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Seizure of Indian Generic Drug Shipment by Dutch Authorities¹

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1. Facts

Between October and December 2008 there were four shipments seized and held by Dutch customs authorities of generic medicine ingredients exported from India to Brazil.

The detained cargo consisted of 500 kilos of losartan potassium which was traded between the Indian company Dr. Reddy's and the Brazilian importer EMS

The actions of Dutch authorities were taken on the request of a company (possibly brand-name drug producer) who holds the patent in the Netherlands. The shipment of the generic version of losartan was on its way to Brazil when seized in transit in the Netherlands. It was held for 36 days by customs authorities in Rotterdam which were stating that it infringed the existing patent in the Netherlands of the original drug named Cozaar. However, Losartan is not patented neither in India nor Brazil. After it had been established that these goods were not intended for the EC market, they have finally been released by the authorities and have been sent back to India.

2. Relevant legal provisions

The actions by Dutch customs were based on the EC-Regulation 1383/2003. The relevant WTO legal provision related to this case can be found in GATT and the TRIPS Agreements.

With regard to the TRIPS Agreement, the relevant Articles would be Article 28 (*Rights Conferred*); Article 50 in Section 3 of TRIPS relating to Provisional Measures; Article 51 (*Suspension of Release by Customs authorities*), Article 52 (*Application*), Article 55 (*Duration of Suspension*) in Section 4 of TRIPS relating to *Special Requirements Related to Border Measures*

Under the GATT the relevant Articles are Article V (*Freedom of Transit*) and Article XX (*General Exceptions*).

3. Legal assessment

3.1. General remarks

This section aims to examine the seizure of the shipment of generic drugs by Dutch customs authorities and the applicable provisions of the relevant agreements, treaties and regulations. Any eventual violations of GATT or TRIPS provision by the EC-Regulation 1383/2003 could either be challenged through an “*as such*”-claim or through an “*as applied*”-claim under the dispute settlement mechanism of the WTO. An “*as such*” claim is related to the inconsistency of laws or regulations of a given member state with its obligations under the WTO, whereas the “*as applied*” claim relates to the specific administrative measures taken by a member state.

3.2. EU obligations under WTO agreements

According to Article XI (1) of the Agreement Establishing the WTO, the European Union is one of the original Members of the WTO. Article XVI (4) of the same Agreement obliges every member to bring its laws and regulations in conformity with its obligations under the WTO. Accordingly, Article XVI (4) reads as follows:

“Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.”

Due to its obligations as a member of the WTO, the EU must bring its laws and regulations in conformity with the WTO-Agreements in cases where they conflict with WTO provisions. With regard to Article XVI (4) of the Agreement Establishing the WTO, the WTO obligations of the EU take precedence in cases where obligations under EU law or regulations conflict with WTO obligations.

3.3. Legal assesment of relevant provisions under the TRIPS Agreement

Article 28 TRIPS

Article 28 TRIPS deals with the rights conferred under patents and defines the scope of the protection of intellectual property rights. It confers the right holder certain exclusive rights on either products or processes with regard to his patent.

The patent rights conferred under Article 28 are limited to the production, sales and import of a patented product within the territory where the right holder has requested patent protection. Nevertheless, these rights conferred do not apply to goods in transit.

Articles 51 and 52 TRIPS

Section 4 of the TRIPS Agreement deals with special requirements for the enforcement of intellectual property rights related to border measures. There are two Articles which are of particular relevance for the present case.

First, Article 51 dealing with the “Suspension of Release by Customs Authorities”, second, Article 52, dealing with the “Application” for such measures.

Article 51 first sentence obliges Members to adopt procedures which enable “*a right holder, who has valid for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing [...]for the suspension by the customs authorities of the release into free circulation of such goods*”.

In addition to the first sentence, the second sentence of TRIPS Article 51 (Suspension of Release by Customs Authorities) reads as follows:

“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”.

Article 51 second sentence read together with Art. 51 first sentence TRIPS allows countries to adopt procedures which enable a right holder with valid grounds that an infringement of his patent right may take place, to file an application with the responsible customs authorities for the suspension of the release of the suspected goods.

