NEW HURDLES FOR ACCESS TO MEDICINES: A HUMAN RIGHTS PERSPECTIVE OF THE EC-REGULATION 1383/2003 AND THE GENERIC DRUG SEIZURE CASES

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ABBREVIATIONS

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ABSTRACT

People’s right of access to medicines has always been restricted since the adoption of the product patent regime. While the developing countries are fighting for improved access to essential medicines, developed countries are trying to enforce the intellectual property rights beyond what is required by the WTO-TRIPS. The seizure of generic drugs by the European Council (EC) authorities is another example of this developed country approach, which pose serious threats to access to medicines that needs to be resolved not only in the light of the WTO Law, but also in the light of the peremptory norms of International Human Rights Law.
I. INTRODUCTION

Intellectual Property Rights (IPRs) are “trade restrictive” by their very nature and the higher IP enforcement practices are seen as a ‘public health restrictive’. The recent ‘seizures’ of several generic drugs in transit by the European Council (EC) for their alleged infringement of IPRs are classic examples of the risk of ‘IP maximalist’ approaches which pose serious threats to the access to life saving medicines on one hand and impede legitimate trade of generic drugs on the other.


Before the World Trade Organization’s Doha Declaration on TRIPS and Public Health in 2001 was adopted (hereinafter referred as Doha Declaration on Public Health) patents were also considered as ‘public health restrictive’ because of the introduction of product patents which resulted in the higher prices of medicines making it unaffordable to poor people of the developing countries. For example, Cynthia Ho states that, “to the extent that patent rights entitles their owner to exclude others from the making of the invention, the patent owner may price a patented drug at levels that are beyond what some countries can afford.” See, Cynthia m. Ho (2009), Current controversies concerning patent rights and public health in a World of international norms, Chapter 30 in Patent Law and Theory: A Handbook of Contemporary Research (Takenaka, ed., 2009); Also see, Frederick Abbot (2009), Worst Fears Realised: The Dutch confiscation of Medicines Bound from India to Brazil, Bridges, 13(19), http://ictsd.net/i/news/bridges/44192/; Cohen JC, Illingworth P. The dilemma of intellectual property rights for pharmaceuticals: the tension between ensuring access of the poor to medicines and committing to international agreements. Developing World Bioeth 2003; 3: 7-48; Hestermeyer H. Human rights and the WTO: the case of patents and access to medicines, (2007), Oxford: Oxford University Press; Malpani R, Kamal-Yanni M. Patents versus patients: five years after the Doha Declaration [Oxfam briefing paper no. 95], (2006), Oxford: Oxfam International.

3 ‘IP Maximalist’ approach is considered as the quest for higher global IP standards. See, Susan sell, The global IP upward ratchet, anti-counterfeiting and piracy enforcement efforts: the state of play, 9 June 2009, www.twnside.org.sg/title2/intellectual_property/.../SusanSellfinalversion.pdf

4 For instance, Martin Khor states that “[a] new threat to the health of people in developing countries is being caused by European customs authorities seizing legitimate low-cost generic medicines being
It is a known fact that generic drugs are the affordable sources of medicines for most of the developing countries and there has been enormous research on the cost-effectiveness and benefits of the generic drugs. The introduction of the product patent system through WTO-TRIPS has resulted in high price medicines unaffordable to most of the developing world’s people and hindered their right of access to essential medicines. Though, developing countries could succeed in their efforts to promote access to medicines with the Doha Declaration of Public Health, developed countries have always tried for other means to stop generic drugs. And the recent seizures of generic drugs are seen as an example of the IP maximalist actions which also pose serious threats to the access to essential medicines.

II. SEIZURE OF GENERIC DRUGS: ISSUES AND CONCERNS

A. Seizure of generic drugs: Background of the problem


6 It is an established fact that generic low cost drugs play an important and a major role in the health care systems of the developing countries where people have to pay 70% of their income on medicines next to what they pay for food. See, Carlos M Correa, *Intellectual Property Right, the WTO, and Developing Countries: The TRIPS Agreement and Policy Options*, (2000), New York: Zed Books Ltd. P.35. Carlos Correa in this describes various studies that were made on the impact of patents on prices of medicines where he quotes that “the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) would amount to a minimum of US$3.5 billion and a maximum of US$10.8 billion, while the income gains by foreign patent owners would be between US $2.1 billion and US$14.4 billion
IP Watch reported that total 19 consignments carrying generic drugs destined for various developing countries were detained by the customs authorities in different airports of the EC member countries. These seizures have given impetus to test whether the EC actions based on the EC Councils Regulation 1383/2003 are consistent with the World Trade Organization (WTO), the Agreement on Trade Related Intellectual Property Rights (TRIPS) and the WTO Doha Declaration on Public Health.

