THE ISSUE OF FAIRNESS OF THE TRIPS AGREEMENT FOR THE DEVELOPING AND LEAST-DEVELOPED COUNTRIES IN INTERNATIONAL TRADE PRACTICES ON PATENTS OF PHARMACEUTICALS

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ABSTRACT

This paper is based on research in the area of the intellectual property law and the international trade law. The research examines whether the TRIPS Agreement is fair for the developing and least developed countries (DLDCs), particularly in cases of international trade practices on patents of pharmaceuticals. The research is mainly library research, which is conducted at the Faculty of Law, Monash University, Australia. The completion of this paper is using a member of selected books and international journals, case law, documents of international organization, and international agreement and convention.

Important findings were shown by the research that from the perspective of DLDCs, the TRIPS Agreement is unfair due to several significant factors. It is argued that some fundamental differences between DLDCs and developed countries of their economic and legal enforcement conditions are generated imbalance treatment of the TRIPS Agreement in the two-category countries. Several recommendations are also given to governments and international organization in order to evaluate current system of intellectual property rights protection-international trade interface and to create greater fairness in the implementation of the TRIPS Agreement.

1. Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has had an immense role on international trade practice. Although the World Trade Organization (WTO) Members (the Members) must accept provisions of TRIPS as part of the agreement, many developing and least-developed countries (DLDCs) were fairly lacking in readiness to adopt TRIPS. Still, the Members have to provide protection in regards to intellectual property rights (IPR) as given in Sections 1 to 7 of TRIPS.

The patent system, which is one of the substances of IPR arranged by TRIPS, is facing intense criticism from DLDCs especially on its

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* S.H., Lecturer of Business Law at the Faculty of Law, Gadjah Mada University. The writer wishes to thank to Professor Jeff Watney who has examined and given invaluable comments in support of the completion of this paper.
* ibid., p.32

HIMBAR HUKUM
provision on pharmaceuticals. Firstly, the system has to provide protection of inventors' exclusive rights and incentives for innovation resulting from research and development (R&D). Next, it has also an obligation to ensure that there is affordable medicine in all societies. This issue is significantly important, as access to health facilities including access to medicine becomes one of human rights issues. However, it is not easy to balance both obligations of TRIPS at multinational levels.

In developed countries, high-tech R&D becomes a priority while there is a competitive market that needs better products from new inventions. Investors put their capital in R&D to make a profit. For developed countries, there are relatively no economic impediments to developing high-cost R&D in practice. Thus, it is easier for developed countries to conform to TRIPS and it is to their advantage to promote protection on IPR and advance R&D.

On the contrary, for DLDGs, TRIPS and the patent system merely creates a burdensome position. Many DLDGs are facing economic crisis. Because of this, DLDGs have found that patented medicines are unaffordable. Because of the 'monopoly' characteristic of the patent system, there has been a relative shortage of access to patented medicines, for example, HIV/AIDS medicine. Furthermore, there is political pressure from pharmaceutical companies that are mostly based in developed countries for patent protection.

This paper will analyse whether the IPR regime especially TRIPS and the patent systems provide fairness for DLDGs in international trade practices. It focuses on articles in TRIPS related to compulsory licensing and parallel importing for pharmaceuticals. A practical approach will be considered with emphasis on the principle of fairness. Finally, it suggests ways for managing problems faced by DLDGs.

II. Analysis of the Issue of Fairness of TRIPS Related to Patents of Pharmaceuticals for DLDGs

There are some tensions between the pharmaceutical companies that seek protection for their investment in R&D and DLDGs, which look for more access and affordable drugs. These tensions are centred around trade and drug access (getting the drug into the market) and IPR, 'public goods and private profit', and finally between compassionate concerns and IPR.

With respect to the question whether TRIPS offers fairness to DLDGs, we can draw on a principle stated by Rawls in The Law of People:

Just as a citizen in a liberal society must respect other persons' comprehensive religious, philosophical, and moral doctrines provided they are in accordance with a reasonable political conception of justice, so a liberal society must respect other societies organized by comprehensive doctrines, provided their political and social institutions meet certain conditions that lead the society to adhere to a reasonable law of peoples.¹

TRIPS does not respect that principle in that it does not value enough the economic differences between countries. The paper tries


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MEMBAR JUKUM

21
to analyse the problem of implementing TRIPS in light of this basic principle and will suggest ways in which TRIPS could be made more equitable.