The notion of “*goods which involve other infringements of intellectual property rights*” under Article 51 second sentence implies that Member States may authorize their custom authorities to seize goods on the basis of suspected violation of patent and therefore extends the scope of applicability of this article to patents.

Furthermore, the wording under Article 51 second sentence, which says that Member States *may* enable such a procedure in situations falling under Article 51 second sentence, suggests that in cases of possible violation of patent rights, member states are not obliged but may provide right holders with this possibility.

With regard to whether the procedures under Article 51 are equally applicable on goods in transit, footnote 13 of Article 51 TRIPS states the following:

“It is understood that there shall be no obligation to apply such procedures [...] to goods in transit.”

Footnote 13 implies that Member governments can, but are not obliged to apply *such procedures* (meaning border measures under Article 51) to goods in transit on the basis of suspected violation of patent. Nevertheless, the wording of footnote 13 clarifies that goods in transit can be affected by such border measures.

Article 52 TRIPS further determines the necessary requirements for the initiation of any procedure under Article 51 TRIPS by saying that any right holder must provide adequate evidence “*to satisfy the competent authorities that, under the law of the country of importation, there is prima facie an infringement of the right holder’s intellectual property right*”.

Furthermore, Article 52 TRIPS clearly determines that the “*law of the country of importation*” shall apply when deciding whether a patent right had been infringed. Due to this wording,

Article 52, read in conjunction with Article 51, allows for two possible interpretations of the “country of importation” requirement.

1st possible interpretation under Article 52 TRIPS

In the present case, the Netherlands can be considered as a transit country whereas the country of importation would be Brazil. Therefore, referring to the wording of Article 52, the *law of the country of importation* is the Brazilian law and the goods are considered goods in transit to which footnote 13 of Article 51 applies.

2nd possible interpretation under Article 52 TRIPS in conjunction with Article 51 first sentence

On the other hand, the wording of Article 51 TRIPS first sentence, refers to “*valid grounds for suspecting that [...] importation [...] may take place*”.

Reading the Article 52 in the context of Article 51, it could be argued that the Netherlands is the country of suspected importation. In that case, the “*law of the country of importation*” would be the law of the country where the suspected importation might take place, that would be the Dutch law. As a consequence of such an interpretation, any assessment of the Dutch customs action would have to be based on a prima facie infringement of Dutch patent law. According to this interpretation, reading the “*law of the country of importation*” requirement under Article 52 TRIPS would not necessarily mean the law of the country of final destination.

Under the foregoing analysis of Articles 51 and 52, the action by the Dutch authorities based on a possible infringement of patent rights can be assessed differently, depending on the applied definition of “*country of importation*”. The definition of “*country of importation*” is also decisive with regard to the applicable law determining any infringement of intellectual property rights.

Interpreting the criteria of “*country of importation*” in the strict sense of Article 52 would determine Brazil as the country of importation and make Brazilian patent law the applicable law to determine a possible infringement of any patent rights. According to our information,

there did not exist a patent right for the respective product in Brazil. Therefore, the action of the Dutch authorities could be considered as a violation of Article 52 TRIPS.

Contrary to the previous argumentation, interpreting the criteria of “*country of importation*” under Article 52 in combination with Article 51 first sentence, would determine Netherlands as the country of suspected importation and Dutch patent law the applicable law to determine an infringement. In such a case, the action of Dutch authorities would not amount to a violation of the provision under Article 52 TRIPS.

Article 50 TRIPS

Article 50 TRIPS aims to prevent infringements of intellectual property rights and contains provisions allowing for provisional measures to prevent such an infringement. For this reason Article 50. 1 (a) TRIPS authorizes the judicial authorities to order “*prompt and effective provisional measures 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 customs clearance*”.

Article 50 TRIPS therefore is applicable on goods suspected to infringe an intellectual property right, in particular goods which are no more under customs clearance, in order to prevent their entry into the channels of commerce. With regard to the facts of the present case and the fact, that the seized goods did not have entered the channels of commerce yet, it is important to stress that Article 50 TRIPS can not be invoked by the EU as a basis of the action of the Dutch authorities.