The existing literature on the issue expressed concerns mostly from a trade perspective. However, another important issue that needs focus is the human rights argument to present the case of the developing countries. India has rightly claimed that “the seizures run counter to the spirit of the TRIPS Agreement and the resolution 2002/31 of the commission on Human Rights on the right to enjoy the highest standards of physical and mental health”. In addition to this it is also right to claim that the seizures and the EC regulation are in violation of basic human rights norms which have become the basic principles of International Law. The idea behind this approach is to apply the “Doctrine of *Jus cogens*” while deciding a case like the generic drugs seizures which

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9 WTO-Doha Agreement on Public Health [WT/MIN(01)/DEC/2] was adopted at the Doha Ministerial Conference on 14 November 2001 WTO, available at: http://www.wto.org/english/theWTO_e/minist_e/min01_e/mindecl_trips_e.htm


11 The Doctrine of “*Jus cogens*” will be discussed in the next section of this paper.
not only has trade implications, but also the implications of human rights in general (and right to life and right to health in particular). The doctrine of *jus cogens* for this study will essentially refer to the peremptory norms of international law concerned with human rights and states obligations towards these rights. Therefore, while giving an overview of the existing debate on trade perspectives of the generic drug seizures cases, this study will essentially focus on how human rights can form part of these arguments. The study bases its arguments on the basic principles of international law, the law of interpreting the international treaties and human rights.

**B. European Council Regulation 1383/2003: A brief outline**

The genesis of the border detention proceedings for the IP infringing goods on a European Union level was in the European Community Regulation 3295/1994\(^{12}\) which laid down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods. The IP rights covered by this regulation were only trademarks and copyrights. This regulation was subsequently amended in 1999 by another EC Regulation 241/1999\(^{13}\) to cover the protection of patents. Parallel to this procedure, there exist national laws and regulations of the member states to the European Union with regard to border detention proceedings. These national procedures for the most part are considered to be subsidiary in their

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application to the European Regulation or restricted to certain rights of intellectual property not covered by the Anti-Piracy Regulation”. The EC Regulation 1383/2003 in question in the present case was adopted to repeal and replace the first EC Regulation 3295/94 to provide for clarity in the border detention procedures.

The new regulation provides simplified procedure for the Customs authorities to stop goods entering the European Union that are suspicious of infringing intellectual property rights. Even where no application has yet been lodged or approved, the regulation authorizes the EU Member States “to detain the goods for a certain period to allow right holders to lodge an application for action with the customs authorities”.

The border detention procedures under this regulation contain three steps: application, detention, destruction or court proceedings. Normally, the detention proceedings are initiated by an application filed by the ‘right holder’ with one or more of the national customs departments demonstrating the ownership of the right or license and has to


15 Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs actions against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, Official journal of the European Union, L 196/7, (2003), eur-lex.europa (herein after will be referred as EC Regulation 1383/2003).

16 Article 4 of the EC Regulation 1383/2003: Measures prior to an application for action by the customs authorities

1. Where the customs authorities, in the course of action in one of the situations referred to in Article 1(1) and before an application has been lodged by a right-holder or granted, have sufficient grounds for suspecting that goods infringe an intellectual property right, they may suspend the release of the goods or detain them for a period of three working days from the moment of receipt of the notification by the right-holder and by the declarant or holder of the goods, if the latter are known, in order to enable the right-holder to submit an application for action in accordance with Article 5.

17 A ‘right holder’ according to article 2.2. of the EC Regulation means “the holder of a trademark, copyright or related right right, design right, patent, supplementary protection certificate, plant variety right, protected designation or origin, protected geographical indication and, more generally, any other person authorized to use any of the intellectual property rights…”. 
identify the goods that are suspicious of infringing his/her rights. The customs official will detain the goods suspected of infringing an IP including patent and will inform the right holder and holder of the goods and gives them an opportunity to inspect the goods (Article 9.3 of the EC Regulation 1383/2003).

