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JOINT ADMINISTRATIVE ORDER
No. 2021- 0001

SUBJECT: **Supplemental Guidelines to Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01, the Implementing Rules And Regulations of Republic Act 9502 Otherwise Known as the "Universally Accessible Cheaper And Quality Medicines Act of 2008"**

I. RATIONALE

WHEREAS, Republic Act No. 9502, otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008" amending Republic Act No. 8293, or the Intellectual Property Code of the Philippines, Republic Act No. 6675, or the Generics Act of 1998, and Republic Act No. 5921, or the Pharmacy Law became effective on July 4, 2008;

WHEREAS, the Department of Health (DOH), the Department of Trade and Industry (DTI), the Intellectual Property Office of the Philippines (IPOPHL) and the Food and Drug Administration (FDA) issued Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 prescribing the Implementing Rules and Regulations of RA 9502;

WHEREAS, Article 31 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) allows Member to use a patent without the authorization of the right holder under specific grounds and subjective to certain conditions;

WHEREAS, the 2001 Doha WTO Ministerial Declaration on the TRIPS Agreement and Public Health reaffirms that the right of Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility to protect public health and in particular, to promote access to medicines for all;

WHEREAS, the Doha Declaration on Public Health allows flexibilities for Members the right to grant compulsory licenses and freedom to determine the grounds upon which such licenses are granted and determine what constitute a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS,

tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency;

WHEREAS, there is a need to provide supplemental guidelines to the rules and procedure in granting compulsory licenses for drugs and medicines in order to provide an urgent and effective mechanism to address public health emergencies and other cases of extreme urgency.

NOW THEREFORE, these supplemental guidelines to the Joint Administrative Order No. 2008-01 are hereby promulgated.

II. OBJECTIVES

This Order aims to provide mechanism for speedy resolution of petitions for compulsory licenses, particularly, the petitions for Special Compulsory License (SCL) to be filed by the DOH.

III. SCOPE AND COVERAGE

These guidelines shall cover the use by the DOH Offices and DOH *Center for Health Development (CHDs)* of the flexibilities on the granting of compulsory licenses (CL) under the TRIPS Agreement applicable to drugs and medicines, particularly, the filing and issuance of a SCL.

IV. DEFINITION OF TERMS

1. **Compulsory license** - refers to a license issued by the Director General of the Intellectual Property Office to exploit a patented invention without the permission of a patent holder either by manufacture or through parallel importation.

2. **Special Compulsory License** - refers to the licensing of import and/or export of patented drugs and medicines as referred to in Section 93-A of the IP code.

3. **"TRIPS Agreement"** or Agreement on Trade-Related Aspects of Intellectual Property Rights- refers to the international agreement administered by the World Trade Organization that sets down minimum standards for many forms of intellectual property regulation.

V. GENERAL GUIDELINES

1. Special Compulsory License shall only be available to drugs and medicines.
2. The requirements, timelines and process for the application and issuance of the SCL shall be in accordance with this Joint Administrative Order.

3. The patent holder shall be paid adequate remuneration taking into account the economic value of the grant or authorization and the remaining patent life. The rate of royalty payment shall be in accordance with the latest guidelines of the United Nations

Development Programme (UNDP) and international practices and standards in setting the royalty rate for drugs and medicines.

VI. SPECIFIC GUIDELINES

A. Grounds for Issuance of Special Compulsory License

The petition for the issuance of SCL to drugs and medicines shall state any of the following circumstances:

1. National emergency or other circumstances of extreme urgency;
2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires;
3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his/her licensee is anti-competitive;
4. In case of public non-commercial use of the patent by the patentee without satisfactory reason;
5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, That the importation of the patented article shall constitute working or using the patent; and
6. When the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms as determined by the Secretary of Health.

B. Procedure for Special Compulsory License

The procedure shall be as follows:

1. **Letter of Intent.** The DOH Program Manager shall submit a letter of intent (LOI) to the DOH-Pharmaceutical Division to file the petition for SCL at the IPOPHL. The LOI shall contain all relevant information which is hereto attached as Annex A.

2. **Filing of Petition.** The written petition for SCL must be verified by the Secretary of the DOH recommending that the IPOPHL issue the SCL and stating that negotiations to purchase the patented drugs and medicines from the patent owner were conducted but no agreement was reached by the parties.

3. **Notice to Answer.** Within three (3) days from receipt of the petition and written recommendation from the Secretary of DOH, the Director General of the IPOPHL shall issue an Order directing the patent holder to file an answer to the petition.

4. **Filing of Answer.** The patent holder is required to file the answer to the petition within ten (10) days from receipt of the Order.

5. **Issuance of SCL.** The Director General of the IPOPHL shall immediately issue the SCL for the importation of patented drugs and medicines on any of the following instances:

    a. Upon failure of the patent holder to file the answer to the petition; or
    b. Upon review by the Director General that the petition satisfies the circumstances and the requirements for the issuance of the SCL.

6. **Terms and Conditions of SCL.** The SCL to be issued by the Director General shall state the following:

    a. Authority for the DOH to import the patented drugs and medicines;
    b. Scope and duration of the SCL;
    c. Payment of adequate remuneration to the patent owner taking into account the economic value of the authorization payable in Philippine peso; and
    d. Requirement for the DOH to take reasonable measures to prevent the re-exportation of the imported patented drugs and medicines.

7. **Notification.** Upon issuance of the SCL, the Director General of the IPOPHL shall immediately issue a notification to the DOH and the patent holder informing them the terms and conditions of the SCL.

8. **Certificate of Product Registration.** To avoid the commercialization and market distribution of the generic product, the Philippine Pharma Procurement, Inc. (PPPI), or the authorized government agency, or the registered holder of the Certificate of Product Registration (CPR) of the approved generic product, shall design the packaging for the exclusive use of the government.

C. Expedited processes in SCL and compulsory licensing petitions in the Intellectual Property Office of the Philippines (IPOPHL)

The Office of the Director General of the IPOPHL shall receive petitions for compulsory licenses including the petition for SCL filed by the DOH and shall prioritize and promptly resolve these petitions. In cases filed by the DOH, the alternative dispute resolution mechanism on mediation proceedings will not be applied.

VII. SEPARABILITY CLAUSE

In case any provision in this order shall be deemed invalid, illegal or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. All other provisions of existing issuances such as the Joint Administrative Order No. 2008-001, which are not affected by this Order shall remain valid and in effect.

VIII. REPEALING CLAUSE

The provisions of other issuances inconsistent with this Joint Administrative Order are hereby repealed, amended or modified accordingly.

IX. EFFECTIVITY

This Order shall take effect immediately upon its publication in a newspaper of general circulation or in the Official Gazette, and upon filing three (3) certified true copies to the Office of National Administration Register (ONAR) of the University of the Philippines (UP) Law Center.

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