[REPUBLIC ACT NO. 9502, June 06, 2008]

AN ACT PROVIDING FOR CHEAPER AND QUALITY MEDICINES, AMENDING FOR THE PURPOSE REPUBLIC ACT NO. 8293 OR THE INTELLECTUAL PROPERTY CODE, REPUBLIC ACT NO. 6675 OR THE GENERICS ACT OF 1988, AND REPUBLIC ACT NO. 5921 OR THE PHARMACY LAW, AND FOR OTHER PURPOSES

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

CHAPTER 1

GENERAL PROVISIONS

SECTION 1. *Short Title.* — This Act shall be known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008".

SEC. 2. *Declaration of Policy.* — It is the policy of the State to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all.

Pursuant to the attainment of this general policy, an effective competition policy in the supply and demand of quality affordable drugs and medicines is recognized by the State as a primary instrument. In the event that full competition is not effective, the State recognizes as a reserve instrument the regulation of prices of drugs and medicines, with clear accountability by the implementing authority as mandated in this Act, as one of the means to also promote and ensure access to quality affordable medicines.

SEC. 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.

SEC. 4. *Definition of Terms.* — For purposes of this Act, the following terms are to mean as follows:

a. "Compulsory License" is a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the permission of the patent holder, either by manufacture or through parallel importation;

b. "Drug outlet" refers to drugstores, pharmacies, and any other business establishments which sell drugs and medicines;

c. "Drugs and medicines" refers to any chemical compound or biological substance, other than food, intended for use in the treatment, prevention or diagnosis of disease in humans or animals, including but not limited to:

    1. any article recognized in the official United States Pharmacopoeia-National Formulary (USP-NF), official Homeopathic Pharmacopoeia of the United States, Philippine Pharmacopoeia, Philippine National Drug Formulary, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, Indian Pharmacopoeia, any national compendium or any supplement to any of them;
    2. any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
    3. any article other than food intended to affect the structure or any function of the human body or animals;
    4. any article intended for use as a component of any articles specified in clauses (1), (2), and (3) not including devices or their components, parts, or accessories; and
    5. herbal and/or traditional drugs which are articles of plant or animal origin used in folk medicine which are:

        i. recognized in the Philippine National Drug Formulary;
        ii. intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;
        iii. other than food, intended to affect the structure or any function of the human body;
        iv. in finished or ready-to-use dosage form; and
        v. intended for use as a component of any of the articles specified in clauses (i), (ii), (iii), and (iv);

d. "Essential drugs list or national drug formulary" refers to a list of drugs prepared and periodically updated by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria;
e. "Importer" refers to any establishment that imports raw materials, active ingredients and finished products for its own use or for distribution to other drug establishments or outlets;
f. "Manufacture" includes any process or part of a process for making, altering, finishing, packing, labeling, breaking or otherwise treating or adapting any drug with a view to its sale and distribution, but does not include the compounding or dispensing of any drug in the ordinary course of retail business;
g. "Manufacturer" refers to any establishment engaged in the operations involved in the production of a drug with the end view of storage, distribution, or sale of the product;
h. "Multisource pharmaceutical products" refers to pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable;

i. "Retailer" refers to a licensed establishment carrying on the retail business of sale of drugs and medicines to customers;
j. "Trader" refers to any licensed establishment which is a registered owner of a drug product that procures the materials and packaging components, and provides the production monographs, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer;
k. "TRIPS Agreement" or Agreement on Trade-Related Aspects of Intellectual Property Rights refers to the international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation; and
l. "Wholesaler" refers to a licensed establishment or drug outlet who acts as merchant, broker or agent, who sells or distributes for resale or wholesale drugs and medicines.

CHAPTER 2

AMENDMENTS TO REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES

SEC. 5. Section 22 of Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to read as follows:

"SEC. 22. *Non-Patentable Inventions.* — The following shall be excluded from patent protection:

"22.1. Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, 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 property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant.

"For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

"22.2. x x x;

"22.3. x x x;

"22.4. x x x;

"22.5. x x x; and

"22.6. x x x."

SEC. 6. 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. (n)

"26.2. In the case of drugs and 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 property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant."

SEC. 7. 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 and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: *Provided, further,* That the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party;

"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 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. In the case of drugs and medicines, 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 or of another country 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, 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 the enactment of this law;

"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 presciption or acts concerning the medicine so prepared; and

"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. 8. 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 licensee, is anti-competitive; or

"(c) In the case of drugs and medicines, there is a national emergenvy or other circumstance of extreme urgency requiring the use of the invention; or

"(d) In the case of drugs and medicines, there is public non-commercial use of the patent by the patentee, without satisfactory reason; or

"(e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the Department of Health."

"74.2. Unless otherwise provided herein, the use by the Government, or third person authorized by the Government shall be subject, where applicable, to the following provisions:

"(a) In situations of national emergency or other circumstances of extreme urgency as provided under Section 74.1 (c), the right holder shall be notified as soon as reasonably practicable;