An important feature of this regulation which has given rise to the current controversy is that it does not only come into play with regard to the importation of patent infringing goods into the European Union but rather refers to several “situations” in which goods may be detained. Article 1 of the EC Regulation 1383/2003 sets out conditions for action by the customs authorities when goods are suspected of infringing an IP right in the situations where goods are entered for release into free release into free circulation, export or re-export, checks on goods entering or leaving the European Union, where goods are placed under a suspensive procedure or are in the process of being re-exported, or placed in a free zone or free warehouse. However, the law is not clear whether the goods suspected of infringing patents whether entering the free zone or in transit may also be detained. Opinions about this controversy are mixed. For example, Cordes presents a mixed approach taken by the European Courts on the issue of applying EC Regulation over in-transit goods. His study claims that “German Courts distinguish between transit in the narrow sense and in a broader sense where as Dutch High Court opined that regardless of whether goods are detained in transit or in any other situation mentioned in art.1 par. 2 Anti-Piracy Regulation, the national patent law applies under a fiction that the goods are detained.”

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C. Legal Issues and Concerns

i. Jurisdiction Over Goods In Transit – A Barrier To Legitimate Trade

The seizures of generic drugs raised the issue of jurisdiction of a state over the goods in transit. India and Brazil complained to the WTO claiming that the “EC actions and the EC Regulation 1383/2003 are contrary to Article 51 of the TRIPS Agreement.”

Article 51 of the TRIPS Agreement states as follows:

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52 of the TRIPS Agreement states as follows:

“Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder’s intellectual property right and to supply a sufficient detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted to application and, where determined by the competent authorities, the period for which the customs authorities will take action”.

The EC actions and the EC Regulation 1383/2003 are contrary to Article 51 of the TRIPS Agreement. Article 51 demands for the actions to be taken by the importing country (Article 52) and specifically exclude the goods in transit in the note 13 of Article 51.

Whereas, in the present case, the goods that were seized, were not imported by any of the EC countries. Therefore, EC has no jurisdiction to seize the goods in transit. In this


20 Article 51 of the TRIPS Agreement states as follows: Suspension of Release by Customs Authorities

21 Article 52 of the TRIPS Agreement states as follows:

22 Article 52, Note 13: It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.
context, Henning Grose Ruse-Khan and Thomas Jaeger referring to the Article 1 of the EC Regulation claimed that the EC Regulation 1383/2003 is “beyond TRIPS”. However, this argument can be contested by the claim that EC Regulation is TRIPS consistent because the language of Article 1 of the EC Regulation does not mention anywhere or even refer to the goods in transit. And moreover, the terms like ‘entered for free release for free circulation’, or ‘export’ or ‘re-export’ or ‘entering or leaving the community makes sense that the goods are meant for the importing country or the exporting from the country where actions are to be taken. But if EC takes this stand, then the EC actions are in violation of its domestic law and hence can be voided. Additionally, EC actions resulted in restricting the legitimate trade of generic drugs which violate the basic principle of the TRIPS Agreement that “measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.” In any of these cases, developing countries have a strong case to make the jurisdiction argument before the WTO panel in case of a WTO dispute.


24 Article 1 of the EC Regulation 1383/2003 concerning the customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, says as follows:
   1. This Regulation sets out the conditions for actions by the customs authorities when goods are suspected of infringing an intellectual property rights in the following situations.

25 Generic drugs do not violate IP rights in any case and are legal according to flexibilities provided in the TRIPS Agreement. The Doha Declaration on Public Health also authorized the trade of generic drugs between member states. See Article 30 of the TRIPS Agreement.
ii. Territoriality Principle

Continuing the jurisdiction argument, India, Brazil also claimed that the EC Regulation violates the basic IP principle of territoriality. TRIPS Agreement provides for the minimum standards of IP protection which the member states have to implement through their national legislations (Article 1.1 of TRIPS).\textsuperscript{26} This implies that the rights conferred are also enforceable only within the territory of the State. In the present case, the seized goods – generic drugs were not patented in the exporting country and also in the importing countries. The allegation was that the goods infringed the patent rights in the country where they were seized. But since goods were not intended for any of the EC country’s markets there is no question of causing any harm or damage to the right holder.

Article 51 and 52 of the TRIPS Agreement specifically require \textit{prima facie} infringement of rights holder’s intellectual property rights, which in this case is not satisfied and hence the EC actions are against the TRIPS Agreement. Xavier Seuba also claims EC actions as WTO inconsistent mainly on the ground of the “territoriality principle. He describes the EC regulation as “a scheme of uncertain compatibility with World Trade Organization law and fundamental intellectual property law principles and norms: the territorial nature of intellectual property rights and the rights conferred to intellectual property rights.”\textsuperscript{27} According to him, “intellectual property rights are

\textsuperscript{26} Article 1.1 of the TRIPS Agreement says: “Members shall give effect to the provision of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

territorial and its protection depends on each country’s national legislation. EC Regulation 1383/2003 hardly reconciles with said principle because in seizing a specific product not intended for the EC market it mandates taking as reference the patent status in the European Member State in which application for customs action is made.”