Comparison of Article 50 with Article 51 TRIPS

Article 50 and Article 51 TRIPS Agreement both aim to prevent infringements of intellectual property rights.

Article 50 TRIPS Agreement deals with provisional measures to prevent an infringement of intellectual property rights. For that reason Article 50. 1 (a) TRIPS authorizes the judicial authorities to order “*prompt and effective provisional measures 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 customs clearance".

Article 50 TRIPS therefore is applicable on goods suspected to infringe an intellectual property right which are no more under customs clearance in order to prevent their entry into the channels of commerce. With regard to the facts of the present case, it is important to stress that Article 50 TRIPS can logically consistent not be applied to goods in transit.

It might seem that this article describes only internal measures specifying the imported goods immediately after customs clearance. However, this interpretation might be too restrictive with regard to the expressions "in particular" and "including" in Article 50 TRIPS, as they not necessarily must have a restrictive meaning. It could be argued, that the sections of the provision following the expression "in particular" should be read merely as an example of goods to which such measures should be applied.

Article 51 TRIPS by contrast defines the requirements for the suspension of the release of goods which are suspected to infringe an intellectual property right by customs authorities. The requirements of Article 51 TRIPS especially apply to measures at the border before the respective goods can enter into the channels of commerce. This means that Article 51 TRIPS applies to goods which are still under customs clearance in contrast to the requirement of "imported goods immediately after customs clearance" under Article 50 TRIPS.

Generally, Article 50 and Article 51 TRIPS Agreement seem to be mutually complementary provisions. In case the right holder has failed to lodge an application for suspension by customs authorities under Article 51 and the goods suspected to infringe an intellectual property right are already about to enter into the channels of commerce of the respective country, then provisional measures under Article 50 TRIPS can be applied.

Article 55 TRIPS

In order to establish whether the detention of 36 days exceeded the time periods mentioned under Article 55 TRIPS and has therefore violated Article 55 TRIPS, it would be necessary to have more detailed information about the action of the Dutch authorities.

TRIPS Article 55 states that the duration of suspension should not exceed 10 working days and may be extended by another 10 working days in appropriate cases. One has to take into account, that this period starts after the applicant has been served notice of the suspension, which might take several days. Furthermore, this period is to be respected only, if the customs authorities have not been informed that proceeding leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods. Therefore, even if the goods were seized for 36 days, it would be necessary to examine the details of the procedure in order to conclude whether it was a breach of TRIPS agreement.

In accordance with the known facts, the delay amounted to 36 calendar days. Due to the detainment of the generics on December 04, 2008, goods have been released after 36 days on January 08, 2009. This means that the goods have been seized for the time of 23 *de facto* working days, if weekends, December 25, 26. and January 1. are not taken into consideration as they were public holidays.

Applying Article 55 TRIPS to this calculation, the detention should not exceed $x + 20$ working days, where x stands for the period in which the applicant should have been informed. In this case it seems that this was 3 days, which seems to be an appropriate delay for informing the applicant.

Therefore, any assesment of an violation of Article 55 TRIPS depends on the time necessary to inform the applicant about the beeginig of the detention of the goods by the customs authorities.

Enforcement of patent rights under the TRIPS Agreement

Article 41 TRIPS, which is dealing with the general obligations concerning the enforcement of intellectual property rights, states that members “*shall ensure that enforcement procedures [...] are available under their law so as to permit effective action against any act of infringement if intellectual property rights covered by this Agreement [...]*”. This general obligation for Member States has to be read in connection with Article 51 first sentence and its authorization under footnote 13 to apply such enforcement procedures also to goods in transit.

Furthermore, as already elaborated under the first question, the criteria for initiating an enforcement procedure under Article 52 TRIPS is whether under the *law of the country of importation* a patent right had been infringed. This suggests that the customs authority of any Member State can enforce the patent right as soon as the good infringes a patent right under the law of the country which is the place of final destination of that good.

