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REVISITING STATE OBLIGATION ON VIRUS SAMPLE SHARING; FROM COMMON HERITAGE OF MANKIND TO STATE'S SOVEREIGN RIGHT

Nurul Barizah*

ABSTRACT**

This paper examines the tradition of free international exchange of viruses developed by the World Health Organization (WHO) on the basis of protecting global health. This part also examines whether WHO Constitution provides an obligation to Member States to share pathogen materials, including virus for the purpose of preventing global public health emergency and the position of WHO Collaborating Centres to share virus and research data to private sector. Furthermore, it examines the provisions of International Health Regulation (IHR) to address the international spread of disease and whether there is an explicit obligation for Member States share physical samples of viruses.

This papersalso examines several international legal norms that regulates biological resources, in which the concept of free exchange of viruses may derived from. This part reviewsthe historical development of international law governing natural and biological resources. It derived from the concept of common heritage of mankind and public domain to sovereign right of state including the access to a fair and equitable benefit sharing from the use of resources. The most important part of this paper is that it examines whether virus fall within the scope of the Convention on Biological Diversity (CBD), including Cartagena Protocol on Biosafety and Nagoya Protocol.

Lastly, this paper discusses the whether there is state obligation under international human rights norms and international trade law, particularly from WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) on patent to share samples of virus. It covers the patentability of viruses and human body's cell as well as the reason why the notion of a fair and equitable benefit sharing under the CBD do not exist in this WTO Agreement.

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1. Introduction

In the era of trade on intellectual property,[1] biological material, including viruses are one of the most valuable international commodities. Although viruses have coexisted with humans throughout history,[2] the development of modern biotechnology made viruses as a property as the main ingredient of drugs and vaccines to cure certain types of diseases. However, international legal norms governing viruses are far from settled, particularly in the context of virus sample sharing. This particularly true when Indonesia rejected to share influenza virus to the WHO and because of that state's obligation of virus sample sharing should be revisited, not only to create legal certainty, but also fairness among states.

This paper examines the WHO's tradition of free international exchange of virus. It was probablyderived from the concept of common heritage and mankind applied to genetic resources under International Undertaking of Plant Genetic Resources for Food and Agriculture (IUPGRFA).[3] Then, it examines the concept of state's sovereign right under the CBD which can be used to govern biological resources including viruses. This paper also examines whether there is a state obligation to share samples of virus from the perspective of international human rights norms and international trade law of WTO-TRIPs Agreement[4] on patent.

2. WHO's Tradition; Free International Exchange of Virus

It is a tradition that international community has freely shared virus samples by sending specimens to the WHO and this practice of free international exchange of viruses have been

maintained by WHO more than five decades.[5]This tradition have developed by obtaining virus samples from countries where infected patients are located and distributing those samples to WHO's Collaborating Centers that worked on identifying appropriate vaccine candidates and drugs. However, international customary law that regulates virus sample sharing is weak because there is no legally bound (*opiniojuris*) which requires Statesto such sharing.[6] Furthermore, it would be unlikely that if States have participated in the WHO's Global Influenza Surveillance Network can be used as justification that States have a legal obligation to share samples of virus. This is becausethe Network has operated without reference to international law since its establishment in 1950s.[7]

In accordance with their terms of reference, the result of research and support of Collaborating Centers then made available to WHO. Interestingly, there was no prohibition for those Collaborating Centers to provide and share samples of virus and research data to private sector companies that develop medicines and vaccines.[8]As Fidler argues that such tradition and practice play a significant role in the support of global health.[9]

It is important to note that there is no international obligation under treaty or agreement for Members to follow such practice. The articles 64 and 65 of WHO Constitution respectively requires Members to "provide statistical and epidemiological reports in a manner to be determinated by the Health Assembly" and to ' transmit upon the request of the board such additional information pertaining to health as may be practicable'.[10]However, Abbott states that these provisions may be interpreted to allow the organs of WHO to instruct Member States to provide certain pathogen materials to the WHO.[11]

Furthermore, International Health Regulation (IHR)[12] provides authority to the Director-General of WHO to declare an international public health emergency and to made recommendation regarding the steps Member States should take to address the emergency. It is expected that Member States also implement those recommendations.[13] Under the IHR, Member States are obligated to provide information concerning conditions that may considered as emergencies to international public health.[14] It is also clear the IHR does not require specifically that a Member State share physical samples of biological material, althoughunder the general undertaking to protect against and provide a response to the international spread of disease, such requirement might be implicit.[15]