India also claimed that, 'territoriality' is a key stone in the edifice of the TRIPS Agreement and a widely understood and accepted principle.

iii. Misconception of generic drugs as counterfeit drug, spurious and fake drugs

The EC actions are also contested for treating generic drugs as counterfeit, spurious and fake drugs. India reported that, the grounds stated by EC include counterfeits, fake drugs, substandard, potentially dangerous products, patent violations and so on. The EC have also made allegations of drug trafficking after three months of seizure of a particular consignment. In its statement at the WTO TRIPS Council meeting, EC also claimed that “although customs controls of this kind of goods are often difficult, their role is crucial to prevent the flow of fake medicines in transit from reaching the populations of EU and other countries, in particular developing countries.”


30 EU Intervention at the TRIPS Council
And that the “EU customs actions have saved lives in final destination countries – often developing countries.”  

India seriously contended this argument of EC that “Underlying the drug seizures is also a deliberate mixing up of the issue of spurious/sub-standard drugs … with IPRs”.

It is also debated that generic drugs are in no comparison to counterfeit medicine. Counterfeit drugs are those “including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such foods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the right of the owner of the trademark in question under the law of the country of importation (Article 51, note 14.a of TRIPS).

31 Ibid

32 Indian Statement at the WTO TRIPS Council states that, “EC has sought to justify the action of customs authorities to control goods in transit suspected of infringing IPRs as a means to stop “traffic of potentially dangerous products, such as fake medicines, even when the shipments were destined for any country.” It seems that it has been ingrained very deeply within the EC authorities that IP violative products are synonymous with potentially dangerous substances. This clearly is an untenable logic. We doubt such simplistic linkages. Moreover, we are talking about generic medicines, which neither infringe IPRs nor are they ‘potentially dangerous’. EC takes pride in its claim that ‘EU customs actions in the past had saved lives in the final destination countries which were often developing countries.’ We wish to remind the EC that the concept of ‘territoriality’ is a key stone in the edifice of the TRIPS Agreement and a widely understood and accepted principle. In our view, sovereign functions of the country of destination should be exercised by the country itself and other countries may assist in enforcement of their law, if requested. It may be farfetched to claim that the country of transit will have sound understanding of the IPR laws of country of destination or origin and will have the authority to enforce them during transit. It would also be incorrect to presume that the sovereign countries, to which pharmaceutical goods are consigned, are not responsible for ensuring health, safety and expectations of consumers in their countries. In such situations, an information sharing mechanism is what is needed and definitely not action under the laws of the country in transit. If there is a reason to doubt the quality of goods, enforcement action should follow from domestic regulations in importing country and not from WTO rules, which do not provide for the same or from rules of a third country.” Also see, Kaitlin Mara, Medicines Access again captures attention at WTO as progress urged on the round,  
Spurious drugs are those that are deliberately and fraudulently mislabeled with respect to their identity and/or source.\textsuperscript{33} Substandard drugs refer to low-quality drugs.\textsuperscript{34}

However, all this confusion or misconception as to what are counterfeit drugs is mainly due to the WHO which defines counterfeit medicine as “…one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.”\textsuperscript{35} The WHO definition is different from the TRIPS definition of a counterfeit medicine, in which the former considers medicines which are fake, spurious and mislabeled as counterfeit which are dangerous for the public health whereas the later considers counterfeit only which infringes copyright and trademark.

So, even though the issue of counterfeit drugs is IP related, it is related only in the sense of trademark, copyright and most importantly public health issue but essentially not a patent issue.\textsuperscript{36} And moreover, generic drugs are neither fake, nor spurious nor substandard drugs. Generic drugs are the unpatented drugs, sometimes even licensed, which are legal according to the TRIPS Agreement. In the present case, the confusion regarding the counterfeit drugs and the language of the EC Regulation

\textsuperscript{33} Third World Network (2008), Unpacking the issue of counterfeit medicines, Draft (5/1/08),

\textsuperscript{34} Ibid


which includes patent infringing goods as counterfeit has given rise to the seizures.\textsuperscript{37} This is clearly a violation of the TRIPS Agreement. Therefore, “given these important differences between generic and counterfeit products, any move to curb the free flow of lawfully produced generic medicines would seriously undermine the production and trade of good quality generic medicines, and consequently access to affordable medicines”.\textsuperscript{38}

iv. Unreasonable delay in the legitimate trade of generic drugs impedes freedom of transit