The question of whether the patent system of TRIPS provides fairness comes up instantly when health and profit are in conflict. A patent gives exclusive privileges and it is equivalent to granting a monopoly to some extent in a market for a certain product. While a patent gives benefit to the holder, there is a need for low-price pharmaceuticals. This will not happen because practically a patent leads to higher prices. Therefore, the two interests are not balanced.

Prior to TRIPS, the absence of patent protection had permitted easy and cheaper access to generic drug equivalents. For many DLDGs, unaffordable prices and shortage of medicine have become a problem particularly since the patent system applied by TRIPS. It is argued that these problems result from the functioning of the patent system especially in pharmaceuticals, which needs reasonably high-cost R&D.

The concept of TRIPS came from strong economy-based countries, which wanted to protect their rights on intellectual property. The desire for protection has increased because of the need for investment in R&D. Further, without investment in R&D, new drugs might not be tested and developed. The pharmaceutical industry, which is a competitive and a high-cost industry, depends on the success of R&D. It creates a certain bargaining power for the investor. So, without encouragement of IPR protection, R&D might not survive. However, R&D is essential for improved health. R&D in pharmaceuticals has made a significant contribution to prevention, cure, management of health care systems, and it increases quality of innovation on new medicines. Unfortunately, DLDGs are not in a situation where IPR and R&D have much priority.

Under TRIPS, while the patent system was seen as a credit given to a person who has invented something new and it is judged as an incentive to improve the quality of certain field of human life, the Members were given a certain autonomy in regulating their patent laws and were permitted to exclude pharmaceuticals as a subject matter of patents as it measure necessary to protect public health. The Members can provide limited exceptions to the patents by issuing compulsory licensing and parallel importation of patented products. This is supposed to benefit DLDGs.

The Preamble of TRIPS acknowledges the concern of DLDGs and their need for special treatment. It has recognized the particular needs of these countries in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a reliable and feasible technological base. These countries should be able to use flexibility in TRIPS provisions to protect their public health. This flexibility can be read which is covered in Article 31. However, because of the

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1 Fitzpatrick, Rem, Loc. Cit.
5 Id.
6 Ibid., p20
7 Article 8 (1) of TRIPS
8 Article 31 of TRIPS
9 The TRIPS Agreement, Preamble, para 6
there are insufficient manufacturing capacities in the pharmaceutical sector in most LDCs or there is no domestic manufacturer in these countries capable of handling a compulsory licensing granted by the Article, 12 the flexibility of the use of patents without authorization in the Article is ineffective.

Further, globalisation increases income and wealth in areas with high capital ownership while impoverishing societies with little capital. Every so often economic development grows faster than the policy or laws drawn up by government. This economic pressure with its interest in profit can override the interest of fairness, 13 which is the concern of polical-making.

The economic and political condition of LDCs means they are treated unequally by TRIPS. The economic differences between developed and LDCs places pressure on LDCs. Political pressure comes from developed countries, which pharmaceutical companies are mostly based in. Though TRIPS allows the Members to exclude pharmaceuticals from patentability inventions, 'this pressure prevents LDCs from regulating what is legal under TRIPS.

A solution to the problem of fairness in TRIPS competition policy is beyond LDCs capacity. So long as their economic and political situations are unstable, they will be unable to compete with developed countries as the patent systems work against them developing their own industries. France, Germany, Japan, Switzerland, Italy and Sweden introduced patents only after development of their own industry. Before TRIPS, some developing countries such as India, Brazil, and Mexico tried to develop industry by acquiring basic technology through reverse engineering, and then patenting products. However, TRIPS will automatically prevent such development and the growing pharmaceutical industry in developing countries is likely to collapse. Therefore, some changes in TRIPS provisions, clearer interpretation of TRIPS, support of legal technical assistance, and technical cooperation, 14 which includes policy analysis and development from WTO, governments (developed countries), are urgently needed. It is essential to make changes to balance values of fairness and efficiency in IPR protection of TRIPS.

III. The Doha Declaration on the TRIPS Agreement and Public Health

Since the Ministerial Conference of WTO adopted the Declaration on the TRIPS Agreement and Public Health on 14 November 2001 in Doha (Doha Declaration), there is a greater chance of fairness in TRIPS for LDCs. The declaration addressed a number of significant points concerning on the public health problems in LDCs and the need to postpone implementation of TRIPS in those countries to facilitate flexibility of TRIPS on access to medicine.