If the above interpretation can be justified for the sake to protect certain pandemic, it is important to note the IHR does not provide a detailed approach for handling such samples or to deal with issues in relation to the rights of third parties with respect to them. This unclear obligation leads to uncertainty of right and obligation of the Member States in the context of sharing virus. Because of that, prior to Indonesia's decision to reject the virus sharing, the WTO and its Member States recognized that the global system for creating and distributing vaccines to alleviate the impact of pandemic influenza is inadequate.[16] There was no clear restriction placed upon the uses of virus samples except for purpose of good research and clinical practice and nothing to prevent a private sector obtaining patent related to such biological material and its derivatives.[17]

3. Viruses; From Common Heritage of Mankind to State's Sovereign Right

The concept of "common heritage of mankind" (CHM) was firstly used to regulate genetic resources, and it enshrined under International Undertaking on Plant Genetic Resources for Food and Agriculture (IUPGRFA).[18] According to Brush, term 'common heritage' refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest.[19] The logical foundation of common heritage is in the nature of a crop's genetic resources, the universal processes of diffusion and dispersal, and historical practices of reciprocity. Crop's genetic resources derive originally from natural and amorphous processes or crop evolution; like mutation, natural selection, exchange, and decentralized selection, and because no person or group control crop evolution, it is inappropriate for anyone to claim authorship or ownership.[20]

This means that they were treated as a free good and everybody had the right to use them. Based on this principle, as stipulated under Article 5, States which had Plant Genetic Resources under their control expected 'to allow access to samples of such resources, and to permit their export, if the resources have been requested for the purpose of scientific research, plant breeding or genetic resources conservation'.[21] Such access will be made free of charge 'on the basis of mutually agreed terms' (MATs).[22]

Historically, this 'common heritage concept' of international law is based on the notion that humanity has a vital interest in certain natural resources and because of that the benefit and burdens related to the exploitation and preservation of such resources should be shared by all.[23] This concept has been applied to regulate 'area'[24] in accordance with the United Nations Convention of the Law of the

Sea (UNCLOS)[25] and outer space under international law. This principle then was in contrast to the 'common concern' and 'national sovereignty' or state controlled approach of the CBD.

Furthermore, the principle of 'common heritage' under the IUPGRFA can be regarded as providing an opportunity for developed countries to obtain easy access to the resources of developing countries, and then as a result of such access, the production of the result protected by intellectual property. Marin referred to Kloppenburg and Kleinman'sarguments, stated that:

> Germplasm flows from the South as the 'common heritage of mankind,' it returns as a commodity. Therefore, the value of PGRs is recognized as soon as it enters the markets. PGRs have undergone biotechnological processing, they are highly priced, while germplasm is taken for granted.[26]

This approach them regarded as unfair by a number of developing countries, because it facilitates the free movement of genetic resources from developing countries to developed countries. Then it was revisited under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which this free access principle was then limited by three resolutions[27] to achieve a more fair and equitable balance of the concerns of developed and developing countries. Even though like that, some argues that in practice they are still contradictory with each other.[28] Furthermore, Resolution 4/89 emphasizes that free access does not necessarily mean 'free of charge'.[29] Such an approach might be useful in developing an equitable sharing benefit scheme under the CBD.

The CBD[30] is a convention that is not directed toward establishing commercial private property interests and promoting trade policy. It is the first international treaty in environmental law

to deal with all aspects of biodiversity.[31] The CBD was negotiated under auspices of the United Nations Environment Program (UNEP) and drafted under the spirit of the Rio Earth Summit 1992. This CBD, however, suddenly has become a very prominent instrument in the discussion on virus sample sharing, since the rejection of Indonesia to share samples of influenza virus H5N1 around February 2007.

From an environmental law perspective, the CBD provides a comprehensive and holistic approach[32] of the three important goals; (1) the conservation of biological diversity; (2) the sustainable use of natural resources, and; (3) fair and equitable sharing from the use of genetic resources.[33] It also regarded as the first international agreement acknowledging the role and contribution of the indigenous and local community in the conservation and sustainable use of biodiversity.[34]

One of the most important questions is that whether virus falls within the meaning of "genetic resources" under the CBD. Indeed, the argument for this is technically complex from legal perspective.

The CBD defines "biological diversity" under its article 2, as follows:

> Biological diversity, means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystem.

In interpreting this article, Abbott states that viruses may also be part of the variability among living organisms within the definition of "biological diversity".[35] Viruses may also be included

within 'living organisms" because they replicate within host biological organisms.