As the TRIPS Agreement under Article 41 TRIPS does not explicitly limit the enforcement procedure to the country of importation and does extend the enforcement procedures related to border measures to goods in transit, a possible argumentation would be such that the law on enforcement of patents is not only territorial but also applies to goods in transit.

3.4. Legal assessment of relevant provisions of the GATT

Possible violation of Article V GATT

Article V determines the freedom of transit between WTO members. Article V paragraph 1 contains the definition of “traffic in transit” whereas Article V paragraph 2 defines “freedom of traffic” under the GATT Agreement. Paragraph 2 confers Member States the right to “*freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties*”.

Article V paragraph 3 further states that this traffic in transit, *except in cases of failure to comply with applicable customs laws and regulations [...] shall not be subject to any unnecessary delays or restrictions [...]*. In addition, all formalities and charges with regard to traffic in transit shall be reasonable (Article V paragraph 4) and are subject to the MFN treatment obligation under paragraphs 5 and 6 of Article V GATT.

With regard to the sub-paragraphs under Article V GATT, the following questions arise in order to determine whether Article V GATT has been violated by the action of the Dutch authorities:

- 1.) The right of Freedom of Transit of India under Article V GATT
- 2.) Whether the length of time of the seizure (36 days) amounts to an unnecessary delay or restriction
- 3.) Whether the EC-Regulation 1383/2003 must be considered as an applicable customs regulation under Article V (3) GATT and whether therefore India has failed to comply with applicable customs laws and regulations
- 4.) Whether the transit from India had been accorded treatment no less favourable than traffic to or from other third countries

Due to Article V (2) first sentence, India, as a WTO member state, had the right to use the Dutch territory for the transit of its exports to Brazil.

According to paragraph 3 this transit shall not be subject to *unnecessary* delays or restrictions. In the present case, the Dutch authorities held the cargo for 36 days after which it was released. As the facts of the present case remain silent about the particulars concerning the seizure of the cargo, the provided arguments are based on the assumption that there have been no particular circumstances during customs actions with regard to this case.

In order to assess the necessity of a period of 36 days to establish the legality or illegality of the goods, reference must be made to Article 55 TRIPS. As it was argued under the relevant Section 3.3, Article 55 TRIPS permits for a duration of suspension of the transshipment of the cargo by customs authorities for a period of 20 working days after the applicant has been served notice of the suspension at the longest if no further proceedings have been initiated. Even though Article V GATT does not contain any similar provision, a conclusion by analogy suggests that under normal circumstances customs authorities are not supposed to hold back goods for longer than 20 working days after the applicant has been served notice of the suspension. In addition to Article 55 TRIPS, the EC Regulation 1383/2003 under Article 13 equally allows only the maximum period of 20 days for the suspension of goods suspected to infringe an intellectual property right, after notifying the applicant about their detention.

The assessment of an “unnecessary delay” and a possible violation of Article V (3) GATT therefore mainly depends on the definition of the period of time defined in Article 55 TRIPS as explained under Section 3.3.

According to Article V (3) GATT, the requirement to avoid unnecessary delays or restrictions does not apply in cases of *failure to comply with applicable customs laws and regulations*. As has already been described in the section describing the relevant rules, the provisions of the EC-Regulation 1383/2003 are not in conformity with the TRIPS Agreement. Even though the EC-Regulation is inconsistent with the requirements of the TRIPS Agreement, it does fall under the category of applicable customs laws in the meaning of Article V (3) GATT. Due to the fact that the definition of goods which are infringing intellectual property rights under the EC-Regulation is applicable law under Article V (3), the EC-Regulation applies with regard to determine whether India failed to comply with applicable custom laws.

Apart from the violation of Article V GATT due to an unnecessary delay, paragraphs 5 and 6 of Article V GATT provide further criteria under which the action of the Dutch authorities could be challenged if further facts of the present case could be established. Paragraph 5 contains a most-favored-nation treatment obligation for goods in transit. This means that any measures by the Dutch authorities which has been applied in a discriminatory manner compared to the treatment of goods in transit from other member states, would violate the obligation under Article V (5) GATT. Furthermore, according to Article V (6) GATT, the treatment should not be less favourable than that which would have been accorded to such products had they been transported from their place of origin to their destination without going through the territory of such other contracting party. This means, that if there exists a route where the treatment is more favourable, Article V (6) GATT would be violated.

