NEUTRALIZING DISPUTES RAISED BY THE USA ON PROTECTION OF PHARMACEUTICAL INVENTIONS DURING TPP NEGOTIATIONS

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Abstract:

This paper deals with disputes on protection of pharmaceutical inventions between the nations participating in the negotiations of Trans-Pacific Strategic Economic Partnership Agreement (referred afterwards as TPP). The case study is related to a traditional receipt of which would show clearly the differences in legal regulations of protection of inventions among certain nations. At the same time, the paper presents the studies of proposals made by the US during the TPP negotiations in connection to pharmaceutical inventions. The paper proposes a consensus solution for the raised disputes on basis of studies made for TRIPS Agreement, comparison of UD proposals with the stipulations of human rights, Doha Declaration on TRIPS Agreement and Health of Communities 2001 and the International Convention 1966 on Economic, Social and Cultural Rights.

Keywords: *Intellectual property; TPP Agreement; TRIPS Agreement; Doha Declaration.*

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1. Introduction

The TPP negotiations are the rounds of multi-lateral free trade negotiations which target the integrations of the economies in the Asia-Pacific region. Up to now, there are 12 nations participating in the negotiations including Brunei, Chile, New Zealand, Singapore, US, Australia, Peru, Vietnam, Malaysia, Mexico, Canada and Japan.

1.1. November 2008, Vietnam participated in the TPP negotiations as associate member. November 2010 Vietnam participated in the TPP negotiations as full member.

1.2. Initial targets of TPP was to reduce 90% of all the import-export taxes among country-members before 1st January 2006 and then to cut down to 0% by 2015. One of studies made public in June 2013 shows that the total import-export volume of commodities and services among and the concerned TPP members is as follows.

Table 1. Total import-export volume between Vietnam and TPP members

No.	Export to		Import from	
	Nations	**USD million**	**Nations**	**USD million**
1	US	19,426.90	US	5,085.74
2	Japan	13,726.90	Japan	11,802.10
3	Malaysia	4,739.96	Malaysia	4,209.76
4	Australia	3,261.76	Australia	2,034.56
5	Singapore	2,044.94	Singapore	11,421.20
6	Canada	1,618.06	Canada	407.29
7	New Zealand	239.45	New Zealand	405.27
8	Mexico	1,153.99	Mexico	84.10
9	Chile	186.78	Chile	408.32
10	Peru	113.30	Peru	93.71
11	Brunei	16.01	Brunei	197.23

Source: Collected from studies by Brock R. Williams [12]

In order to have backgrounds for assessment of the Vietnam position among TPP members, we make references in Table 2.

Table 2. Total import-export volume between the US and TPP members

No.	Export to		Import from	
	Nations	**USD million**	**Nations**	**USD million**
1	Canada	291,758.00	Canada	328,719.00
2	Mexico	216,331.00	Mexico	280,025.00
3	Japan	70,046.50	Japan	150,401.00
4	Australia	31,208.30	Australia	9,851.60
5	Singapore	30,560.70	Singapore	20,455.10
6	Chile	18,885.80	Chile	10,096.50
7	Malaysia	12,854.30	Malaysia	26,652.00
8	Peru	9,357.40	Peru	6,679.90
9	Vietnam	5,085.74	Vietnam	19,426.90
10	New Zealand	3,223.30	New Zealand	3,623.50
11	Brunei	157.20	Brunei	89.00

Source: Collected from studies by Brock R. Williams [12]

Table 1 shows that the US is the biggest trade partner of Vietnam which has the biggest trade surplus of import from Vietnam among TPP members. In

addition, Singapore is also a big trade partner of Vietnam but from the other extremity where Vietnam has a huge trade surplus of import from Singapore (5.6/1 rate).

Table 2 shows that in terms of the benefits earned by the US through exports, Vietnam in 9th ranked. It is clear that merely from economic point of view in trade relations probably Vietnam is not the top priority target for the US. The information provided in Point 1.4 under here shows additionally the disadvantageous position of Vietnam facing the US in the TPP negotiations.