Since the majority of WTO Members are developing countries, the WTO has received

13 Mehtan, Om, Mendes, Erol, and Sading, Robert, Towards a Fair Global Labour Market: Avoiding a New Slave Trade (Routledge, 1999), p19
14 Zaif, Edward L, Political Economy of Fairness (The MIT Press Cambridge, Massachusetts, 1999), p5
15 Ibid, p79-81
16 Article 27 (2) of TRIPS
17 Obada, Eva, Loc. Cit
18 The WTO, Ministerial Declaration (Adopted 14 November 2001), p4
19 Mehtan, Om, Mendes, Erol, and Sading, Robert, Op. Cit., p124
The declaration was responding to a deadline proposal by a group of developing countries to both the WTO and the European Union. The proposal recognized the problem of TRIPS and proposed a waiver from the obligations of the treaty. However, the African Group, represented by South Africa, argued that the waiver would not be sufficient and that a more comprehensive approach was needed. The declaration further emphasized the need for a more equitable and balanced trade framework.

The WTO Members’ Declaration on the Waiver for Medicines (21 September 2001)
up a deadline for the end of 2002 for proposal
reaching to the declaration.

IV. Analysis of Proposal Regarding Com-
~.mpliance Licensing and Parallel Importing

1. The United States Model
a. Background Paper or IPR and Health.
In the United States Trade Re-
presentative (USTR) background paper on
IPR and health issued on 10 November
2001, the U.S. is aiming of flexible
measures on TRIPS. It extends the period
for DLDCs to fulfill their patent obligations
to the U.S. under TRIPS until 2016. It pro-
poses five year suspension of obligations
for sub-Saharan African developing
countries that are facing a problem with
HIV/AIDS and other health crises. 3
The question is: does it solve the
problem of implementing TRIPS? 
Responding to the U.S. proposal, there are
certain issues that might be taken into
consideration. It merely leaves the DLDCs
from enormous risks of legal action taken
by the U.S. and other developed countries,
and owners of pharmaceutical compa-
nies. 4 This extension does not deal with
the root of the problem faced by DLDCs
in enforcing TRIPS. However, the
extension is useful because it gives more
time to DLDCs to set strategies to manage
their weaknesses to enforce an IPR regime
under TRIPS. Thus, until this date, DLDCs
might legally manufacture generic (not
produce under a patent) pharmaceuticals,
and export them to countries which are
Members, where these drugs are not
patented or to Members which have
issued a compulsory license for certain
pharmaceuticals.

The U.S. paper also recognizes an
obligation of developed countries to give
incentives for its private sector and
institutions to promote and encourage
technology transfer to DLDCs. 5 It has not
been enforced in practice since TRIPS
was established. To guarantee enforcement, it
is urgent for the Doha Ministerial to create
a monitoring mechanism and to implement
the obligation, to assist DLDCs in the
transfer of new technologies to
developed countries.

b. Proposal for Emergency Compulsory
Drug Licensing
On 24 June 2001, the U.S. proposed a
way to make effective Article 31 of TRIPS
on compulsory licensing. It offers the
use of compulsory licensing for domestic
pharmaceutical suppliers during a health
emergency when the products are not
available in the domestic market. 6 The
purpose of this proposal is to strengthen
the performance of compulsory licensing
and parallel importing practices.
Therefore, with regards to compulsory
licensing, a government may give
permission to a third party to provide a
patented product without consent from a

Drugs and Developing Worlds, The Role of Patents in the Access to Medicines, Fordham Intellectual
Property, Media & Entertainment Law Journal (2002), 12, 67, 012
4 In spite of this, the delay, which also affirmed by the Council for TRIPS (the TRIPS Council) as the WTO,
has brought concerns to developing and least-developed countries to prepare itself to implement TRIPS.
5 Nielsen, June, Pharmaceutical Patents and Developing Countries: the Conundrum of Access and Incentives.
6 European Intellectual Property Journal (2001), 13, 540
7 Article 66 para 2 of TRIPS
8 The USTR, U.S. Antitrust Framework to Improve Access to Drugs to Fight HIV/AIDS and other Public
Health Crises (24 June 2002).
http://usinfo.state.gov/leipical/econ/wor/02062403.htm (Accessed on 28/10/02)

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patent holder. In parallel, imposing an authorized patented product may be imported into a country without permission of the patent holder.

