owner of a patent has 2 no right to prevent third parties from performing, without his 3 authorization, the acts referred to in Section 71 hereof in the following 4 circumstances:

"72.1. Using a patented product which has been put on the market 5 in the Philippines by the owner of the product, or with his express consent, 6 7 insofar as such use is performed after that product has been so put on the said market; PROVIDED, THAT, WITH REGARD TO DRUGS OR 8 MEDICINES. THE LIMITATION ON PATENT RIGHTS SHALL 9 APPLY AFTER A DRUG OR MEDICINE HAS BEEN INTRODUCED 10 11 ANYWHERE IN THE WORLD BY THE PATENT OWNER, OR BY ANY PARTY AUTHORIZED TO USE THE INVENTION. 12

13 "72.2. Where the act is done privately and on a non-commercial
14 scale or for a non-commercial purpose: *Provided*, That it does not
15 significantly prejudice the economic interests of the owner of the patent;

"72.3. Where the act consists of making or using exclusively for 16 [the purpose of experiments that relate to the subject matter of the patented 17 18 invention;] EXPERIMENTAL USE OF THE INVENTION FOR SCIENTIFIC PURPOSES OR FOR COMMERCIAL PURPOSES THAT 19 DO NOT UNREASONABLY CONFLICT WITH A NORMAL 20 EXPLOITATION OF THE PATENT AND THAT DO NOT 21 UNREASONABLY PREJUDICE THE LEGITIMATE INTERESTS OF 22 PATENT OWNER, TAKING INTO ACCOUNT THE 23 THE LEGITIMATE INTERESTS OF SUCH THIRD PARTIES; 24

25 "72.4 WHERE THE ACT INCLUDES TESTING, USING,
26 MAKING OR SELLING THE INVENTION INCLUDING ANY DATA
27 RELATED THERETO, SOLELY FOR PURPOSES REASONABLY
28 RELATED TO THE DEVELOPMENT AND SUBMISSION OF
29 INFORMATION REQUIRED UNDER ANY LAW OF THE

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

4 "[72.4] 72.5. Where the act consists of the preparation for 5 individual cases, in a pharmacy or by a medical professional, of a 6 medicine in accordance with a medical prescription or acts concerning the 7 medicine so prepared;

8 "[72.5] 72.6. Where the invention is used in any ship, vessel, 9 aircraft, or land vehicle of any other country entering the territory of the 10 Philippines temporarily or accidentally: *Provided*, That such invention is 11 used exclusively for the needs of the ship, vessel, aircraft, or land vehicle 12 and not used for the manufacturing of anything to be sold within the 13 Philippines. (Secs. 38 and 39, R.A. No. 165a)"

SEC. 3. Sec. 74 of Republic Act No. 8293 is hereby amended to read as follows:
 "Sec. 74. Use of Invention by Government. - 74.1. A Government
 agency or third person authorized by the Government may exploit the

(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

invention even without agreement of the patent owner where:

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(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

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

27 "74.2. UNLESS OTHERWISE PROVIDED HEREIN, [T]the use
28 by the Government, or third person authorized by the Government shall be
29 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:

- 3 (A) IN SITUATIONS OF NATIONAL EMERGENCY OR
 4 OTHER CIRCUMSTANCES OF EXTREME URGENCY,
 5 THE RIGHT HOLDER SHALL BE NOTIFIED AS SOON
 6 AS REASONABLY PRACTICABLE;
- 7 (B) IN THE CASE OF PUBLIC NON-COMMERCIAL USE,
 8 WHERE THE GOVERNMENT OR CONTRACTOR,
 9 WITHOUT MAKING A PATENT SEARCH, KNOWS OR
 10 HAS DEMONSTRABLE GROUNDS TO KNOW THAT A
 11 VALID PATENT IS OR WILL BE USED BY OR FOR
 12 THE GOVERNMENT, THE RIGHT HOLDER SHALL BE
 13 INFORMED PROMPTLY;
- 14 (C) THE SCOPE AND DURATION OF SUCH USE SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS 15 AUTHORIZED, AND IN THE CASE OF SEMI-16 CONDUCTOR TECHNOLOGY, SHALL ONLY BE FOR 17 18 PUBLIC NON-COMMERCIAL USE OR TO REMEDY A PRACTICE DETERMINED AFTER JUDICIAL OR 19 20 ADMINISTRATIVE PROCESS TO BE ANTI-21 COMPETITIVE;
- 22 (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;
- 27 (F) THE LEGAL VALIDITY OF ANY DECISION RELATING
 28 TO THE AUTHORIZATION OF SUCH USE SHALL BE
 29 SUBJECT TO JUDICIAL REVIEW; AND

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1 (G) SUBJECT TO THE CONTROL, SUPERVISION AND 2 DETERMINATION OF THE RESPECTIVE 3 SECRETARIES OF THE DEPARTMENT OF HEALTH AND DEPARTMENT OF TRADE AND INDUSTRY, THE 4 USE OR OTHER **EXPLOITATION** 5 BY THE GOVERNMENT OR ANY OF ITS AUTHORIZED 6 7 REPRESENTATIVES OF DRUGS OR MEDICINES TO PROTECT PUBLIC HEALTH SHALL 8 BE 9 IMMEDIATELY EXECUTORY AND SHALL NOT BE SUBJECT TO ANY TEMPORARY RESTRAINING 10 ORDER OR PRELIMINARY INJUNCTION OR SUCH 11 OTHER PROVISIONAL REMEDIES THAT 12 WILL PREVENT ITS IMPLEMENTATION. NO SUIT OF ANY 13 KIND RELATED TO SUCH MAY BE FILED AGAINST 14 THE RELEVANT PUBLIC OFFICIALS OR OTHER 15 16 AUTHORIZED PERSONS ACTING UNDER THE DIRECTION OF THE SECRETARIES OF 17 THE DEPARTMENT OF HEALTH AND THE DEPARTMENT 18 OF TRADE AND INDUSTRY. ALL CASES ARISING 19 20 FROM THE IMPLEMENTATION OF THIS PROVISION BE COGNIZABLE BY COURTS 21 SHALL WITH APPROPRIATE JURISDICTION PROVIDED BY LAW." 22 SEC. 4. Sec. 147 of Republic Act No. 8293 is hereby amended to read as 23

25 "Sec. 147. *Rights Conferred.* – 147.1. EXCEPT IN CASES OF
26 IMPORTATION OF DRUGS OR MEDICINES ALLOWED UNDER
27 SECTION 72.1, [T]the owner of a registered mark shall have the
28 exclusive right to prevent all third parties not having the owner's consent
29 from using in the course of trade identical or similar signs or containers

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follows:

1 for goods or services which are identical or similar to those in respect of 2 which the trademark is registered where such use would result in a 3 likelihood of confusion. In case of the use of an identical sign for 4 identical goods or services, a likelihood of confusion shall be presumed.

"147.2 The exclusive right of the owner of a well known mark 5 defined in Subsection 123.1(e) which is registered in the Philippines, shall 6 7 extend to goods and services which are not similar to those in respect of which the mark is registered: Provided. That use of that mark in relation to 8 9 those goods or services would indicate a connection between those goods 10 or services and the owner of the registered mark: Provided, further, That 11 the interests of the owner of the registered mark are likely to be damaged 12 by such use.(n)"

13 SEC. 5. Separability Clause. – Any portion or provisions of this Act that may be 14 declared unconstitutional or invalid shall not have the effect of nullifying other portions 15 and provisions hereof as long as such remaining portion or provision can still subsist and 16 be given effect in their entirety.

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

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