Then, the CBD defined "biological resources" that includes "genetic resources, organism or part thereof, populations or any other biotic component of ecosystem with actual or potential use or value for humanity."[36]

Furthermore, the Article 15.1 of the CBD provides that "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and its subject to national legislation." This article is essential to the CBD, at least in two ways. Firstly, it recognizes that states have 'sovereign rights over their natural resources' in their territories.[37] However, the "natural resources" is not specifically defined in the CBD. "Natural resources" consists of the term "natural" that refers, *inter alia*, to "existing in or formed by nature; consisting of objects or materials of this kind; not artificially made or constructed.[38] While the term 'resources' refers to "a means of supplying a deficiency, a stock or reserve which can be drawn on when necessary.[39] Based on the above definition, it can be seen that term 'natural resources' is very broad.

Secondly, the national governments have the authority to determine access to genetic resources and this second clause of article 15 operationalizes the recognition of sovereign rights over natural resources with specific reference to "genetic resources". This "genetic resources" means "genetic material of actual or potential value".[40]While, 'genetic material' means "any material of plant, animal, microbial or other origin containing functional units of heredity."[41]

Therefore, virus may fall within the definition of 'biological diversity' and 'biological resources' as well as within the definition of 'genetic resources" under the CBD. However, there is no established authoritative interpretation regarding whether virus contains 'functional unit of heredity' within the meaning of "genetic material" under the CBD. Virus, as a part of pathogen materials contain heredity information and are capable of reproduction, but only within living host cells. Virus do not contain "functional units of heredity" if virus may not reproduce outside of a host organism, so the units of heredity might be considered 'non-functional."

It is acknowledged that there are two conflicting arguments for and against the inclusion of virus under the CBD. The argument in favor to include the virus falls within the CBD is based on the reason that the CBD was aimed to preserve biological diversity and would permit further research and development of biological resources that might be used to develop drugs to cure of disease.[42] The CBD was also intended to prevent bio-piracy and to provide an opportunity for developing countries to share in benefits from exploitation of biological resources. Viruses, can be used to develop drugs and vaccines for human and animal use, because of that it have value, including monetary value.

While those who against the inclusion of virus under the CBD stated otherwise, that virus do not have 'actual and potential use or value for humanity' as stipulated under article 2 of the CBD. Although virus represents a form of biodiversity, the main interest of science and public health is to remove dangerous viruses, and not preserve them. The term 'biological resources' implies that the subject materials have a "positive value" of their own, and not a "negative value" that can be turned positive only as a means of reversing themselves. Furthermore, philosophically, the CBD is a conservation-oriented agreement and because of that CBD did not

committed to protect biological materials that cause harm to human and should not have its objective to conserve inherently dangerous materials like virus.

However, it seems uneasy to exclude virus from the scope of CBD on the ground that CBD was negotiated to protect the interest of developing countries in a fair and equitable benefit sharing from ownership, preservation as well as the use of biodiversity, while during the time of negotiation, biological resources were well understood as a basis for development of drugs and vaccines.

The CBD, in its preamble "Reaffirm[s] that states have sovereign rights over their own biological resources". The CBD's principle also in its preamble as follows:

> State have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

From the above principle, it is important to note that the state's sovereign right to control biological resources including virus within its territory does not suggest an absolute right to control. Under international law, there is exception to the rights of states, for example, the human rights principles protect certain fundamental rights to individuals regardless of their nationality. In the above principle of article 3, CBD recognizes a balance of rights and responsibility of states.

If viruses are genetic resources within the meaning of CBD, the Article 15 of the CBC also applies to such viruses. This Article

requires Contracting Party to have endeavored to create condition for access based on mutually agreed terms (MAT),[43] and subject to prior informed consent (PIC).[44] This Article also requires that scientific research based on genetic resources conducted by Contracting Party shall carry out with the full participation of such Contracting Party.[45] Furthermore, legislative, administrative or policy measure shall be taken by Contracting Party though financial mechanism if necessary with the objective to achieve a fair and equitable sharing of benefit derived from the utilization of genetic resources.[46]

In addition, the CBD provides an international regulatory framework to reconcile the need for trade and environment protection under the Cartagena Protocol,[47] focusing on trans-boundary movement of living modified organisms resulting from the use of modern biotechnology that may have significant impact on human health and environment.[48] Under this Protocol, living organism is defined as "any biological entity capable of transferring or replicating genetic materials, including sterile organisms, viruses and viroids".[49] This definition, advocates that parties to the Protocol recognized the ambiguity inherent in the definition of genetic resources and required to clarify the scope of coverage of the Protocol. Interestingly, this Cartagena Protocol clearly applies to viruses which regarded as 'living organism' which transfer or replicate genetic matter,[50]but not essentially because viruses 'contain functional unit of heredity".