DDLCs meet both capital and cultural barriers in their efforts to enforce TRIPS in general to ease restrictions on the manufacture of pharmaceuticals. The countries have limited funds because of a severe economic crisis that has lasted for the past five years. Moreover, the cultural problem appears when in fact IPR has not been yet recognized broadly within the country as important as other basic needs such as food, shelter, clothing, health care, and education.

Another problem in implementing compulsory licensing arises. A court order in a particular country is required to approve the license. The approval is needed to decide the time period of compulsory licensing. This can lead to a problem of difference of legal system and a court jurisdiction. There should be an understanding and cooperation between the WTO and the judiciary authority among countries.

Another issue regarding the proposal is that the U.S. might apply the proposed compulsory licensing as a measurement to remedy anti-competitive practice. This practice can prevent patent owners and other holders of IPR from abusing IPR, unreasonably restraining trade, or hampering the international transfer of technology (in aridest case).

2. The European Communities Model

The EC issued a paper responding to the Doha Declaration on the TRIPS Agreement and Public Health on 1 March 2002. The paper focuses on the problem of making effective use of compulsory licensing while there is no domestic manufacturer in DDLCs.

In regards to a compulsory license, the paper argues that DDLCs cannot grant compulsory licensing to a foreign manufacturer, because patents laws in two countries are independent of each other. However, DDLCs might grant the license to import a patented product from other countries. But, there is no guarantee that sufficient supply will be accessible.

Under Articles 31 to 31 (f) of TRIPS a compulsory license should be made only for the supply of a domestic market. From the patents perspective, problem would be more complicated if there is insufficient patent protection for pharmaceuticals in DDLCs. According to the EC paper, Article 31 (f) merely gives flexibility to DDLCs and it needs to be amended.

Article 30 of TRIPS regulates exceptions to the supply of products by compulsory license. However, presenting what is excepted is unclear. There is unclear meaning of exception in this article. It should be made clearer and a careful interpretation presented. This is important in order to create limited agric basi devel coun coun halar natur oven in ov solv reta to it

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2. The Department of Foreign Affairs & Trade (DFA) Australia, The Implementation of TRIPS in Australia (2009), 19
4. The WTO, TRIPS and Pharmaceutical Patent (April 2001)

26 MIMBAR HUKUM
exception only for certain countries, which are facing public health crises. Failure to clarify exceptions could undermine industry support on pharmaceuticals and could damage protection of IPR system as a whole arranged by TRIPS.

Notably, the E.C. paper goes beyond the U.S. proposal in anticipating procedural difficulties in the TRIPS Council. It highlights the importance of TRIPS interpretation, and proposes amendments to certain articles in TRIPS that require full compliance with other relevant provision of TRIPS in order to avoid inconsistence on TRIPS procedure.

V. Analysis of the Model Implementation and Possible Problem Solving of Creating Greater Fairness of TRIPS for DLDcs

Some DLDcs are recognised as agricultural countries or nature, resources-based countries. They are very different to developed countries that are industrial-based countries or further, "knowledge-based" countries. This gap becomes a problem in balancing the needs between the two distinct natures of the countries.

TRIPS might create its own system for overcoming the problem of implementation. In other words, there should be problem-solving arrangement in TRIPS that is able to resolve the problems particularly with respect to its enforcement on DLDcs. By making compulsory licensing and parallel importing effective and by creating monitoring measures of its practice, TRIPS can help countries to get affordable medicine. By allowing parallel importing, it might prevent 'piracy' of patented pharmaceuticals, while the patent holder is enabled to control their product distribution. However, some articles of TRIPS should be changed to take into account recent conditions of DLDcs.

To begin with, quality of life is still insufficient and it is necessary to improve it in DLDcs. Next, in the area of manufacture it is necessary to make an agreement to develop "manufacturing capacity" of pharmaceuticals in a country. When compulsory licensing and parallel importing are allowed for particular conditions in a country, a manufactures will be able to provide medicines to the signatory countries of an agreement. This is one way to solve the problem of a deficiency of a pharmaceutical manufacturing facility in a country.