India expressed concerns that the delay violated the objectives and principles of the TRIPS Agreement set out in Article 7 and 8 of the TRIPS agreement.\textsuperscript{39} Brazil added that a “decision to impede the transit of cargos of generic medicines violates the freedom of transit” in a statement issued at the same meeting.\textsuperscript{40} Article 7 of the TRIPS prescribes that the protection and enforcement of IP should contribute to the promotion


\textsuperscript{40} See, Kaitlin Mara, India may be nearing WTO dispute settlement with EU over generic drug seizures, http://www.ip-watch.org/weblog/2009/08/28/india-may-be-nearing-dispute-settlement-with-eu-over-generic-drug-seizures/
of innovation and dissemination of technology in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 8 allows members to take “measures to protect public health”\textsuperscript{41} and to “prevent the abuse of intellectual property rights by right holders which unreasonably restrain trade or adversely affect the international transfer of technology.”\textsuperscript{42} Besides this, Article V of GATT provides the freedom of transit principle. Article V.2 lays down the fundamental principle of freedom of transit and Article V.3 requires that the contracting parties shall not be subjected to unnecessary delays or restrictions. Therefore, in light of this, seizures of the generic drugs in transit which resulted in unreasonable delays and restrictions are prohibited under the GATT and also under the TRIPS.\textsuperscript{43}

\textbf{v. The Doha Declaration on the TRIPS Agreement and Public Health}

Frederick Abbot identifies the EC Regulation as “beyond what is required by the TRIPS Agreement and the Paris Convention and its application of patent law is not ‘supportive to public health’.”\textsuperscript{44} He describes the generic drug confiscations “as

\begin{itemize}
\item \textsuperscript{41} Article 8.1 of TRIPS: Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
\item \textsuperscript{42} Article 8.2 of the TRIPS Agreement: “Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”
\item \textsuperscript{44} See, Frederick Abbot (2009), Worst Fears Realised: The Dutch confiscation of Medicines Bound from India to Brazil, \textit{Bridges}, 13(19), Available at: http://ictsd.net/i/news/bridges/44192/}
\end{itemize}
contrary to the ‘letter and spirit of the Doha Declaration’ on TRIPS and Public Health,” which requires that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health and that the Agreement should be interpreted in a manner supportive of WTO Member’s right to protect public health, and in particular, to promote access to medicines for all.”

India contended that the seizure of the generic medicines risked undermining “the public health dimension of the TRIPS agreement and goes against the spirit of a rules based trading system”. Brazil claimed that “the measures taken by the Dutch authorities clearly violates the freedom of transit, which is a right enshrined in GATT Article V and the extra territorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration on TRIPS and Public Health … [and] the protection

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45 For a discussion on the legal status of the Doha Declaration of the TRIPS Agreement, see, Carlos Correa (2002), Implications of the Doha Declaration on the TRIPS Agreement and Public Health, WHO. 
http://www.gefoodalert.org/library/admin/uploadedfiles/Implications_of_the_Doha_Declaration_on_the_TRIPS_Agreement_and_Public_Health.pdf; (“given the content and mode of approval of the Doha Declaration, it can be argued that it has the same effects as an authoritative interpretation. In particular, in providing an agreed understanding on certain aspects of the TRIPS Agreement in paragraph 5, Members have created a binding precedent for future panels and Appellate Body reports”).

46 See, Xavier Seuba, (European regulation and seizures not only jeopardize the pro-public health interpretation of the TRIPS Agreement, but also the WTO General Council Decision of 30 August 2003 and the proposed mendment to TRIPS Article 31, p.18). Also see, Decision of the General Council of 30 August 2003, “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, IP/C/W/405, 


48 India intervention in the TRIPS Council
of public health and the promotion of the public interest are still part of TRIPS fundamental principles.\textsuperscript{49}

vi. Human Rights Obligations and the WTO

Starting from the fundamental principles of human rights set out in the Charter of the United Nations Organization and other international human rights treaties, customary international law, human rights are recognized as “inherent entitlement of all human beings with universal value and are interdependent, interconnected and indivisible. Any person has the right to enjoy all human rights on the basis of non-discrimination and any violation of certain human rights under specified circumstances amounts to crimes against humanity over which universal jurisdiction could be exercised”.\textsuperscript{50} Studies also say that “not only states but also multilateral institutions such as the WTO fall within the purview and operation of international human rights law and no entity that claims international legal personality can claim exemption from that regime.\textsuperscript{51} While the WTO itself is bound by the international human rights norms, the member States of WTO are also bound by these norms and to this effect the principles of the WTO TRIPS Agreement allows the member States to “adopt measures necessary

\textsuperscript{49} Brazil and India intervention in the TRIPS Council


\textsuperscript{51} Ibid, p.14 (“the claim of multilateral institutions such as the WTO that only individual member States are obliged and not the institution itself – since the institution deals with relation between States rather than that between individuals and States – are untenable in international law. If such a claim were to be considered legitimate, it would seriously erode the international rule of law. Rules governing inter-State relations cannot themselves be formulated in such a way as to defeat the fundamental tenets of international law, including human rights norms”)
to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”.  