The CBD accomplished a major achievement when this Convention established the Decision VI/24 of the Bonn Guidelines.[51] This Guidelines aims to provide assistance for parties and other stakeholders in developing access and benefit sharing strategies in general and in helping to establish legislative, administrative or policy measures on access and benefit sharing or

when negotiating contractual arrangements for access and benefit sharing in particular. Unfortunately, the implementation of the provision related to access to benefit sharing is very slow.[52] Accordingly, some groups of developing countries, including the Group 77 and China, as well as the Like-Minded Megadiverse Countries (LMMC),[53]pressed for a specific protocol on access and benefit sharing (ABS).

As a result, the Nagoya Protocol[54]adopted by the Parties to CBD and it opened for signature on February 2, 2011 and enter into force after its fiftieth ratification.[55] This Protocol, as its preamble refers to some of difficulties in the implementation of the CBD, and consequently it recognizes the importance of promoting equity and fairness in the negotiation of MAT between providers and users of genetic resources.

One of the most important aspects of this Protocol is the provision on benefit sharing and the regulation of access. Under the Article 5, benefit sharing in a fair and equitable manner divided into three categories that are; (1) benefits arising from the utilization of genetic resources; (2) benefits arising from genetic resources that are held by indigenous local community; and (3) benefits arising from the utilization of traditional knowledge associated with genetic resources. It means that this Protocol designed to improve many inadequacies found throughout the CBD.

4. State Obligation on Virus Sample Sharing; From the Perspectives of International Human Rights Laws and International Trade Law of Intellectual Property

Under international human rights instruments, it is recognized that rights to life and health are part of fundamental rights of individual,[56] and there is an obligation for each state to protect the life and health of individual from whom it exercises

responsibility. It is a generally accepted proposition that a state would not be responsible for the protecting life and health of individual in other states because state does not have legal authority to regulate or act in other states.[57] On the basis of CBD's principle, a state may not be engage in activities that threaten or cause harm to other states.[58] Similarly, international human rights instrument also should prevent one state from engaging a conduct that may threaten enjoyment of human rights in other states. Paul Hunt states that:

> As a minimum, all states have a responsibility to cooperate on transboundary health issues and to 'do no harm' to their neighbors. High-income States have an additional responsibility to provide appropriate international assistance and cooperation in health for low-income countries.[59]

Similarly, Abbott argues that it would be inconsistent if international legal rules prevented states from acting to contaminate the environment of neighboring states, but did not prevent them from acting to injure the life or health of individuals in neighboring states.[60]Even though Fidler argues that "precise obligations created by the right to health remained unsettled, particularly the duty to participate in international cooperation".[61] Abbott further states that:

> It may well be that each state has an obligation under international human rights law to take reasonable steps to assist other states in the prevention of pandemic disease. For example, the refusal by a state to share virus samples when the outbreak of a pandemic was imminent could constitute a violation of international human rights standards. However, the refusal to share pathogen materials in non-emergency situations may not raise the same level of human rights concern.[62]

Because of that, according to Abbott, the question of whether there is an international human rights obligation to share virus probably must be assessed from the standpoint of the intensity and immediacy of a threat to public health.[63]

Under international law, there is a situation which can create an international legal responsibility for state to prevent a threat of international peace and security, for instance if a decision to withhold virus threaten the capacity of WHO and its member states to deal with a potential pandemic might constitute an imminent threat of serious harm to individuals and other states.[64]If due to the withholding of virus by a member state would prevent the development of vaccine against influenza pandemic and because of the pandemic, cause death of ten millions of individuals. It means that states likely to suffer from the lack of vaccine due to a member state refuse to share virus, and therefore, the refusal to share can be regarded as to threaten national security.

Simultaneously, if there is failure of states to address problem of access on affordable medicines lead to millions of people die every year from treatable diseases, there should be an international human right obligation to assure the access of affordability of medicine and vaccines. In this context, if Indonesia, for instance, have international human rights obligation to share H5N1 virus sample to WHO, Member states as a producer of drug and vaccine, like the United States, Japan and other European nations should also have the same international human rights obligation to assure the affordability access of drug and vaccine. As the representative of Thailand at the WHO's Executive Board meeting in January 2007 argues as follows:

> [w]e are sending our virus [samples] to the rich countries to produce antivirals and vaccines. And when the pandemic

> occurs, they survive and we die...We are not opposed to the sharing of information and virus [samples], but on the condition that every country will have equal opportunity to get access to vaccine and antivirals if such a pandemic occurs.[65]

Accordingly, the above arguments support the notion of a fair and equitable benefit sharing from the utilization of genetic resources including virus provided by the CBD. Through this approach, both the provider states and receiver states will have an equal obligation to maintain the condition of global public health.

While from the perspective of international trade law, particularly from the perspective from patent law, viruses together with other biological resources is one of the main material of drugs and vaccines.Patents are relevant to the issue of virus samples sharing because public and private corporation may protected their investment on research and development, for instance, on isolated viruses and its derivative products in the form of drugs or vaccines. Such approach can be justified under the principles of patent law.

