SEIZURE OF GENERIC PHARMACEUTICALS IN LOSARTAN CASE: THE CONFORMITY OF EC REGULATION 1383 WITH THE INTERNATIONAL STANDARDS OF IP PROTECTION

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INTRODUCTION

One of the most heated debates in the IP field has started on 2008, when the Dutch custom authorities seized a big amount of containers of in transit generic pharmaceuticals originated from India and having Brazil as their final destination. The legal basis of this particular seizure was the application of the EC Regulation 1383/2003 concerning the Border measures and Freedom of Transit in EU countries[i]. From the first reactions of the two countries involved in the incident, namely Brazil and India as well as from other developing countries, it is possible for someone to understand the main concern related to the application of EC Regulation 1383 to the trade of generics in transit. In the International IP Protection, the emergence of a strong lobby of developing countries at the World Trade Organization (hereinafter WTO) has made it harder for the developed countries, such as the members of European Union to achieve a very high standard of IP protection by introducing strong and effective trade and IP policies in the WTO[ii]. Thus, these countries has used their independence to select appropriate measures for the implementation of IP protection so as to introduce measures of absolute and high standard protection in regional and multilateral Agreements[iii], such as the EU law. As a result, this high standard protectionism in the regional level has several consequences on the flexibilities and policy space left under the TRIPS Agreement by making meaningless the use of these flexibilities by developing countries in important policy sectors such as Public Health and the Access to Knowledge[iv].

On 19 May 2010, India and Brazil submitted their request for consultation with the European Union and the Netherlands to the WTO with express reference to the specific incident involving

the seizure of the shipment of the generic Losartan Potassium by customs authorities, while in transit through the Netherlands.[v] In their requests, the countries claimed several provisions of EC Regulation 1383 and their application to be inconsistent with provisions of WTO and international intellectual property law. In 2011, India has agreed in the non- establishment of a Panel for the dispute, after signing a mutual 'Understanding' with EU, in which European Union has agreed to an amendment of deficiencies of the Regulation 1383[vi]. However, the request of Brazil is still pending for a Panel establishment and it will be really interesting to examine some of the main arguments related to the dispute before the final decision by the Panel.

This paper is intended to look through the EC Regulation 1383 and its subsequent application by the custom authorities and judicial fora within the Union, in order to track down the inconsistency of EU border measures with the TRIPS Agreement and the principles of international intellectual property law.

Part II of the paper provides the factual background of Losartan incident and the reactions and arguments of the involved countries at the WTO General Council meeting. In Part III, we move to the meticulous examination of the origin and the scope and content of EC Regulation 1383. We examine as well the application of the Regulation by custom authorities of the Member States and the interpretation of the Regulation by national and regional courts. In Part IV, we examine the consistency of the regulation with TRIPS Agreement and Doha Declaration as well as with other principles of international IP law and trade law.

FACTUAL BACKGROUND OF LOSARTAN INCIDENT AND THE REACTIONS OF INVOLVED PARTIES AT THE WTO GENERAL COUNCIL MEETING

The Factual Background of Losartan incident

Losartan Potassium is a drug for the clinical treatment of hypertension. By the time of the incident, the drug was not patented in either India or Brazil. However, the drug was patented in Europe under the name 'Cozaar' with EI Du Pont Nemours & Co owning the patent and Merck Sharp and Dohme holding the marketing rights[vii].A cargo of 500 kilograms of this drug was being transacted between Indian manufacturer Dr. Reddy's Laboratories Ltd and the Brazilian importer Grupo EMS Sigma Pharma (EMS)[viii], while was seized in transit by the Dutch customs of Rotterdam port on charge of patent infringement. The basis for the

abovementioned action of the Dutch Customs Authorities was the administrative request lodged by Merck Sharp and Dohme, which was the European patentee of 'Cozaar'[ix]. The measure was justified as a response to patent rights violation pursuant to provisions set out in the EC Regulation 1383 and the Dutch Patent Act of 1995.

The Countries' Interventions at the WTO General Council Meeting and the basic argumentation of the parties to the dispute.