Coming to the human rights obligation of States individually, the ECOSOC says that that States have immediate legal obligations in relation to the right to health, such as the guarantee that the right will be exercised without discrimination of any kind and the obligation to take steps towards the full realization of article 12. Such steps must be deliberate, concrete and targeted towards the full realization of the right to health.

In addition to this, ECOSOC General Comment No. 3 drew attention to the obligation of all State parties to take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realization of the rights recognized in the ICESCR, such as the right to health. In the spirit of article 56 of the Charter of the United Nations, the specific provisions of the Covenant (articles 12, 2.1, 22 and 23) and the Alma – Ata Declaration on primary health care, States parties should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health. Not only this, to comply with their international obligations in relation to right to health specified in article 12 of the ICESCR, States

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52 Article 8: Principles of the TRIPS Agreement:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries. Moreover, States also have obligations to facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required.\(^{54}\)

As it is said in the previous section that the Doha Agreement mandates that the TRIPS Agreement should be interpreted in a manner supportive to public health and according to the analysis of the human rights obligations of states in this section, it is not wrong to say that member States of the WTO and the WTO itself are bound to respect the right to health of peoples. Therefore, in the light of this, it is also not wrong to say that EU actions of seizing the generic drugs, which are completely legal according to the WTO and also the destination and source countries, have violated EU’s international obligation towards right to health and access to medicines. By stopping the life saving generic drugs from reaching thousands of people waiting for these medications, EC has definitely violated the right to life of all the people who were expecting those medications.

D. Policy Issues and Concerns

i. Inability to supply affordable medicines to the poor

In connection with the seizure of generic medicines, there were debates regarding the ability of providing affordable medicines to the people of developing and least-developed countries who do not have the manufacturing capacities but are in dire necessity of life saving medicines. Public health groups claims that “the [EC] action

undermines the trade liberalization provisions of the WTO and the WTO TRIPS accord, as they relate to the necessary freedoms to transport legitimate goods to legitimate markets, in a world where territorial patent rights could otherwise present barriers to trade.\textsuperscript{55} and also that “the European Union rules and actions are clearly in conflict with WHO resolution WHA61.21, which states that ‘international negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health’.\textsuperscript{56}

\textit{ii. Big hurdles for access to affordable medicines}

Concerns were also expressed by the generic companies for unnecessary detention of their goods by the EC authorities. For example, the Missionpharma states on the seizures of its two consignments consisting of life-saving medicines ARVs procured for the Clinton Foundation HIV/AIDS Initiative under UNITAID, that “the random seizures seriously impact our ability to service the healthcare needs of people living in developing countries in a timely manner, forcing us to consider re-designing our entire supply chain to avoid any transit through European territories.\textsuperscript{57} A similar view of Health Action International is reported by Kevin Outerson that, “[t]his is a


\textsuperscript{57} See, Missionpharma, Seizure of generic medicine destined for developing countries, (2009), \url{http://www.missionpharma.com/content/us/about_us/news/seizure_of_generic_medicine_destined_for_developing_countries}
grave situation. If the shipment is not allowed to pass, HIV positive Nigerian will miss out on critical treatment. We’re concerned about what appears to be confusion between counterfeit medicines that kill people and generic medicines that save lives”.  

iii. Negotiations for Anti-counterfeiting Agreements: Are Generic drugs under threat?

Ever since the adoption of the TRIPS Agreement its main promoters have strived to raise the standards set forth therein and to guarantee the enforcement of TRIPS provisions through various new paths. One of these paths had been the promotion of new bilateral, regional and multilateral agreements with higher IP enforcement measures including higher border IP enforcement not only for the products


59 See, Xavier Seuba (2009), Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit, Working Paper, International Centre for Trade and Sustainable Development, Geneva, Switzerland. Available at: http://www.iprsonline.org/New%202009/Seuba_Border%20Measures.pdf (Due to the difficulties in increasing the TRIPS standards through the adoption of new WTO obligations, the United States and the European community have followed different paths to enshrine new and higher intellectual property regulations.).