Although a traditionally accepted principle of the patent law provided that life forms were disqualified from patentability,[66] the practical application proved contrary to such principle.[67] Article 27 of the TRIPs Agreement deals with the patentable subject matters, and provides that patents shall be granted to 'inventions', in the form of all new and useful products and processes in all fields of technology without discrimination.[68] This Article also requires member nations to grant patents in micro-organisms and non-biological and microbiological processes.[69] Accordingly, Article 27 provides a legal basis for patent protection related to viruses.

It is not only viruses that can be patented, but also other 'products of nature'. Some experts argue that a mere discovery can be transferred into an invention if there is a degree of technical human intervention. This begs the question of what degree of human intervention is required under the patent law. The possible answers to this question vary. For example, Ducor points out that:

> Generally, 'products of nature' are patentable when some human intervention has been necessary to make them available. The intervention generally resides in the isolation or purification of naturally-occurring product, and translates in claim language as 'essentially pure', 'biologically pure', or isolated. The current situation is well summarised by the Court in Diamond v Chakrabarty; patentable subject matter includes 'anything under the sun that is made by man.[70]

Furthermore, human's cell and tissue can also be patented. The Decision on*John Moore v.The Regents of the University of California*[71]clearly stated that patent regime providesan incentive for human creativity and "it is the inventive effort that patent law rewards, and not discovery of naturally occurring raw material."[72]Surprisingly, this cell and tissue is owned by those who have spent their labor to create a property right in the cell as provided under the decision of *Moore'scase* in which Moore's spleen is regarded as simply a raw material, and it has no value until the work of a medical research is invested in the raw material, and thus create value.[73] Moore cannot own his spleen because it is a mere raw material and the medical researcher, through their labor, create a property right in Moore'cells. The Court decides that the spleen has no worth to Moore, otherwise, it has negative worth as a cancer-causing agent that could potentially lead to Moore's dealth. Moore also have no right to receive any benefits from the commercialization drugs derived from their body part although his

cell line was sold to a Swiss drug company resulting in a drug worth millions of dollors.[74]

Interestingly, the Court used the term 'raw materials'throughout its decision to refer to Moore's tissue. When the court argues that research will be hindered if Moore is give a patent interest in his cells, the court states that "the extension of conversion law into this area will hinder research by restricting access to necessary raw materials."[75] Furthermore, the court suggests that "if anyone is to limit the scientific communities's access to raw material, it should be the legislature."[76] Similarly, Boyle also argues that:

> View through the lens of authorship, Moore's claim appear to be a dangerous attempt to privatize the public domain and to inhibit research. The scientists, however, with their transformative, Faustian artistry, fit the model of original, creative labor. For them, property rights are necessary to encourage research.[77]

From the above arguments showed that the international trade law of intellectual property approach regarding the ownership and control on viruses are completely different from the CBD and international human rights approach. Because of that, patent regime rejects the notion of a fair and equitable sharing benefit derived from the utilization of genetic resources, including viruses, human's cells and tissues. This is in line with Boyle's argument above which seenviruses, human's cell and tissues as a public domain.

Such condition lead to a concern about the relationship between the TRIPs Agreement and the CBD, in the absence of CBD principles like PIC, disclosure of origin and benefit sharing scheme in TRIPs. The absence of such principles in TRIPs is simply

because this Agreement is designed under a private property approach for fostering the liberalization of international trade. The driving force behind the conclusion of this Agreement were the most powerful actors of developed nations in high technology and creative industrial sectors, as well as multinational corporations' elites holding significant IPRs portfolios.[78] The TRIPs agreement is intended to ensure private rights through the protection of IP and also to secure these rights by appropriate and effective means.[79] The CBD, however, is intended to ensure the conservation of biological diversity, sustainable use of genetic resources and fair and equitable sharing of any benefit arising from the use of the resources.[80]Thus, they have different rationales and objectives.

Developing countries argue that TRIPs may have undesirable effects on the CBD and consider that this Agreement lacks balance because TRIPs does not require benefit sharing.[81]TRIPs also does not require applicants for IPR to provide information concerning the origin of genetic resources,[82] or the sharing of economic and technological benefits of genetic resources related patents.[83]

It has been a point of criticism that these differences of underlying principles has meant that the TRIPs Agreement does not effectively complement other international legal instruments and indeed is a source of disharmony. Countries required tofulfill these international obligations which are signatories to both TRIPs and other conventions must now examine the relationship between TRIPs and other conventions to have appropriate national legislative implementation. The WTO itself had measured this relationship in 1995 through the Committee on Trade and Environment.[84]

Based on the above condition, in the Doha Ministerial Declaration, the TRIPs Council was instructed "to examine, *inter alia*, the relationship between the TRIPs Agreement and the CBD,

and protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to TRIPs Article 71.1."[85] Until 2010, the result of the consultations were reported to the Director-General by stating that "while my consultations have not created convergence they have certainly shed clearer light of the divergences".[86]

5. Conclusion

There is no explicit legal obligation for state to share samples of virus under International Health Regulation (IHR), although under the general undertaking to protect against and provide a response to international spread of disease, such requirement might be implicit.