The involved parties, e.g. India and Brazil reacted instantly on this seizure of generics and brought up the issue at the WTO General Council Meeting of February 2009. The Ambassadors of both countries at the WTO claimed that the Netherlands, as WTO member, had no grounds to block legitimate shipping of generic medicines on the basis of potential IP rights conflicts in the transit country and they underlined that the continuous incidents of this kind by the same country as well as by other European countries call into question WTO law. Particularly, Roberto Azevedo, the ambassador of Brazil in the WTO has made a very powerful intervention by stating, first of all, that under TRIPS Agreement, medicines are considered to be generics based on the country in which they are meant to be commercialized- in the current case either Brazil or India- and consequently the law of the country of transit does not matter.[x] India supported this argument strongly and expressed the idea that the concept of territoriality is a milestone of the TRIPS Agreement.[xi]

The Brazilian Ambassador also claimed that the measure taken by Dutch custom authorities violated the freedom of transit in trade as it has been expressed in Article V of the General Agreement on Tariffs and Trade, 1994 (GATT 1994). Only exceptional circumstances are allowed to derogate freedom on transit and the present circumstance was not prompt for derogation of Article V.[xii] In relation to the incident and the WTO law, the Brazilian ambassador has pointed out that the seizure of the shipment of generic medicines by the authorities of the port of transit has set a dangerous precedent[xiii] for the enforcement of IP protection by custom authorities and in combination with similar incidents held in EU member states, it has created systemic problems with WTO rules such as the extension of the rights granted by patents beyond national borders.[xiv]

In relation to his previous statement on the extraterritoriality of patents rights particularly when it comes to the trade of pharmaceuticals and generics, the Brazilian Ambassador acknowledges

that the 2001 Doha Declaration on TRIPS and Public Health[xv], which enshrines the context of TRIPS Agreement on health priority and protection, is not possible to justify the extraterritorial enforcement of patent rights[xvi]. On the contrary, the seizure of the generic pharmaceuticals by the Dutch custom authorities sets in real danger the implementation of 'paragraph 6 mechanism' at the WTO, which refers to the flexibility of countries lacking manufacturing ability to import needed medicines from other members under a compulsory cross- licensing arrangement.[xvii]

Despite the practical character of the Brazilian intervention, which underlined the different negative aspects of the current situation and the conflicts with the international intellectual property protection standards, it was the intervention of India that set the problem on the actual political context. As it was referred in the introduction of the current paper, developing countries express lots of concerns due to the fact that developed countries are using legal ways out of the WTO in order to raise the standards of intellectual property protection and undermine the use of flexibilities granted to developing countries. This concern has been raised by the Indian Ambassador and supported by Brazil and other developing countries. Indian Ambassador was concerned about efforts by some of the countries to increase the 'IP maximalist agenda'[xviii] , meaning to increase the enforcement on goods in transit and blur the line between generic and counterfeit medicines in international organizations such as the World Customs Organization (WCO), the World Health Organization and the Universal Postal Union. India noted also that, under this IP maximalist agenda, there is an attempt bu developed countries to enlarge the definition of counterfeits beyond its definition in the TRIPS Agreement so as to include TRIPS-plus provisions in regional and border measure agreements and consequently reduce the flexibilities of IP protection for the developing countries.[xix] As final statement, the Indian Ambassador reminded to the representatives]that continuous incidents like the Losartan incident could result to a general threat concerning the access to medicines for many countries, since the re-routing of shipments for avoiding seizures of pharmaceutical cargos would have great impact on the public health budgets of developing countries[xx].

In defence for the actions of the Dutch authorities, the EU Ambassador stated that the seizure of the cargos by the Dutch authorities was in conformity with EU and WTO law, in particular with Article V of GATT and Article 51 of the TRIPS which allows custom authorities to suspend the release[xxi]. In order to explain the nature of the measure, he categorized the action

as a 'temporary detention'[xxii] which was allowed by TRIPS and was based on provisions in EU customs law that allow customs to temporarily detain any goods if they suspect that these goods infringe an intellectual property right[xxiii]. In response to India's concerns on the IP maximalist agenda, he clarified that EU' s intention is not to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries.[xxiv]

The same argumentation and statements has been followed by the involved parties in the consultations documents, however, it safer for the research purposes of this paper to investigate on our own the consistency or not of the action in issue with the TRIPS and the principles of International IP protection, instead of relying on a case analysis. For this reason, in the next part, we will analyze the origin, scope and interpretation of the EC Regulation 1383 so as to give the exact legal context on which the seizure of generic pharmaceuticals by the Dutch authorities has been based.