Other solutions include balancing the protection of intellectual property, which serves the needs of the IPR holder, with the need for affordable-priced drugs for DLDcs. This problem might be solved by using the patent principle that requires full disclosure of one invention to the public, and enable other people to study the invention.

Furthermore, developed countries might give incentive for R&D into of diseases and

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4 (Had, para 29 (See Article 30 and 27 para 1 of TRIPS))
5 The WIPO, Vision and Strategic Direction of WIPO (Endorsed in Geneva 29-29 September 1999)
6 Rothem, Warwick, Parallel Imports (Sweet & Maxwell, 1991), p471-3
7 Reves, John, "Trade-Related Aspects of Intellectual Property Rights in Industrial and Intellectual Property Materials (Faculty of Law, University of New South Wales, 2006), p11
8 The DFAT Australia, "TRIPS and Public Health", TRIPS Update (3 April 2002)
9 The WTO, Technical Assistance and Capacity Building (8 October 2002)
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12 The Zambian Declaration, Integrated Framework for Trade Related Technical Assistance to Least-Devel-
14 Loughlin, Patricia, Intellectual Property: Creative and Marketing Rights (LRC Information Services, 1998), p141

MIMBAR HUKUM

27
technology transfer to DLDCs. Finally, it is important to ensure harmonization of differences among countries. Harmonization means the coordination of economic policy actions and measures in order to lessen international differences in such actions, not necessarily uniformity of system. Such harmonization will lead to greater democracy, justice, and fairness in international law. In this case, understanding and awareness are needed to create harmonization in international scope.

VI. Recommendations

Based on the above analysis, several recommendations can be made with the purpose of creating greater fairness in TRIPS implementation:

The Doha Ministers should adopt the U.S. model for raising TRIPS in its relation to DLDCs and should adopt the C.E. model in its proposal concerning amendment of Article 31 (c) of TRIPS to make TRIPS effectively useful for DLDCs;

The developed countries should adopt the U.S. model and apply the minimum standard only that TRIPS recommends in situations where DLDCs have a health crisis;

The TRIPS Council should provide clarity of interpretation of TRIPS in a way that supports public health, access to medicines, and gives incentives to R&D interested in new medicines, by providing uniform interpretations especially to determine the exceptions provided by Article 31 of TRIPS. It is important also to ensure that exceptions only apply to countries which have public health crises. The safeguards are sufficient to protect the rights of the patent holder from frivolous conduct or unfair commercial use of patents related to public health crises.

The WTO should manage more effectively the peaceful IP dispute settlement system in pharmaceutical patents;

International organizations such as the WTO and the World Intellectual Property Rights (WIPO), should cooperate to facilitate agreement between them in regards to promoting protection of IP in Members countries and to give supporting assistance to DLDCs to make TRIPS useful in practice and a study should be conducted by the World Health Organization (WHO) on policy-making related to international trade and public health.

VII. Conclusion

From the perspective of DLDCs, TRIPS, which set up the principles of IP in unfair, is}

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3. Ibid., p127.
8. The Agreement between the WIPO and the WTO (21 June 2003, 22 November 1995)
seems that international trade practice brings advantages to the world as a whole, but not automatically provide equal benefit to each country involved in the practice (especially DLDGs). TRIPS protects the rights of producers of intellectual property, but many DLDGs are not in a position to engage with R&D to produce new inventions. Therefore they cannot benefit from these provisions, and in fact, the provisions work against DLDGs developing a domestic industry. It is not solely IPR that disseminates against DLDGs. Several provisions on TRIPS are unsuitable for conditions in these countries resulting in TRIPS being ineffective. If TRIPS is enforced without the attendance of Article 31(0), it becomes inapplicable for DLDGs. It is a challenge for WTO to gather all possible solutions by the end of 2002. However, this attempt to find a solution is very difficult.

In summary, regarding these facts, it is important for countries and WTO to create greater fairness in TRIPS. Delaying the implementation of TRIPS for DLDGs is only temporary. TRIPS should not adopt arguments that could be used by a powerful party to protect corporate profit regardless of the cost in human life. Therefore, appropriate approaches and mechanisms with the purpose of fulfilling the basic purpose of patents, which is to ensure society, continue making innovation in technology, and with the purpose of ensuring fairness of IPR implementation in international trade practices, should be formulated.

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