Virus are genetic resources under the meaning of CBD, and consequently, States have sovereign rights over viruses located in their territories, and have authority to determine the conditions of access. The CBD also requires Contracting State to have an endeavor to create condition for access based on mutually agreed terms (MAT) and prior informed consent (PIC). And to implement this Convention, the Nagoya Protocol adopted by the Parties to CBD to deal with access to genetic resources and a fair and equitable sharing of benefits arising from their utilization. However, under this CBD, Contracting State also have responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states.

It would be inconsistent if international legal rules prevented states from acting to endanger the environment of other states, but did not prevent them acting to injure the life or health of individuals in other states. However, if there is an international human rights obligation to share virus, there should also be an international human rights obligation to assure the access of affordability of drugs and

vaccines. Thus, each state will have an equal obligation to enhance the global public health.

From the perspective of WTO-TRIPs Agreement on patent, virus and other 'product of nature' is patentable based on the article 27. Human's cell and tissue are regarded as a raw material and it will be owned by those who have spent their labor to create a property rights. This raw material is regarded as public domain, thus restricting access to such material will hinder research. Because of that, patent regime rejects the notion of access to and a fair benefit sharing for the utilization of viruses enshrined under the CBD.

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[19]Stephen B Brush, 'the Demise of "Common Heritage" and Protection for Traditional Agricultural Knowledge', 6-7, available from <http://law.wustl.edu/centeris/Confpapers/PDFWrd/Doc/StLouis1. html>.

[20]*Ibid.*

[21]In interpreting this article, according to Cooper in Kemal Baslar, ' The Undertaking sought to put all plant genetic resources on an equal footing as 'the heritage of mankind', which mean that this heritage should be preserved for the use of present and future generations...and be freely available to benefit all peoples', see the analysis about this concept in Kemal Baslar, *The Concept of the Common Heritage of Mankind in International Law* (M. Nijhoff Publishers, the Hague; Boston; Cambridge, MA, 1998) 307-310.

[22]*Ibid.*

[23]*Ibid.*

[24]According to *The United Nations Convention of the Law of the Sea* (UNCLOS) of 10 December, 1982, UN Doc.A/Conf.62/122 (entered into force on 16 November 1994) available from <http://un.org/Depts/los/convention_agreements/textx/unclos/part11-2.htm>, the term 'Area' means the seabed and ocean flour and subsoil thereof, beyond the limits of national jurisdiction', see UNCLOS Article 1 (1).

[25] For example, Under the UNCLOS, Section 2 Regarding Principles Governing the Area, Article 136 provides that 'the Area and its resources are the common heritage of mankind'. Then, article 137 regarding the Legal status of the Area and its Resources provides that:

(1) No state shall claim or exercise sovereignty or sovereign right over any part of the Area or its resources, nor shall any State or natural or juridical person appropriate any part thereof. No such claim or exercise of sovereignty or sovereign rights nor such appropriation shall be recognised.

(2) All rights in the resources of the Area are vested in mankind as a whole, on whose behalf the Authority shall act. These resources are not subject to alienation. The minerals recovered from the Area, however, may only alienated in accordance with this Part and the Rules, regulations and procedures of the Authority.

(3) No State or natural or juridical person shall claim. Acquire or exercise rights with respect to the minerals recovered from the Area except in accordance with this Part. Otherwise, no such claim, acquisition or exercise of such rights shall be recognized.

[26]Jack Jr. Kloppenburg and Daniel Kleinman, 'Plant Genetic Resources; The Common Bowl', in Jack Jr. Koppenburg (ed), note 4, p. 10 in Patricia Lucia Cantuaria Marin, *Providing Protection for Plant Genetic Resources; Patent, Sui Generis Systems and Biopartnerships* (Kluwer Law International, New York, 2002). 49.

[27](1) Resolution 4/89 about Agreed Interpretation of the International Undertaking; (2) Resolution 5/89 about Farmers' rights); and (3) Resolution 3/91. Those three resolutions where then enclosed as Annex of the Undertaking, as above n 3.

[28]Patricia Lucia Cantuaria Marin, above n 26, 50.

[29]Resolution 4/89 point 5 (a), above n 3.