THE ORIGIN, SCOPE AND CONTENT OF EC REGULATION 1383

The origin and scope of EC Regulation 1383

The Regulation 1383 is an EU law prescribing the scope and procedure for border enforcement of IP rights and forms the central pillar of the European Commission' s efforts to secure greater protection of IP rights. The process for the formation of the absolute EC Regulation 1383 has began in 1986, with the EC Regulation 3842/86 which was allowing border measures to be imposed by the custom authorities of the legal space of the European Communities in cases of importation of counterfeit goods[xxv].This EU border enforcement law was limiting protection to copyright infringing goods and was providing no ex officio procedure for the initiation by the custom authorities. The scope of border measures was expanded with EC Regulation 3295/94[xxvi]to pirated goods, meaning goods infringing copyrights and design rights. This protection was available in case of importation of the goods and in cases of exportation, re-exportation and suspensive procedure. However, it is only on 1999, when an amendment on the regulation expanded protection so as to include protection of patent and supplementary protection certificate rights[xxvii] As Enrico Bonadio has successfully stated the 1999 amendment represented the realization of a long- cherished dream of European pharmaceutical companies to include patent infringing goods within the scope of the border enforcement law[xxviii].

In 2003, the EC Regulation 1383 was enacted to expand much further the scope of IP rights protected.

THE NORMATIVE CONTENT OF THE EC REGULATION 1383

The EC Regulation 1383, as it is now, covers patents, supplementary protection certificates, plant variety rights, designations of origins and geographical indicators, in addition to the protected trademarks and copyrights, as we mentioned above[xxix]. According to article 1.1, customs authorities are permitted to take action against goods suspected of infringing IP rights when they enter the EC territory for release for free circulation, export or re- export, as well as in cases of infringing goods found during checks when entering or leaving the EC territory, placed under a suspensive procedure, in the process of being re- exported subject to notification or placed in a free zone[xxx]. The law covers also goods placed under suspensive procedures, not intended for the EC and merely transiting through the customs territory of the EC[xxxi]. Thus, the allowance of border authorities to take action in cases of transhipment of goods, provides European authorities with the opportunity to impede a large volume of trade in generics between developing countries, as it has happened in the Losartan incident.

Nevertheless, it is wise to examine how the normative content of the Regulation 1383 has been interpreted by European and national courts of the member States in cases of border enforcement of IP rights against goods in transit. Despite the dichotomy in the practice of the European Court of Justice in relation to the application of the predecessors of the present EC Regulation 1383, the European Court of Justice has given only one decision related to the application of the Regulation to goods in transit. In the Montex case of 2006, the ECJ has said that only if the goods in transit are subject to the act of a third party while placed under the external transit procedure which necessarily entails them being put on the market in that Member State of transit, it is possible for the trademark holder to prohibit such transit[xxxii]. This line of reasoning has been followed as well in Nokia case before the High Court of England and Wales. The case was about the detention of counterfeit mobile phones in transit and the Court held that EC Regulation 1383 did not cover counterfeit goods that were merely in transit and not meant for the UK markets. According to the ruling, the goods must have been used in the course of trade within the territory of UK for them to be detained of seized under EC Regulation 1383[xxxiii].

However, in the Netherlands, the Dutch courts have taken a complete contrary position. This explains at a certain point why Dutch custom authorities implement the EC Regulation 1383 in such a way for goods in transit. In the Sisvel case, the District Court of The Hague upheld the detention of a stock of MP4 players in transit from China to Brazil by Dutch Customs. The court based its judgement on the reasoning that a 'manufacturing fiction' could be derived from Recital 8 of the EC Regulation 1383[xxxiv]. In other words, in order to establish infringement of IP rights, goods in transit can be considered as goods which have been manufactured and produced within the transit country. This legal structure allows Dutch customs authorities to detain goods, which in their country of origin and final destination do not fell under IP protection. This legal structure is against what has been established by ECJ jurisprudence in reference to the application of the Regulation 1383 in goods in transit. Furthermore, this legal structure seems to go against a well- established principle of international IP law: the independence of patents[xxxv]. The independence of patents and the principle of national treatment in Article 2 of the Paris Convention seem to suggest the elimination of the possibility of interdependence between patents in different countries for the same invention. The rational for this principle is the Paris Convention's recognition that the laws governing patents differ from one state to another[xxxvi]

CONSISTENCY OF EC REGULATION 1383 WITH THE TRIPS AGREEMENT STANDARDS AND OTHER PRINCIPLES OF INTERNATIONAL IP PROTECTION LAW

The Regulation 1383 and the TRIPS Agreement standards

Under the general notion of international IP law, which sets the minimum standards for IP protection, countries are allowed to freely decide whether or not they want to extend the minimum standards required by international IP Agreements. For the border measures, in particular, the TRIPS Agreement codifies the relevant minimum standards of IP law in Part III, section 4. In relation to the present issue of border measures for goods in transit, Article 51 of TRIPS states that:

'Members shall, in conformity with the provisions set out below, adopt procedures (13) to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods(14) may take place (...)'[xxxvii]

By the analysis of its wording, article 51 states that there is no obligation for the Member States to apply border measures to cases of IP infringement other than trademarks and copyright. Additionally to this footnote 13 of this Article refers to border measures to goods in transit and states that ' there shall be no obligation to apply such procedure 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'. This wording indicates that the footnote offer border measures to goods in transit as a possibility and not as an imposed obligation to member States[xxxviii]. The EC Regulation 1383 extends the minimum standard of protection, set by both Article 51 of TRIPS and Footnote 13, since it extends border measures to transit goods and in cases of infringement of IP rights other than trademarks and copyrights[xxxix]. Taking as given that countries are allowed to extend the minimum standards required by International IP Agreements, the Regulation, prima facie, seems to be consistent with TRIPS.

Nevertheless, the TRIPS Agreement sets a limit on the extension of the minimum standards by the Member States, which is contained in the second sentence of Article 1.1:

'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**[xl]'

The importance of this provision 'as such, it does not set out any binding limits. It however opens the door for examining the consistency of TRIPS- plus norms with TRIPS provisions'[xli].

Except of the provisions of the TRIPS Agreement, the extension of border measures should not contravene the second sentence of Article 51, which states that any border measure affording greater protection than the minimum contained in TRIPS must specifically be in accord with Section 4 of Part III of TRIPS, meaning in conformity with Articles 51-60. Thus, we cannot admit that EC Regulation is in conformity with Article 51 on the extensions of standards unless we examine that this extension contravenes any other TRIPS Provision and more particularly any of the Articles 51-60.

The issue of the law of country of importation

Article 52 of TRIPS requires that the applying right holder provide adequate evidence to satisfy the competent authorities that 'under the law of the country of importation' there is an

infringement of the right holder's IP right[xlii]. In addition to this Footnote 14 of Article 51 defines counterfeit trademark goods and pirated copyright goods according to the 'law of the country of importation', since it is the law that determines the infringement of IP rights. Thus it is important to determine which the law of country of importation is in order to determine the consistency of EC Regulation 1383 with TRIPS. There are two scenarios in this case: a) If the meaning of the phrase 'country of importation' means the country of final destination, the Regulation will be inconsistent with Article 52 and Footnote 14 and b) If the concept of 'country of importation' means the country through which the goods are in transit then the Regulation will be fully consistent with TRIPS.

TRIPS itself does not define the notion 'country of importation' explicitly. The issue has been a matter of dispute before many national courts, where the context of importation has been decided on the context of the specific dispute.[xliii] In order to resolve this ambiguity, it is wise to use the toolbox of Public International Law and more particularly the Vienna Convention of the Law of Treaties (hereinafter VCLT). Article 31 of VCLT on the interpretation of treaties requires that:

'A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the lights of its object and purpose''.

The context to be taken into account for interpreting treaty provisions must be derived from the text of the treaty and any other agreement or text concluded by the parties in connection with that treaty.[xliv]

In order to define the context of 'importation' in the TRIPS Agreement, there are some provisions in the TRIPS Agreement that might be able to help us. For example, Article 44 of TRIPS understands the imported goods as destined or likely to enter channels of commerce in a country, by stating that:

'1. The judicial authorities shall have the authority to order a party to desist from an infringement , inter alia to prevent the entry into channels of commerce in their jurisdiction of imported goods that involve the infringement of the intellectual property right, immediately after customs clearance of such goods'.

Besides, Article 50 in its first section states that : 'The judicial authorities shall have the authority to order prompt and effective provisional measures : a) to prevent an infringement of any intellectual property right from occurring and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after custom clearance.'' The wording of this article suggests that imported goods are those destined for commercial use in the country where customs clearance takes place. Thus, from these two provisions we understand that one possible interpretation of the word 'importation' would be the possibility of the goods entering the channels of commerce in a country.

Another provision that could amount to a successful interpretation of 'importation' is Article 41.1 of TRIPS in combination with the Preamble of TRIPS. In the Preamble of TRIPS, it is stated that WTO Members are obliged to:

'... ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.''