With regard to the known facts and based on the interpretation outlined above no violation of the Freedom of Transit by Dutch authorities could be established.

Possible justifications of GATT-inconsistent measures under Article XX

The provisions under Article XX GATT contain general exceptions to GATT obligations, which can be invoked by a Member if a measure of this Member is inconsistent with other obligations under the GATT. The Member state which is in breach of a GATT violation can employ the exceptions under Article XX GATT in order to justify its GATT-inconsistent measure.

Article XX GATT requires any GATT-inconsistent measure to meet certain requirements in order to be justified. The exception under Article XX GATT, which is of relevance to the present case, is contained in paragraph d, which says the following:

Subject to the requirements under the chapeau, *“nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, [...], the protection of patents [...].”*

Due to the reference made by Article XX (d) GATT to the protection of patents, this provision could be invoked by the EU to justify the otherwise Article V GATT- inconsistent measure to seize goods infringing an intellectual property right under the EC-Regulation 1383/2003, provided that the requirements under Article XX GATT are met. However, the burden of proof to invoke the exception is on the EU.

In order to assess the possibilities to invoke Article XX (d) GATT, several criteria have to be considered whose meaning have been essentially developed by jurisdiction. Due to the wording of the provisions under Article XX (d) GATT, there are different ways to interpret the notion of *“this Agreement”* under this paragraph. One possible way would be to argue that this notion only refers to the GATT 1994 (Solution 1). Another argumentation concerning the notion of *“this Agreement”* would imply that the provisions of the TRIPS Agreement must be

taken into consideration in order to establish the consistency of the EC-Regulation under Article XX (d) GATT (Solution 2).

a.) Solution 1:

Solution 1 assumes that the criteria to secure compliance with laws or regulations which are not inconsistent with the provisions of *this Agreement* under Article XX (d) GATT only refers to the GATT 1994 and examines Article XX GATT according to this interpretation.

1st criteria under para. d: “to secure compliance”

First, the suspension of release of goods suspected to infringe intellectual property rights is allowed under Article 9 (1) EC-Regulation. This measure is designed and was employed to secure compliance with the other provisions of the Regulations protecting patent rights. The wording of Article XX (d) GATT clearly states, that the measure is only applicable to “*secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, [...], the protection of patents [...]*”

As had been established under Article 31.1 VCLT, treaty interpretation shall be “*in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose*”. Due to this provision, the notion of “this Agreement” in Article XX paragraph (d) GATT must be understood to apply to the consistency of the respective laws or regulations with the GATT 1994.

The GATT 1994 as a reference for the consistency of the laws or regulations whose compliance had to be secured by the measure inconsistent with the GATT 1994, had been reaffirmed by the Appellate Body in *Korea – Various Measures on Beef* in the year 2000, stating that “*the measure must be one designed to ‘secure compliance’ with laws or regulations that are not themselves inconsistent with some provision of the GATT 1994 [...]*”².

² *Korea – Various Measures on Beef (DS 161/169)*, 11. December 2000, para. 157.

The EC-Regulation, even though inconsistent with the TRIPS Agreement, does not conflict with obligations under the GATT 1994. Therefore, literal interpretation according to Article 31.1 VCLT suggests that the EC-Regulation is a regulation whose securing of compliance can be invoked for a general exception for the protection of patents under Article XX (d) GATT.

2nd criteria under para. d: “necessary”

With regard to the requirement of “necessity”, the AB came to the following conclusion in *Korea – Various Measures on Beef*³:

The “*determination of whether a measure, which is not ‘indispensable’, may nevertheless be ‘necessary’ within the contemplation of Article XX (d), involves in every case a process of weighing and balancing [...]*”.

This “weighing and balancing” is further defined as determining whether the WTO-Member could have reasonably been expected to employ a WTO-consistent or a less WTO-inconsistent measure.⁴

The determination whether the measure by the EU was necessary to comply with its regulation therefore rests upon a case-by-case evaluation of the respective measure.