[30]*The United Nations Convention on Biological Diversity,* done at Rio de Janeiro, 5 June 1992, 31 ILM 822, opened for signature 5 June 1992 (entered into force 29 December 1993). Text and information on the CBD can be found at the site of the Secretariat of the Convention on Biological Diversity, UNEP (CBD Secretariat), The Rio Declaration, UN.Doc.A/CONF.151/5/Rev.1 (1992) available from< http://www.cbd.int/convention/convention.shtml>

[31]This Convention regulates all aspects of biodiversity covering the conservation of biological diversity and its sustainability, access to biotechnology and genetically modified

organisms or modified living organisms and its safety aspects, See Michael Bowman and Catherine Redgwell (eds), *International Law and the Conservation of Biological Diversity, International Environmental Law and Policy Series* (Kluwer Law International, Deventer, NL, 1996) 1.

[32]Sam Johnston, 'Sustainability, Biodiversity and International Law', in Michael Bowman and CatherineRedgwell (eds) *International Law and the Conservation of Biological Diversity, International Environmental Law and Policy Series* (Kluwer Law International, Deventer, NL, 1996) 51-76, 53.

[33]See the CBD Article 1 (Objectives) above n 30.

[34]*Ibid,* the CBD Article 8 (j).

[35]Frederick M. Abbott, above n 11, p. 12.
[36]See Article 2 of the CBD, above n 30.

[37]*Ibid,*Article 15 (1) of the CBD.

[38]The New Shorter Oxford English Dictionary (1993 ed.), p 1888-89, def.4.

[39]*Ibid.*

[40]See Article 2 of the CBD, above n 30.

[41]*Ibid.*
[42]Frederick M. Abbott, above n 11, p. 13.
[43]Article 15 (4) of the CBD, above n 30.

[44]*Ibid,*Article 15 (5) of the CBD.

[45]*Ibid.*Article 15 (6) of the CBD.

[46]*Ibid,*Article 15 (7) of the CBD.

[47]It was finalised and adopted in Montreal on 29 January 2000, at an extraordinary meeting of the Conference of the Parties. See Cartagena Protocol on Bio-safety to the Convention on Biological Diversity Text and Annexes, The Secretariat of the Convention on Biological Diversity-World Trade Centre- Montreal, 2000, Jan 29, 2000, 39 I.L.M.1027.

[48]*Ibid,*Article 1 (objective) of the Cartagena Protocol.

[49]*Ibid,* Article 3 (h).
[50]Kenan Mullis, "Playing Chicken with Bird Flu: "Viral Sovereignty," the Right to Exploit Natural Genetic Resources, and the Potential Human Rights Ramifications, (2009) *24 Am. U. Int'l L. Rev. 943*, 954.

[51] Bonn Guidelines *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation*, adopted at the COP VI of CBD at Hague, on 7-19 April 2002, UN Doc UNEP/CBD/COP/6/20 access at Convention on Biological Diversity available from <http://biodiversity.org/decisions/default.asp?m=coop-06&d+24>.

[52]Konstantia Koutouki & Katharina Rogalla von Bieberstein, "The Nagoya Protocol: Sustainable Access and Benefits-Sharing for Indigenous and Local Communities, (2012) *13 Vt. J. Envtl. L. 513,* 522.

[53] Up to now, there is no obvious information regarding the number of countries which established this group. Based on the Cancun Declaration of Like-Minded Megadiversity Countries, this declaration was formed by the Ministers in Charge of the Environment and the Delegates of Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela (12 nations). According to the LLMC website, this group was established in February 2002 in Cancun, Mexico (Cancun Declaration) and formed by Bolivia, Brazil, China, Colombia, Costa Rica, Ecuador, Filipinas, India, Indonesia, Kenya, Malaysia, Mexico, Peru, South Africa, and Venezuela. See http://www.megadiversity.org. Furthermore, according to the UNDP data, this group was formed by Seventeen Countries which are rich in biodiversity and traditional knowledge, that are: Bolivia, Brazil, China, Costa Rica, Colombia, the Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, South Africa, the Philippines and Venezuela, available from <http://undp.org/biodiversity/events/Megadiverse_Meeting.htm>p1.

[54]Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Oct. 29, 2010 UNEP/CBD/COP/DEC/X/1 of 29.

[55]*Ibid,* Nagoya Protocol, Article 33.
[56]Frederick M. Abbott, "TRIPs and Human Rights; Preliminary Reflections", in Frederick M. Abbott, et.al (eds) (2), *International Trade and Human Rights; Foundations and Conceptual Issues*, University of Michingan Press, 2006, 145.

[57]*Ibid.*

[58]See the principles of CBD in its Preamble, above n 30.