On basis of targets to cut the import-export tax rate "*down to 0% by 2015*", we can see that in the international trade relations the economic benefits belong to the partner who holds the export surplus. Therefore, the neutralization of Intellectual Property (IP) - related disputes with the US during the TPP negotiations is very important from stand of economic benefits.

1.3. TPP is a global agreement which covers all the aspects of a free trade agreement. It includes the trade of commodities, services and investments, public purchases, State-owned enterprises, commerce and labors, commerce and environment, e-commerce, IP and etc.

The TPP Agreement has the IP-related regulations stipulated in Chapter 10 where Article 10.1 provides the definition of the "IP" term. This term is interpreted according the regulations of *(Agreement on Trade-Related Aspects of Intellectual Property Rights, referred afterwards as TRIPS)*. TRIPS is one of the important agreement of WTO. Therefore, IP, in interpretations by TPP, is identical to the interpretation by WTO which includes Copyrights and Neighboring rights, inventions, industrial designs, IC arrangement, marks, geographical indications and etc.

In terms of principles of IP protection, Article 10.2.1 of TPP Agreement notes clearly that the parties acknowledge the importance of IP rights for promotion of socio-economic development, particularly for new digital economy, technological innovations and trade. Article 10.2.2 emphasizes also "the Parties recognize the need to achieve a balance between the rights of right holders and the legitimate interests of users and the community with regard to protected subject matter"[1].

Article 10.2.2 is an important regulation, as a matter of principle, which is noted in TPP Agreement. However, due to different levels of socio-

[1] Article 10.2.2. of Trans-Pacific Strategic Economic Partnership Agreement. Intellectual Property Principles: *The Parties recognise the need to achieve a balance between the rights of right holders and the legitimate interests of users and the community with regard to protected subject matter.*

economic development of the country-members, some disagreements occurred during the negotiations. For example, Article 10.3.4 of TPP Agreement mentions two international documents for IP rights, namely: *World Intellectual Property Organization Copyright Treaty*, referred afterwards as WCT, and *World Intellectual Property Organization Performances and Phonograms Treaty*, referred afterwards as WPPT. Up to now, Vietnam does not participate in these international treaties.

1.4. Information for attention: on 07th February 2014, Office of the United States Trade Representative (abbreviated afterwards as USTR) announces that Vietnam is in the list of the world's top nations to violate IP rights[2]. It is a disadvantage for Vietnam during the TPP negotiations in terms of IP related subjects.

1.5. Scope of studies

The IP related problems which are under interests by TPP negotiations include: extension of protection terms for copyrights and neighboring rights, protection of pharmaceutical inventions, protection of test data of pharmaceutical products and chemico-agriculture products, enforcement of IP rights (particularly in digital environments), criminal sanctions and administrative sanctions in enforcement of IP rights.

Due to limited format of presentation, this paper deals only with the protection of pharmaceutical inventions and the protection of test data of pharmaceutical products.

The term of "patent" is referred to the only meaning of the certificate of exclusive rights of inventions.

On basis of the above reasons, the following part of the paper is focused on the analysis for: (1) Differences of particular attention in regulations towards inventions of the US and Vietnam; (2) Proposals by the US for pharmaceutical inventions; and (3) Proposals of disputes neutralizing solutions.

2. Differences of particular attention in regulations towards inventions of the US and Vietnam

Here the paper takes the case of a traditional receipt[3] for illustration purpose. This topic is a strong point of Vietnam but not the one of the US in the field of pharmaceutical products.

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[2] According to *Special 301 Report 07.02.2014 by USTR*, the Priority Watch List of IPR violations includes 9 nations, namely Argentina, Chile, China, Costa Rica, India, Indonesia, Russia, Thailand and Vietnam. In fact, it is the list of the world's top ranked nations to violate IP rights and it is the first time Vietnam is in this list.

