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TRIPS Agreement and Pharmaceutical Patent Protection in Indonesia

Cita Citrawinda¹

Promotion and improvement protections in intellectual property rights (IPRs), particularly in the developing countries with weak tradition in the protection of IPRs has become new major factor that potentially affecting state's ability to guarantee the access to drugs. Access to drugs is the main issue in public health, especially regarding to patent that has impact on drugs prices. This article discusses how Indonesia, as one of developing countries, can ensure access and protection of the IPRs in drugs issues.

Keywords: Trips, Pharmaceutical Patent, Compulsary License

I. Introduction

The introduction and expansion of intellectual property protections in countries around the world, particularly developing countries with weak traditions of intellectual property protection, is a major new factor potentially impacting on countries' ability to ensure access to drugs. Access to medicines as human rights to obtain health service has occurred as main issue in the public health, particularly with regard to patent that has impact to the medicine prices. Pharmaceutical patent gets more obvious after establishment of the Trade-Related Aspects of Intellectual Property Rights (TRIPs), agreement in the World Trade Organization in 1995. The agreement obligated the WTO members to include medicines in the regime of patent product and patent process.²

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² Martin Khor, "Paten dan Akses Terhadap Obat-obatan: Langkah yang Harus Ditempuh di Setiap Negara", *Media HKI* Vol III/No. 3/June 2006 (Jakarta: Direktorat Jenderal Hak Kekayaan Intelektual, Departemen Hukum dan HAM

Options are given for countries to establish policy measures to import, produce and export affordable medicines through measures that are consistent with TRIPs Agreement. These measures include compulsory licensing, 'government use' procedures, and the parallel importation of drugs that are patented in countries, thus enabling the use of cheaper generic versions of patented branded drugs, and also cheaper versions of the same branded products. The TRIPs Agreement does contain flexibilities, for example if patented drugs cost too much, the government authorities can take measures such as issuing a compulsory license to an agency or company to manufacture or import a generic version of that patented drug, which can then be given greater availability to patients at a lower price.³

II. Exclusive Rights and Obligations of a Patent Holder

As stipulated in Article 16 of Law No. 14 of 2001, a patent holder shall have the exclusive rights to exploit his patent and prohibit any other party who without his consent:⁴

RI), p. 7. See also *The TRIPS Agreement and Pharmaceuticals*, Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals that was organized by Directorate General of Drug and Food Control, Ministry of Health, Indonesia, World Trade Organization and Rockefeller Foundation, Jakarta, 2 – 4 May 2000, p. 6 that "...In the pharmaceutical sector, patents are the most important form of IPR protection. Patents are more difficult to obtain than other forms of IPR (an application has to be filed at, and approved by the patent office)..."

³ Cita Citrawinda, "Patent Law and Access to Medicines in Indonesia from the Public Health Perspective", a report of the In-Country Workshop held by the National Project Coordination Committees (NPCC), Jakarta (21 May 2004) p. 1. See also Cita Citrawinda, "Patent and Public Access to Drugs in Indonesia", paper presented on 14 March 2008 at the 2008 ASEAN IPA Annual Conference with theme of "Economic Driver: Role and Importance of Intellectual Property in Areas of Growth" held at the Renaissance Hotel, Makati City, Philippines, 13 – 15 March 2008 p. 1.

⁴ See also Article 28 of TRIPs Agreement

- a. *in the case of product-patent* is to make, use, sell, import, rent out, deliver, or to make available for sale or rental or delivery of the patented products;
- b. *in the case of process-patent* is to use the patented production process to make products and commit other activities as referred to above.

In the case of process-patent, such prohibition against any other party who without his consent commits the importation as referred to above, shall only apply to imported products solely produced from the use of the pertinent process patent. Permitted acts include those for purposes of education, research, experiment, or analysis, as long as it is not for commercial exploitation and does not harm the normal interest of the patent holder.

In the case of the importation of a product into Indonesia of which the process to produce the relevant product has been protected by a patent based on this Law, the patent holder of the process shall have the right, based on the provisions of Article 16 paragraph (2) to bring a legal action against the imported product, if the product was made in Indonesia by using the patented process.⁵

A patent holder shall be obliged to make products or to use the process that has been granted a patent in Indonesia.⁶ Exemption from the obligation can be done provided that the production of the product or the use of the process is only suitable to be implemented on a regional scale if the patent holder has submitted a written request that is accompanied by the reasons and evidence issued by the authorized agency.⁷ Government Regulation shall further regulate the requirement concerning the exemption and the procedure of submitting a written request.

⁵ Article 19 of Law No. 14 of 2001 concerning Patents.

⁶ Article 17 para. (1) of Law No. 14 of 2001 concerning Patents.