60 Xavier Seuba, Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit, Working Paper, International Centre for Trade and Sustainable Development, Geneva, Switzerland. (2009), http://www.iprsonline.org/New%202009/Seuba_Border%20Measures.pdf ([I]initiative that has been so successful that presently the normative landscape for the international protection of intellectual property rights is totally different and much stricter than it was in 1995, when the TRIPs entered into force. The non-discrimination principle as enshrined in the TRIPS Agreement has played a decisive role in extending the stringent standards set forth in said agreements. Moreover, these new covenants have been instrumental in securing intellectual property rights enforcement, an objective also pursued through additional means. Up until now, lists of allegedly infringing countries, retaliatory measures resulting from those lists diplomatic and economic pressures, and national and international litigation have been the main tools identified by the US and the EC to guarantee intellectual property rights enforcement. Some describe the EC regulation as “a scheme of uncertain compatibility with World Trade Organization law and fundamental intellectual property law principles and norms: the territorial nature of intellectual property rights and the rights conferred to intellectual property rights).
entering the domestic market but also cover in-transit goods. The detention of the
generic drugs in transit “forces the assessment of EC Regulation consistency with WTO
Law, it puts into question the feasibility of international generics trade and, more
importantly, if norms that back the seizures were to become the general legal
framework, the systemic effects on public health could be more worrying.” 61 “In fact,
EC Regulation 1383/2003 implementation against in-transit generic medicines has
heightened debates regarding the already conflicting relationships between, on the one
hand, public health and intellectual property, and on the other hand, free trade and
intellectual property.” 62

III. HUMAN RIGHTS PERSPECTIVES OF THE GENERIC DRUGS
SEIZURES DISPUTE

A. Direct relationship between right to access to medicines, right to health and
right to life

Health is a fundamental human right indispensable for the exercise of other
human rights. Every human being is entitled to the enjoyment of the highest attainable
standard of health conducive to living a life in dignity. As articulated by the United
Nations Economic and Social Council, “right to health contains both freedoms and
entitlement. The freedoms include the right to control one’s health and body and the
entitlements include the right to a system of health protection which provides equality

61 Xavier Seuba (2009), Border Measures Concerning Goods Allegedly Infringing Intellectual
for Trade and Sustainable Development, Geneva, Switzerland,
http://www.iprsonline.org/New%202009/Seuba_Border%20Measures.pdf

62 Ibid
of opportunity for people to enjoy the highest attainable level of health.”\textsuperscript{63} And “the right to health is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health”\textsuperscript{64} and “right to health is broad concept that can be broken down into more specific entitlements including access to essential medicine [emphasis added].”\textsuperscript{65} From the above sentences, it can be concluded that right to health is an inherent part of right to life with entitlements including access to medicines. Therefore, having established the direct relationship between the right to life, right to health, access to medicine, it is now essential to see how these rights have attained the status \textit{jus cogens}.

\section*{B. Applying the \textit{jus cogens} of international human rights law to the generic drugs seizures case}

‘\textit{Jus cogens}’ also known as a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.\textsuperscript{66} According to this definition, an important requirement for a norm to attain the status of peremptory norm is that it should be accepted and recognized by the States as a whole. That means there has to be established state practice of a norm without any derogation. Applying the same analogy to the principles of human rights, one can say that the norms of

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\textsuperscript{64} Office of the UNHCHR, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, \url{http://www2.ohchr.org/english/issues/health/right/}
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\textsuperscript{66} Article 53 of the Vienna Convention of Law of Treaties, 1969.
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human rights as specified right from the Charter of United Nations, the Universal Declaration of Human Rights (UDHR) and their reiteration in the subsequent treaties like the International Covenant of Civil and Political Rights (ICCPR), the International Covenant on Economic Social and Cultural Rights (ICESCR), the American Charter of Human Rights, the African Charter of Human and People’s Rights, the European charter of Human Rights as well as many other UNO’s and its subsidiary agencies S declarations and conventions establishes the fact that human rights have attained the status of *jus cogens*.

As an essential and important human right, right to life, right health and right to access medicines is also guaranteed under various conventions. For example, Article 25 of the UDHR states that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family including food, clothing, housing and medical care and necessary social services and the right to security in the event of unemployment sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”. Article 12 of ICESCR enshrines right to health as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and a duty is imposed on the state to take steps to provide conditions which would assure all medical services and medical services and medical attention in the event of sickness. Right to health is also guaranteed under various conventions. Article 16 of the African Charter of Human and People’s Rights also says that “every individual shall have the right to enjoy the nest attainable state of physical and mental health”. Reiteration of right to health in all these conventions confirms that there is an established state practice to the acceptance and recognition of right to health and right to
access to medicines. This state practice is further strengthened by the fact that almost 60 nations have confirmed the fundamental rights status to the right to life and right to health in their constitutions. Therefore, there is no doubt to say that right to life and right to health are also the peremptory norms of general international law.