[3] The term of "traditional receipt" is referred to [13, p.7-15].

Article 102 of the US Patent Act stipulates the conditions of patentability including novelty and loss of right to patent. It notes: A person shall be entitled to a patent unless: (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country. The words "in this country" in the text are interpreted as "in the US"[4].

Therefore, the most attention in this regulation shows that the invention would not deem to lose the novelty when it is used, known (without being described in any publication) abroad. Correa Carlos M. had noted it in one of his studies: if a traditional receipt was used publicly without being described in a publication abroad, it is not considered as to lose the novelty and remains patentable by the US Invention Authority [8, p. 56].

This regulation is beneficial to the US since majority of traditional receipts largely used in the community of developing countries are not yet described in a publication remains still patentable by the US Authority. (Note that the principle of "being formed" is seen as the most important principle in protection of copyrights). As evidence, US Patent No. 4178372 can be taken for illustration purpose. It is anti-allergic medicament made from Aloe plants. US Patent No. 4725438 is an ointment taken from the same plant. US Patent No. 4696819 is made on basis of extraction from coca leaves [13].

This is the US regulations but in practice, the United States Patent and Trademark Office (USPTO) made errors. For example, on 31st July 2002, USPTO had granted Patent US 2003/0152651 A1 Herbal composition for angina pectoris, method to prepare same to the co-authors Xijun Yan, Naifeng Wu, Zhixin Guo, Zhengliang Ye and Yan Liu. But, in fact, this invention lost the novelty and then naturally is not patentable. The causes are:

- The invention was noted in the receipt of "Gia vi ich tam thang" (which can be translated as "Good Spice for Heart") in the book *Thien gia dieu phuong* (which can be translated as Miracle Receipts from Heaven Family). The book was published in 1989 by Institute of Information, Central Institute of Medical Research of Vietnam;

[4] United States Patent Act, Chapter 35 of the U.S. Code § 102 - Conditions for patentability; novelty and loss of right to patent: *A person shall be entitled to a patent unless: (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country.*

- The invention was noted also in the receipt of "Phuc phuong dan sam phien" (which can be translated "Lucky extraction as if made from ginseng") in the book *Nhung bai thuoc Y hoc co truyen Trung Hoa* (which can be translated as Chinese Traditional Receipts) published by Hanoi Medical Publishing House in 1995.

This turns out to be a disadvantage for Vietnam. In fact, assuming that a Vietnam enterprise export to the US market the medicine Gia vi ich tam thang as noted in the book *Thien gia dieu phương* published in 1989 by Institute of Information, Central Institute of Medical Research of Vietnam, surely they would get the objections and claims for damages from the holder of Patent US 2003/0152651 A1 and be treated by the US Authority;

The above noted case occurs not only in connection to inventions between Vietnam and the US. Another case to be referenced is related to India (this country does not participate in the TPP negotiations) and it serves to show that the US legal regulations for inventions are always interpreted for their advantages.

In 1982, Indian scientists produces some reports recorded in publications, national and international workshops on the diversified pharmacological effects of the neem plant (*Azadirachta indica*). They identified more than 140 pharmaceutical components which are extracted from the neem plant, including effects against inflammations, ulcers, mycosis, microbes, viruses, oxidization and, particularly anti-cancer agents [7, p. 82]. But statistic figures show that in 2011, the US Authority granted 54 patents which are related to the neem derivative traditional receipt[5].

Another case, also related to India, is the diverse curing effects of Curcuma tubers which are known well by Indians from long centuries ago. Nevertheless, on 18 March 1995, USPTO had granted Patent US 5.401.504A which is related to Curcuma tubers to two co-authors Harihar Cohly and Suman K. Das. Council for Scientific and Industrial Research (CSIR), New Delhi, on behalf of the Indian Government, expressed the objections to the decision of USPTO. CSIR made the reference to filed documents and proved that Patent US 5.401.504A does not possess the novelty and the creativity. Then, on 13th August 1997, USPTO had made the decision to cancel Patent US5.401.504A.