⁷ Article 17 para (2) and (3) of Law No. 14 of 2001 concerning Patents.

Exempted from criminal action as stipulated under Article 135 of Patent law Number 14 of 2001, are as follows:

- a. the importation of a pharmaceutical product protected by a patent in Indonesia and that the product has entered into the market in a country by the rightful patent holder provided that the product is imported in accordance with the prevailing rules and regulations.

The exemption of the importation of a pharmaceutical product as stated above is to guarantee and maintain the reasonable and equitable prices of pharmaceutical products that are urgently needed for public health. This provision can be used if the price of a pharmaceutical product in Indonesia is very high compared with the price of a pharmaceutical product that has been legally circulated in the international market.

- b. the production of a pharmaceutical product protected by a patent in Indonesia within a period of 2 (two) years prior to the expiry of the patent protection, for the purpose of obtaining approval and thereupon conduct marketing upon the expiry of the patent protection.

The exemption of the production of a pharmaceutical product as stated above is to guarantee the supply of pharmaceutical products by other parties after the expiration of the patent protection period. Therefore, by this exemption, the effort to achieve reasonable prices for pharmaceutical products can be sought.

III. Legal Situation and Compulsory License

TRIPs Agreement provides for a number of safeguards which may be used to protect public health and promote competition, such as compulsory licensing, and allows for exceptions which may facilitate the marketing of generic drugs ("*Bolar Exception*").⁸ These safeguards can be used to mitigate potential negative impacts

⁸ See Article 30 of TRIPs Agreement: Exception to Rights Conferred.

of increased IPR protection in the pharmaceutical sector on access to drugs. However, these safeguards can only be used if they have been incorporated in the national legislation.⁹ Measures to protect the public interest ought to be included in the national legislation, and should encompass public health aspects. TRIPs Agreement is the most far-reaching international instrument ever negotiated on intellectual property rights with which the Patent law of WTO members must comply.¹⁰ It is the Agreement that allows a pharmaceutical company to monopolize the production, marketing and pricing of patent protected drugs.

In the course of the implementation of the TRIPs Agreement that formulated minimal standards for most fields of intellectual property law, for the first time internationally binding regulations on compulsory licenses were set. As has been confirmed by the Doha Declaration,¹¹ TRIPs Agreement and Public Health, each

⁹ *The TRIPS Agreement and Pharmaceuticals*, Report of an ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals that was organized by Directorate General of Drug and Food Control, Ministry of Health, Indonesia, World Trade Organization and Rockefeller Foundation, Jakarta, 2 – 4 May 2000, p. 1.

¹⁰ See Phillippe Cullet "Patents and Medicine: The Relationship between TRIPs and the Human Right to Health", p. 140 accessed from http://www.ielrc.org/research_intellectual_property.php dated 27 March 2007 that "Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings which can always be ceded in voluntary transactions. As codified in the two UN covenants and other relevant instruments, human rights constitute the basic framework guiding state actions at the domestic and international levels. As a result, states must bear in mind their human rights obligations when they negotiate and implement international rules on intellectual property rights or trade liberalization."

¹¹ A ministerial conference held in Doha, Qatar in 2001 produced a consensus of sorts on how Article 31 of the TRIPs Agreement should be interpreted thereafter. It was agreed that TRIPs did not preclude WTO members from taking measures to protect the health of their citizens and Article 31 should be viewed in this context. See *WHO Drug Information* Vol. 19 No. 3, 2005 p. 239 that "...The Doha Declaration refers to several aspects of TRIPs, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency, and the freedom to establish the regime of exhaustion of intellectual property rights."

country has the right to determine the grounds for compulsory licensing. The implied grounds specifically referred to national emergencies or other circumstances of extreme urgency, dependency of patents, anti-competitive practices, and public non-commercial use; however, this does not limit the grounds on which a compulsory license may be granted. Article 31 of the TRIPs Agreement stipulates legal requirements for obtaining a compulsory license for national emergencies; and at present, the TRIPs Agreement only allows the production of patented drugs in the territory of countries that face a national emergency.¹² However, this provision is not helpful to countries that do not have the necessary manufacturing capacities. Therefore, some developing countries should be permitted to import drugs at a less expensive price. However, there is always the danger that drugs sold inexpensively in a developing country are not supplied to patients there but resold in the developed world, thereby undercutting the direct seller there. The discounted drugs would therefore need to be clearly packaged and labelled as for sale in the intended country only. Thought would consequently have to be given as to how this would impact on the parallel import system.

It is now agreed under the Doha Declaration on how Article 31 of the TRIPs Agreement should be interpreted in the future and it is affirmed that Article 31 of TRIPs Agreement can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote access to medicines for all. Therefore, each member state has the right to determine what constitutes a national emergency and the circumstances of extreme urgency to merit compulsory licensing.¹³ By the TRIPs Agreement, industrialized countries, the

¹² See Article 31 of TRIPs Agreement.