In addition to this, Article 41.1 also acknowledges that the enforcement procedures specified under Part III of TRIPS ' **shall be applied in such a manner as to avoid the creation of barriers to legitimate trade...**'. Consequently, the interpretation of the notion 'country of importation' prohibits measures posing obstacles to the legitimate trade.

From the interpretation given above there are two questions that might be raised, particularly in the context of the case examined here, meaning the trade of generics; first of all what constitutes legitimate trade and secondly if trade in generics is indeed legitimate. The Panel in Canada – Pharmaceutical Products has acknowledged as legitimate trade the one that:

' .....must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are justifiable in the sense that they are supported by relevant public policies or other social norms'[xlv]

From the definition given above, it seems that it is important to answer to two issues for giving the exact content of the legitimate trade. First of all, we need to establish if the goods being in transit are a part of the legitimate trade and, for the judgement whether or not the application of the Regulation 1383 is in conformity with TRIPS provision 52 in the current case, we need to establish the legitimacy of trade in generic pharmaceuticals. In relation to the first issue

regarding transit forming a part of legitimate trade, we need to make a distinction based on the interpretation of 'importation' given above. In one hand, normal transit in due course of goods being traded between two nations may be seen as constituting part of legitimate trade. On the other hand, cases of transit of goods where there is a possibility of the entry of the goods in the channels of commerce of the country through which they transit may not be seen as constituting a part of legitimate trade. Thus, only in cases where there is a risk that goods in transit may enter the local market of the transit country, the law of the country in transit is included in the notion of importation. However, this distinction of goods in transit seems to be effective only regarding counterfeited or pirated good in transit.

In relation to the issue of the legitimacy of trade in generic pharmaceuticals, when the generic drugs are legitimate in the exporting country and in the importing country, the legitimacy of trade in generic pharmaceuticals is beyond any doubt[xlvi]. According to Shashank Kumar, it is unfair to equate trade in generic pharmaceuticals with trade in counterfeit or pirated goods, since the former trade activity has established its legitimacy of trade in the Doha Declaration and in the document of Paragraph 6 Decision, where it is provided a mechanism within the TRIPS itself for the manufacture and trade of such pharmaceuticals.[xlvii]

Concluding the current section, according to the Preamble and Article 41.1 of TRIPS, importation should be read in a manner that does not allow the existence of barriers to legitimate trade. In order to define as legitimate the trade of generics, this should be defined as legitimate both by the country of exportation and by the country of importation. Thus the interpretation of the importation country in this discourse is a one way road, meaning the importation country of the final destination, whose legal framework establishes the legitimacy of trade of generics. Any other interpretation of importation in this discourse, such as the one of EC Regulation 1383 where the transit country is considered as the importation country clearly hinders legitimate trade and impedes the transit of generics pharmaceuticals in contravention with Article 52 of TRIPS.

CONCLUDING REMARKS

As it has been stated in the beginning of the current paper, India has withdrawn from the Panel dispute settlement after the signing of a mutual Understanding with EU under the condition that EU would amend in the near future the problematic border measure regulation. However,

Brazil seems to be more determined and her request on the establishment of a Panel still remains pending at the WTO. It would be really interesting, after the analysis of this paper to see how the Panel is going to use TRIPS standards in order to reach a decision on the consistency of EC Regulation 1383 and its application to goods in transit. The current paper made an attempt to use some of the TRIPS standards not as minimum but as maximum standards in order to interpret the extensive protection of IP under EU law and demonstrate the inconsistency of EC Regulation 1383. We would like to see the future Panel, established under Brazilian request, to follow a similar logic in order to interpret TRIPS in a way that its standards would be able to stop the raising protectionism of IP rights by developed countries in regional and multilateral levels.

As far as for the interpretation of Doha Declaration, a future Panel on the dispute of generic pharmaceuticals in transit and the application of border measures would be the ideal test for Doha Declaration so as to establish its normative nature and its primary position on the interpretation of TRIPS Agreement. It will be also a very good occasion for starting again the debate on the deficiencies of Paragraph 6 mechanism so as to establish a more effective framework for the trade of generic pharmaceuticals in the future.

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[xxxix] Article 2.1(c), EC Regulation 1383.

[xl] Article 1.1, second sentence, TRIPS Agreement.

[xli] Grosse Ruse – Khan, *Supra* note 4, p. 71

[xlii] Article 52, TRIPS Agreement

[xliii] Gramophone Company of India v. Birendra Bahadur Pandey & Ors. A.I.R. 1984 SC 66, Supreme Court of India, para 29.

[xliv] Article 30.2, VCLT

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