Probably these details should be kept in mind during the TPP negotiations.

[5] For more information, see *Total Patents on Neem* of the document [10, p.80].

3. Proposals made by the US in connection to pharmaceutical inventions

During the negotiation process, the US announced their proposals related to pharmaceutical inventions. Among them, the document [5] made public by USTR in November 2013 attracts special attentions. There are so many controversial points in this announcement. Due to the format of presentation, only two points are presented here for notes.

3.1. Rights to produce generic drugs

Generic drugs are medicaments biologically equivalent to specific medicaments in terms of pharmacodynamics. They can be produced largely when the Industrial Property term applied to them expires. Pharmaceutical companies of developing countries, since being financially limited, usually use this regulation to produce generic medicaments.

As measures to prevent the production of generic medicaments, patent holders of the inventions (called original inventions), when it comes to their expiration date, adds new effects and specifications (called subordinate inventions) to make a new invention. The PTT members need to issue the regulations to protect new inventions including the original and secondary ones.

There is also another way to get the protection. The holder of a patent granted by a country, after certain time, would look for chances to file the invention for protection in another TPP country. If it gets successful, the new cycle of protection starts in this new country.

Regarding the proposals made by the US, on basis of conceptual considerations, it is not found possible to extend the protection term for original inventions equal to the one applied for subordinate inventions (if proved that subordinate inventions possess the novelty, creativity and industrial applicability).

The Vietnamese laws do not have concrete regulations towards this. Article 137, however, of the Vietnamese Law of Intellectual Property stipulates: *"Duties to permit to use original inventions for purpose of use of subordinate inventions: (1) Subordinate inventions are those inventions which are created on basis of another inventions (called afterwards as original inventions) and which can be used in conditions that the original inventions have to be used; (2) In case, if the subordinate inventions get proved to create important technical advances in comparison to original inventions and to possess high economic significance, the holder of subordinate inventions are entitled to require the transfer of the rights to use the original invention with reasonable price and commercial terms and conditions"*.

The words *"to create important technical advances in comparison to original inventions"* are so ambiguous because it is very difficult to interpret "important technical advances".

More than that, Article 13 of the Vietnamese Law of Intellectual Property does not mean the acceptance of the US proposals.

3.2. Extension of protection term for test data of biologic medical products

First of all, it is necessary to learn why the US paid particular attentions to biologic medical products which can be understood as biological products such as vaccines, blood and blood components, allergic agents, somatic cells, genetic therapies, tissues, re-combinant proteins or living cells which can be used for therapeutic purpose [4]. Here, biological medicaments are created by biological processes but not by chemical synthesis way.

The US does not make know the conceptual backgrounds for extension of protection term of test data of biologic medical products. The practical backgrounds the US use to justify this proposal is the huge financial investment made to develop the biologic medical products. Then, the investors should get the longer protection term than the one for conventional drugs to cover the costs of research and demonstration of safety of biologic medical products to human health.

It is necessary to note, however, that the US proposals may cause social welfare concerns of developing countries. In case this proposal gets accepted the price of the products will get high and the access of people to the pharmaceutical products will be difficult.

Actually, some TPP members do not have specific regulations towards protection of test data of biologic medical products. Some of them grant from 5 to 8 years for the protection of test data. The US proposed the 5 year term for protection of conventional drugs and the 12 year term for biologic medical products.