¹³ See Samantha Shoell, "Why Can't the Poor Access Lifesaving Medicine? An Exploration of Solving the Patent Issue" available at <http://www.mpr.umn.edu/archive/v4n1/shoell.pdf> p. 162 that "...The ministerial declaration draft composed by the developing countries addressed the "inability of large segments of the population to obtain medicines and treatments at prices they can afford" They proposed that, "[n]othing in the TRIPs Agreement shall prevent Members from taking measures to protect public health..." See also Cita Citrawinda, *Hak Kekayaan Intelektual – Tantangan Masa Depan* (Jakarta: Badan

citizens of which hold most of the world's patents, accommodated the needs of developing countries, since the developed countries now have the power to determine when a situation necessitates a compulsory license.

The TRIPS Agreement only allows a compulsory license to permit manufacture in the country affected by the national emergency in question, but as far as Indonesia is concerned, Indonesia should have the requisite facilities or expertise. Consequently, another option for Indonesia prejudiced by the prohibitive cost of patented drugs is to look to their generic counterparts. The government of Indonesia should prioritize voluntary initiatives and partnerships with the private sector to resolve the problem of access to medicines rather than resorting to a system of unrestrained cross-border licensing which imposes the burden of financing primarily on innovative organizations.

Any party, after the expiration of a period of 36 (thirty six) months commencing from the date of grant of a Patent, may file a request for a Compulsory License at the Directorate General, with the payment of a fee. A request for a Compulsory License shall only be made on the grounds that the relevant Patent has not been implemented or only partially implemented by the Patent holder. A request for a Compulsory License may also be filed at any time after the grant of Patent on the grounds that the relevant Patent has been implemented by the Patent Holder or the licensee in a form and manner that contravenes the public interest.¹⁴

A compulsory license may only be granted if the person filing the request is able to provide convincing evidence that he has the ability to personally and fully implement the relevant patent and has his own facilities to readily implement the relevant patent. In addition,

Penerbit Fakultas Hukum Universitas Indonesia, 2003) p. 58 that "...Compulsory licensing that usually most discussed currently is the license that considered to be badly needed to overcome natural disaster...sometimes to face great epidemic, for instance caused by HIV/AIDS, TBC or malaria, of which the developing countries badly need cheap medicines."

¹⁴ See Article 75 of Law No. 14 of 2001 concerning Patents.

he also needs to provide evidence that he has made efforts during a sufficient period of time to acquire a license from the patent holder on the basis of normal terms and conditions but did not succeed. A relevant patent may also be granted if the Directorate General of IPR is of the opinion that the relevant patent can be implemented in Indonesia on a feasible economic scale and can be of benefit to the majority of the society.

The grant of a compulsory license shall include the followings:

- a. the compulsory license shall be non-exclusive;
- b. the grounds for granting of the compulsory license;
- c. evidence, including convincing information or explanations, which form the basis for granting the compulsory license;
- d. the period of compulsory license;
- e. the payment of royalty and the method of payment;
- f. conditions on the termination of the compulsory license and matters which may cause revocation of the compulsory license;
- g. the compulsory license will be primarily used to supply the demand in the national market; and
- h. other matters necessary to fairly protect the interest of the parties concerned.

IV. Exploitation of Patent by the Government

As far as public necessity is concerned, Patent Law Number 14 of 2001 concerning Patent stipulates that, if the government is of the opinion that a patent in Indonesia is very important for an urgent need to the conduct of State defense, security or for the sake of public interest, the Government may itself exploit the relevant patent.

What is meant by an urgent need for the sake of public interest includes, among others public health aspects such as medicines that are still protected by patent in Indonesia and are needed in facing huge epidemics, where as a developing country there will be a great demand for inexpensive medicines for example in the case of HIV/AIDS. For this reason the Government of Indonesia has issued Implementing Regulation No. 83 of 2004 concerning Patent Exploitation by the Government on the Anti Retroviral Drugs that was stipulated on 5 October 2004.¹⁵

With this regard, for example in China, the Government has taken policy measures to facilitate access to affordable medicines.¹⁶

1. Importing the Drug

A country can import a generic version of the patented product by issuing a compulsory license to a company or agency to import the drug. The imported drug can originate from a country in which the drug is not patented or in which the drug is patented. Import of generic versions of the patented drug can also be imported for 'public, non-commercial use' by the government. This case does not require prior consent of or

