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Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

THIRTEENTH CONGRESS
First Regular Session

HOUSE BILL NO. 498

Introduced by **Hon. Arthur "Dodo" Y. Pingoy, Jr., M.D.**

Explanatory Note

One big impediment to the efficacious implementation of Republic Act 6675 (Generics Law of 1988) is the long period that drug manufacturers have to wait for the patent to expire before it is allowed to manufacture low-priced drugs. Republic Act 8293, otherwise known as the Intellectual Property Code of the Philippines, sets the term of a patent in twenty (20) years from the filing of the application in the Philippines.

Corollary, this issue about patents particularly the monopoly of patents and brand names by multinational drug companies (MNCs) is one of the causes for the continuous price increases of drugs. Because of this, only MNCs can exclusively distribute their products and dictate prices, thereby enabling them to also monopolize the market. In fact, public policy experts of the University of the Philippines do not only consider this as a monopoly but an oligopoly.

It is also worthy to note that even off-patent drugs are comparatively high-priced because MNCs do not license local drug companies to undertake domestic production. Furthermore, most off-patent drugs are imported and sold domestically by local subsidiaries of these companies.

These MNCs are also notorious for price-fixing. It can be remembered that in 1979, the U.S. Supreme Court held that six transnational companies namely Pfizer, American Cyanamid, Bristol Myers, Squibb and Upjohn and Olin were guilty of having conspired to increase the price of tetracycline being sold in the Philippines, India and Iran.

With an estimated hold of 68% of the market to a high of 75%-90% as the remaining 32% is shared by both foreign and local players of the industry, it is easy to conceive how they effectively control drug prices.

In a Department of Health budget briefing on 03 September 2001, Secretary Manuel M. Dayrit estimated the hold of multinationals in the P50-60 million drug industry to be 75%. Filipino-owned and controlled companies manufacturing and distributing mainly off-patent, generic drug comprise a mere 12%-15% of the total market.

It is in this light that a policy of greater state intervention in health and pharmaceutical concerns must be installed and vigorously exercised and maintained whereby the interests and welfare of the people remain supreme.

Thus, apart from this proposed measure, two intertwined bills along this policy line and framework were also filed by the undersigned. This bill deals with the issue of patents and of the need for compulsory licensing, whereby it seeks to shorten the patent period of drugs and thereafter, institutionalize compulsory licensing.

Verily, this will constitute one of the effective strategies of the government to control the prevailing price schemes of drug companies and support the fledgling local drug industry, among other important imperatives in ensuring a safe, effective and affordable drug supply for the Filipinos and one of Congress's cogent and strong response to President Macapagal-Arroyo's exhortation and assurance during her first state-of-the-nation-address (SONA).

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AN ACT
AMENDING REPUBLIC ACT NO. 8293, OTHERWISE KNOWN AS THE INTELLECTUAL PROPERTY CODE OF THE PHILIPPINES, TO LOWER THE COST OF DRUGS AND PHARMACEUTICAL PRODUCTS AND FOR OTHER PURPOSES

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

SECTION 1. Patents of pharmaceutical products. – Section 54 of R.A. 8293, otherwise known as the Intellectual Property Code of the Philippines, is hereby amended to be read as follows:

Sec. 54. Term of Patent. – The term of patent shall be twenty (20) years from the filing date of application, *except for drug and pharmaceutical products which shall be ten (10) years from the filing date of application, be it in the Philippines or elsewhere in the world.*

SEC. 2. Compulsory Licensing. -- Sections 93 and 95 of R.A. 8293 are hereby amended to be read as follows:

Sec. 93. Grounds for Compulsory Licensing. – The Director of Legal Affairs *or the Secretary of the Department of Health, in cases of drug or pharmaceutical products,* may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention, under any of the following circumstances:

x x x x

93.2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy *which shall include the national drug and pharmaceutical industry* as determined by the appropriate agency of the Government, so requires [or] ;

In particular, patented drugs and pharmaceutical products shall now be subject to compulsory licensing.

x x x x

Sec. 95. Requirement to Obtain a License on Reasonable Commercial Terms. –

95.1. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable

commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

95.2. The requirement under Subsection 95.1 shall not apply in the following cases:

(a) x x x
(b) x x x
(c) x x x
(d) *In cases of production of drugs and pharmaceutical products as carried out by the State through accredited local drug establishments.*

SEC. 3. Concurrence of Congress in the Extension of Patents. --No extension of patent of drugs shall be allowed in the Philippines once their approved patent life has expired in the Philippines under any condition or circumstance without the concurrence Congress.

SEC. 4. Implementing Agency. -- The Department of Health (DOH), in coordination with the Department of Trade and Industry (DTI), shall be the main body to enforce this Act. It shall, likewise, promulgate the rules and regulations necessary to implement the provisions of this Act within sixty (60) days from its passage.

SEC. 5. Separability Clause. -- If any provision of this Act is declared invalid, the remainder or any provisions hereof not affected thereby shall remain in full force and effect.

SEC. 6. Repealing Clause. -- The provisions of any law, executive orders, presidential decrees or other issuances inconsistent with this Act are hereby repealed or modified accordingly.

SEC. 7. Effectivity. -- This Act shall take effect fifteen (15) days after its complete publication in at least two (2) national newspapers of general circulation.

Approved.