The US proposal gets into conflict with the Vietnamese IP regulations. The Vietnamese IP regulations do not any differences in terms of protection of test data of biologic medical products, but take them equal to other conventional drugs. Article 128 of Law of Intellectual Property stipulates: *"Duties to keep the test data confidential. (1) In case the laws define that the applicants for license of business or commerce of pharmaceutical products need to provide test results or any other data which are business secrets obtained from considerable investments, and the applicants require to keep this information confidential, the licensing authority agencies have duties to conduct necessary measures to prevent these data from being used*

for unhealthy commercial purposes and being disclosed, except the ones needed for protection of people, (2) the 5 year protection term is applied since the date the application is submitted to the authority agencies…"

The words *"except the ones needed for protection of people"* noted in Article 128.1 of the Vietnamese Law of Intellectual Property are not mentioned in the US proposals.

4. Neutralization of disputes

As it is noted in Point 1.4, Special Report No. 301 made public in February 2014 is a big hinder for Vietnam during the TPP negotiations in connection to IP rights.

4.1. Differences in regulations towards inventions between the US and Vietnam

As noted, the regulations stipulated in Article 102, the US Patent Act are interpreted for their advantages. Then, what is to do to limit the application of these regulations by the US?

As it is known, the crucial importance to make inventions lose their novelty is to show that the concerned inventions were described in written documents. Therefore, it is necessary to show the written descriptions of the Vietnamese traditional receipts if we want prevent them from "exclusive rights". This solution is accepted by the legal regulation of the nations on basis of respect of the "being formed" principle required for the protection of copyrights.

The Indian cases can be taken as references where they raise, sometime successfully, the objections to the developed countries to have granted patents to certain Indian traditional receipts. By June 2011, India completed successfully the Traditional Knowledge Digital Library with more than 34 million pages of information for more than 2,260,000 traditional receipts in various languages including Sanskrit, Persian, Urdu and Tamil. The Traditional Knowledge Digital Library had been translated into other languages such as English, French, German, Japanese and Spanish [11, p. 91].

All individuals/organization are entitles to the rights to request the cancelling of patents granted to traditional receipts which were described in written documents. In our case, the Vietnamese Association of Oriental Medicine should be the representative institution of traditional receipts, according to Point 2, Article 6, Charter of Vietnamese Association of Oriental Medicine. The latter had been approved by the Minister for Home Affairs in Decision No. 162/QD-BNV dated 21st February 2011.

Nevertheless, in practice, on behalf of national interests, it happens that patents may be granted to certain traditional receipts, even, occasionally, they do not meet requirements to be patentable.

Now let come back to section 2 of this paper. We see that USPTO had granted Patent US 2003/0152651 A1 after the invention related information had been documented in Vietnam. But up to now, there is individuals/organizations of Vietnam require the cancelling of this patent, then the patent still keeps the legal validity.

4.2. Comments on the US proposals on pharmaceutical inventions

This is the most controversial point in the TPP negotiation. In this paper, the author suggests some references which may be capable to neutralize the US proposals towards pharmaceutical inventions.

Here we cannot only to argue that the developed countries have duties to favor people in developing countries in rights of access to medicaments. Take notes for the analysis in Section 1 of this paper which shows that TPP is a "fair play yard" from point of view of economic benefits. The US is the biggest trade partner of Vietnam among the TPP members. The data in the studies by Brock R. Williams (2013) show well that Vietnam experiences a very big export surplus to the US. Therefore, it is needed to provide legal arguments during the TPP negotiations.

4.2.1. Rights of access to medicaments - human right approach

The proposals raised in this section are based on backgrounds that both the US and Vietnam are members to WTO. Even the TPP requirements are found tougher than the ones of WTO, but some arguments from WTO can be used for the TPP negotiations. Among them, the most attention is reserved for the fact that TPP defines the IP rights according to TRIPS (one of the three components of WTO).

The studies by Holger Hestermeyer [9] note clearly that the rights of access to medicament are interpreted as the one of human rights. Here some proposals attract attentions, namely:

- 5 models to use out-WTO laws to address the disputes related to the rights of access to medicaments;
- Rights of access are interpreted as *jus cogens*[6] in the process of addressing the disputes.