[59]Paul Hunt, "Promotion and Protectionof All Human Rights, Civil, Political, Economic, Social and Cultural Rights, A/HRC/7/11, Jan 31, 2008, accessed at <http://www2.ohchr.org/english/issues/health/right/annual.htm>
[60]Frederick M. Abbott, above n 11, p. 8.

[61]David Fidler, above n 6, p 5.

[62]Frederick M. Abbott, above n 11, p.8.

[63]*Ibid.*

[64]*Ibid.*

[65]Quoted in H. Branswell, Poor Countries Insisting on Bird Flu Rules; They Want Fair Share of Vaccines, Hamilton Spectator, Feb 12, 2007, at A05, in David Fidler, above 6, p. 2.

[66]As Palombi, in his dissertation concluded that; 'The world 'invention' in Article 27.1 TRIPs excludes products of nature or natural phenomena and their 'artificial' derivatives which do not meet the threshold of artificiality established in *Chakrabarty*'. See in Luigi Palombi, *The Patenting of Biological Materials in the Context of the Agreement on Trade-Related Aspects of Intellectual Property Rights* (Dissertation, The University of New South Wales, Sydney, 2004) 219.

[67]Graham Dutfieldnoted that patents have been granted to some part of life forms; According to him for example, in 1975 German Federal Supreme Court declared that micro-organisms are patentable; in 1980, *Diamond v. Chakrabarty* affirmed that micro-organisms are patentable in the USA; In 1985, US PTO appeals board decided that plants, seeds and plant tissue cultures are patentable; in 1987 US PTO announced that multicellular organisms are patentable; 1988 EPO grants first patent on plant and US PTO were issued 'oncomouse patent'; 1995 EPO declared that DNA is not 'life', but a chemical substance which carries genetic information and therefore constitutes patentable subject matter; See Graham Dutfield, *Intellectual Property Rights and the Life Science Industries, A Twentieth Century History* (Ashgate, England and USA, 2003)151.

[68]See TRIPs Agreement, Article 27. 1, above n 4.

[69]*Ibid,* Article 27 (3) b.

[70]P.G. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules* (Kluwer Law International, London, 1998) 6.

[71]This case began when Moore discovered that his cancerous spleen had been used to create a cell line with commecial value without his consent. Moore suffered from hairy-cell leukimia and the operation on his spleen was considered essential for his death. Dr Golde, Moore's physician, used the extracted tissue to create a patentable cell line from Moore's T-lymphocytes. The Cell line was later sold to a Swiss Drug company resulting in a drug worth millions of dollors. Dr. Golde did not reveal his full interest in Moore's spleen during initial operation, and he did not reveal his ongoing interest in Moore's tissue during the follow-up visits he required Moore to make. More sue UCLA for breach of fiduciary duty and to establish a property right in his spleen under the tortof conversion. See in Debora J. Halbert, *Resisting Intellectual Property* , Routledge, Oxon, 2005, p. 117.

[72]*Ibid,* p. 115.
[73]*Ibid.*

[74]John Vidal " The Story of Life," *Guardian*, 26 June 2000, p. 11 in Debora J. Halbert, *Ibid,*p. 115.

[75]*Ibid,*p. 117.

[76]*Ibid.*

[77]James Boyle, *Shamans, Sofware, and Spleens; Law and the Construction of the Information Society*, Cambridge and London; Harvard University Press, 1996, p. 107, in Debora J. Halbart, *Ibid,*p. 117.

[78]John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge University Press, Cambridge, Melbourne, 2000)75-204.

[79]See, the Objective of the TRIPs Agreement in Article 7, above n 4.

[80]See the objective of the CBD in Article 15, above n 30.

[81] Thomas Cottier, 'The Protection of Genetic Resources and Traditional Knowledge; Towards More Specific Rights and Obligations in World Trade Law, (1998) 1 *J. Int'l Econ. L*, 555, 567.

[82]NunoPires de Carvalho, 'Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPs Agreement; the Problem and the Solution' (2000) 2 *Wash. U. J.L &Pol'y* 371, 372-75.

[83]See, the Convention on Biological Diversity and the Agreement on Trade-Related Intellectual Property Rights (TRIPs); Relationship and Synergies, para 33, in UN Doc. UNEP/CBD/COP/3/23, October 5, 1996.

[84] Barbara LaincKagedan, 'The Biodiversity Convention; Intellectual Property Rights, and Ownership of Genetic Resources; International Developments', Report Prepared for Intellectual Property Policy Directorate Industry Canada, January 1996, 107.

[85]Adopted on 14 November 2001, WT/MIN (01)/DEC/1 (20 November 2001), para 19.

[86]See in Frederick M. Abbott, above n 11, p. 18.

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