¹⁵ See Article 99 para (1) of Law No. 14 of 2001 concerning Patents. See also The Government Regulation No. 27 of 2004 concerning Methods of Patent Exploitation by the Government. See Article 31 point (b) of TRIPs Agreement that states: *...This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonable practicable...* See also Siti Fadilah Supari, *Saatnya Dunia Berubah* (Jakarta: PT. Sulaksana Watinsa Indonesia, 2008) p. 87 that *...the UNAIDS focus in helping Indonesia is in HIV/AIDS, TBC and Malaria...as for the HIV/AIDS prevention program in Papua, that has been issued and known as program of "Save Tanah Papua", there is shortage of fund amounting to USD 50 million, to implement rapid test carried out through door to door, to know HIV/AIDS disease earlier...*

¹⁶ *Cost-Containment Mechanisms for Essential Medicines, Including Antiretrovirals, in China*, Mission Report of World Health Organization Beijing:2002).

negotiations with the patent holder, however adequate compensation has to be paid. This method is most suitable if the imported drug is to be used by the government. 'Parallel importation' of a patented product (i.e. not the generic version) may also be applied in this method. This is allowed under Article 6 of the TRIPs Agreement on exhaustion of rights and the Doha Declaration affirms by stating that each WTO member is "*free to establish its own regime for such exhaustion without challenge*". In this case, there is no need for an importer to obtain a compulsory license, nor to pay compensation to the patent holder.

2. Local Manufacture

If a drug is patented in a country, a local company or agency that has been granted a compulsory license can locally manufacture generic versions of the drug. The government may assign a public or private agency the right to locally manufacture a patented product without the patent holder's permission, as long as the product is to be used for a public non-commercial purpose and a reasonable amount of compensation is paid.

3. Export, including to Countries with Inadequate Manufacturing Capacity

A local producer of generic versions of patented products under a compulsory license or government-use provision may export a portion of its output. Article 31 (f) of the TRIPs Agreement requires that this production shall be 'predominantly for the supply of the domestic market' and thus there is a limit to the amount that can be exported. The restriction on export quantity has posed a problem for developing countries with insufficient or no drug manufacturing capacities, they may find it difficult to import the required medicines due to the limited amount of supply of medicines from the potential exporting countries.

However, the decision to self-exploit a patent as stipulated under Law Number 14 of 2001 concerning Patents shall be further

regulated by Presidential Decree after hearing considerations from the Minister (Minister of Health) and from the minister or head of the agencies responsible in the relevant field. The Presidential Decree should declare the National Emergency Situation, in case that is necessary.

The provisions on the patent exploitation by the government in Indonesia shall also be applied to any invention for which a patent has been requested but has not yet been announced by the Directorate General of IPR. In the event that the government does not or has not yet intended to self-exploit a patent, the exploitation of such a patent may only be undertaken with the approval of the government. The patent holder concerned shall be released from the obligation to pay the annual fees until the relevant patent is exploited.

In the event that the government intends to self-exploit a patent that is important for an urgent need for the sake of public interest, the government shall notify the patent holder in writing based on its purpose by setting forth the following:

- a. the title and number of the relevant patent as well as the name of patent holder;
- b. reasoning;
- c. the period of exploitation;
- d. other matters that are deemed significant;
- e. reasonable compensation to the patent holder;

V. Conclusion

As one of the WTO Members, Indonesia should formulate and implement national policies aimed at providing access to medicines, otherwise the gains made at the international level through the Doha Declaration will not translate into actual benefits for patients. The Indonesian government considers HIV/AIDS prevention and treatment as an important task; therefore, the Indonesian government should further clarify targets, identify responsibilities and improve evaluation, supervision and monitoring should there be a spread of HIV/AIDS spread caused by ineffective work. Moreover, the government should increase political commitment to

provide free medicines for HIV/AIDS patients who are in economic difficulties and this program will cover low-income HIV/AIDS patients in urban areas and all patients in rural areas.

A step-by-step approach on how health policy makers can implement each of the legal options identified, are as follows:

1. The Government of the Republic of Indonesia has the right to determine what constitutes a national emergency and the circumstances of extreme urgency to merit compulsory licensing in terms of the WTO-TRIPs Agreement, taking into account the Doha Ministerial Declaration.
2. To fulfill a large demand and rapid availability of medicines for an urgent need for the sake of public interest, the Government of Indonesia could itself exploit the relevant patent by giving reasonable compensation to the patent holder.
3. Indonesia should be permitted to import drugs at a cheaper price.
4. To look to generic counterparts and give priority to voluntary initiatives and partnerships with the private sector to resolve the problem of access to medicines rather than resorting to a system of unrestrained cross-border licensing which imposes the burden of financing primarily on innovative organizations.
5. To suggest the potential pharmaceutical company to have some mutually contractual arrangement with the generic manufacturer in Indonesia in order to lessen the competition so that the supply of the medicine can be provided for public interest.

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