Now we shall see how the *jus cogens* is applied to the WTO disputes in general and how the present case is bound by the *jus cogens* of international human rights law. The law applicable to the WTO disputes is discussed in the rules set in the WTO Dispute Settlement Understanding (DSU).\(^67\) Article 3.2 of the DSU mandates that, interpretation of the WTO agreements shall be in accordance with the customary rules of interpretation of public international law.\(^68\) On other hand, the Law of Treaties which provides the customary rules of interpretation prescribes that “a treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law.”\(^69\) In the present case of generic drug seizure as justified under the EC Regulation 1383/2003, two issues have to be resolved. One is EC regulation is in violation of the WTO and the TRIPS Agreement. Second is the WTO members are bound by the peremptory norms of international law in general and in the present case the EC actions of seizures have violated the international human right norms which are peremptory norms of international law.

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\(^{67}\) Annex 2 of the WTO – GATT Agreement

\(^{68}\) Article 3.2 of DSU states as follows:

“The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements”.

In the previous sections, the analysis suggests that EC Regulation 1383/2003 is in violation of the WTO and TRIPS provisions. It is also established that the right to health and access to medicines are inherent parts of right to life which is already a peremptory norm of international law. And it is also understood that WTO member states are bound by their human rights obligations and they cannot derogate from their obligations which are also peremptory norms of international law. Therefore, according to Article 53, it would be right to say that EC Regulation 1383/2003 has not only violated the WTO and peremptory norms of international law but has also violated its obligations towards human rights.

IV. CONCLUSION

Right to health and the right to access to medicines are inherent parts of right to life and are also part of *jus cogens* on international law and international human rights law. The sources of human rights relating to the TRIPS are the customary international law, the Universal Declaration of Human Rights and Covenant on Economic Social and Cultural Rights, etc. In accordance with DSU article 3.2, the WTO dispute settlement body would clarify TRIPS provisions “in accordance with customary rules of interpretation of public international law”. Pursuant to the general rule of interpretation of international treaties, contained in article 31 of the Vienna Convention on the Law of Treaties, and more specifically, in accordance with article 31.3.(a), when interpreting a treaty, any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions shall be taken into account. Doha Declaration on Public Health and the WTO General Council Decision of 2003 to implement
paragraph 6 of the Doha Declaration is widely considered as a subsequent agreement to the TRIPS Agreement. Article 4 of the Doha Declaration on Public health requires that “the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

While maintaining its commitment towards public health, Article 5.a) of the Doha Declaration on Public Health provides flexibilities which also includes that “in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles”. So, applying of the international human rights norms as they are part of public international law is mandatory for the WTO DSB. In the present case, it is already established in the prior sections that the EC actions have violated the TRIPS objectives and principles.

In addition to this, the EC Regulation and the EC Actions have seriously affected the rights of the people for whom the medicines were intended. By seizing the medicines, EC actions have not only affected their right to access to essential and life saving medicines, it has also violated the right to health and hence right to life of the peoples of the developing countries for which the medicines were destined.

On the one hand access to medicines is articulated as an essential part of right to health and it is also understood that right to life also includes right of a healthy life. Much has been debated about the implications of the TRIPS Agreement on the right of access to medicines. Though the debate got subsided to some extent with the adoption of the Doha Amendment on Public health, the detentions of the generic medicines have
once again raised this issue of IPRs compatibility of right of access to medicines. However, in the light of the above discussion one thing is clear that the EC actions and the EC Regulation have violated the public health provisions of the WTO-TRIPS agreement and also the Doha agreement on public health by hampering the right of developing country people from access to essential medicines. Having established that the right of access to medicines and right to health are inherent within the right to life, one can confidently claim that the EC Regulation and the actions taken accordingly clearly violates the people’s right to life who are expected to receive the medicines that were detained. Therefore, in addition to trade argument, the generic drug case can also be presented with a human rights argument by applying *jus cogens* of international human rights law.
ANNEX

List of News Posts on the Issue of Generic Drug Seizures


2. CENTAD (2009), India seeks justice as against uncalled for drug seizures by EU, http://www.centad.org/tradenews_1093.asp

3. CENTAD (2009), Rigorous IP enforcement standards can restrict access to generic drugs, http://www.centad.org/tradenews_1069.asp