[6] *jus cogens* is judiciary term which can be interpreted as international order or normative of compulsory respect nature. *Jus cogens* is subject to be replaced only by other normative of the same nature, as it is defined by Article 53, Vienna Convention 1969 on the Law of Treaties.

If it is argued that the human rights can be used only to address the related agreements, then a WTO member cannot rely on these rights for self-justification when it gets claims of having violated WTO regulations, since the basis for justification is not regulated in the related agreements. But the things change when the human rights come up to the *jus cogens* status.

It is necessary to discuss further, if the rights of access to medicament come up to the jus cogens status. Here, if the human rights have the values higher than economic benefits, particularly when the life of peoples in developing countries, if there is no medicaments, are under threats [9, p. 248], then the rights of access to medicament arrive to the *jus cogens* status.

4.2.2. Rights of access to medicament - as seen from TRIPS Agreement

The proposals raised in this section are based on the fact that the US is member to ATO, then they have duties to follow the regulations of TRIPS Agreement.

The rights of access to medicament stipulated in TRIPS Agreement can be used also, namely:

Article 27 stipulates: *"Members can refuse the granting of patents to the inventions, the exploitation of which is banned for commercial purpose, in their territories to protect public order or social morals, and, even, the life and the health of human, animals and plants, or to prevent serious environmental impacts, in conditions that these exceptions are regulated not because of the only reason that the exploitation of those inventions is banned by the laws of these countries".*

Article 31 stipulates that the Government of a country is entitled to grant the Compulsory Licensing in necessary cases for protection of health of people, namely: *"The case when the laws of a country-member regulate the licensing of patents under other forms when not permitted by the right holder".*

4.2.3. Rights of access to medicament - as seen from Doha Declaration

Doha Declaration on the TRIPS Agreement and Public Health, November 2001, notes clearly: *"We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics"*[7].

[7] Doha Declaration: *"We recognize the gravity of the public health problems afflicting many developing and leastdeveloped countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".*

At the same time, Doha Declaration confirms also *"We stress the need for the WTO Agreement on TRIPS Agreement to be part of the wider national and international action to address these problems"*[8].

Therefore, Doha Declaration is a legal background for protection of the rights of access to medicaments of people, particularly for people in developing or least developed countries. It is possible to use this Declaration during the negotiations with the US to neutralize their proposals related to pharmaceutical products. These proposals are seen as to put economic benefits of pharmaceutical companies higher than the health of the community (which is part of the human rights).

4.2.4. Rights of access to medicaments - as seen from International Covenant on Economic, Social and Cultural Rights

International Covenant on Economic, Social and Cultural Rights was approved by the UN Assembly on 16th December 1966 and got valid since 3rd November 1976. Some details of this Covenant can be used during the TPP negotiations. In fact, if the pharmaceutical products are considered as results of scientific research, then people have rights to access on basis of the regulation stipulated in Article 15.1.b of the Covenant, namely: *"…the right of everyone to enjoy the benefits of scientific progress and its application and the freedom to perform scientific research"*[9].

5. Conclusion

The paper does not suggest a solution "to address" the disputes in connection to IP rights between the TPP members but only a solution "to neutralize" them because, in final account of targets, TPP cannot put the community health higher than economic benefits. Therefore, developing countries cannot also emphasize the matter of community health during the TPP negotiations.

The paper would like to underline Article 10.2.2 of TPP Agreement signed on 3rd June 2005 by the 4 founding members Brunei, Chile, New Zealand and Singapore: *"The Parties recognize the need to achieve a balance between the rights of right holders and the legitimate interests of users and the community with regard to protected subject matter"*. But where is the balance between rights and legitimate interests? The answer is within the arts of negotiations./.

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[8] Doha Declaration: *"We stress the need for the WTO Agreement on TRIPS Agreement to be part of the wider national and international action to address these problems".*

[9] International Covenant on Economic, Social and Cultural Rights: 15.1.b: *"…the right of everyone to enjoy the benefits of scientific progress and its application and the freedom to perform scientific research".*

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