Regarding the present case and taken into consideration the interpretation of the “necessity” criteria, the measure of the EU can be considered as being necessary, even though not indispensable, to secure compliance with the provisions of EC-Regulation 1383/2003 to protect patent rights.

³ *Korea – Various Measures on Beef (DS 161/169)*, 11. December 2000, para. 164.

⁴ See *Korea – Various Measures on Beef (DS 161/169)*, 11. December 2000, para. 166.

Criteria under the chapeau of Article XX: “Arbitrary or unjustifiable discrimination between countries where the same conditions prevail” and “Disguised restriction on international trade”

The facts of the present case do not indicate any discriminatory practice of European authorities targeted especially at India or Brazil. The intellectual property protection standard of the EC-Regulation is applied as soon as the criteria for the infringement of intellectual property rights under this regulation are fulfilled, without any element of discrimination in the EC-Regulation itself. As to the application of the EC-Regulation, it was not possible to establish any discriminatory practice based on the provided facts.

Furthermore, there are no indications that the action of the EU authorities amounts to a disguised restriction on international trade, as the EU action seems to be based on the concern that importation of goods infringing intellectual property rights under a Member State of the EU could take place.

b.) Solution 2:

Another reading of the requirement of the consistency of laws and regulations with provisions of “*this Agreement*” under Article XX (d) GATT would be to argue that the TRIPS Agreement is contextual related to the GATT according to Article 31 (1) and (2a) VCLT .

Article 31 (1) VCLT states as follows:

“Any 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 light of its object and purpose”.

Paragraph 2 defines the notion of context under paragraph 1 (a) as “*any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty*”. The GATT agreement as well as the TRIPS Agreement have been concluded at the same time and are part of the same treaty, the WTO Agreement. Therefore, the possible interpretation of Article XX (d) in connection with Article 31 (1) and (2a) VCLT assumes, that the provisions of the TRIPS Agreement must be taken into consideration in order to interpret Article XX (d) with regard to the consistency of the EC-Regulation under this provisions. According to this, solution 2 therefore suggests that if the EC-Regulation would be inconsistent with TRIPS, it could not be taken into account to justify any measure under Article XX GATT.

1st criteria under para.d: “to secure compliance”

As had been already argued under foregoing solution 1, the EC-Regulation does not conflict with obligations under the GATT 1994, but is inconsistent with the TRIPS Agreement. Due to the fact that the TRIPS Agreement has to be taken into account to determine the consistency of laws and regulations with provisions of this Agreement under Article XX (d), the EU can not invoke the necessity to secure compliance with its TRIPS-inconsistent Regulation 1383/2003 in order to justify any violation of GATT obligations under Article XX (d).

Comparing these two possible interpretations of “*this agreement*” under Article XX (d), it can be seen that either interpretation has a different effect on the EU’s possibility to invoke Article XX (d) GATT to justify any possible GATT- inconsistent measure. Nevertheless, no violation of Article V GATT, which would make it necessary for the EU to rely on the exceptions of Article XX, could have been established under the legal assessment of Article V.

3.5. EC-Regulation 1382/2003

The EC-Regulation 1383/2003 concerns customs actions against goods suspected of infringing certain intellectual property rights and provides measures to be taken against goods found to have infringed such rights.

This section will therefore analyse the consistency of the EC-Regulation with the TRIPS agreement.

Article 2(1c) (i) of the EC-Regulation defines “*goods infringing an intellectual property right*” as follows:

“*For the purposes of this Regulation ‘goods infringing an intellectual property right’ means: (a) counterfeit goods [...], (b) pirated goods [...], (c) goods which, in the Member State in which the application for customs action is made, infringe: (i) a patent under that Member State’s Law; [...]”.*

According to Article 9 (1) of the EC-Regulation, customs authorities of the EU Member States can take action to “*to suspend release of the goods or detain them*” as soon as goods

are suspected to infringe an intellectual property right according to the definition under Article 2 of the Regulation.

Compared to the EC-Regulation, Article 52 TRIPS allows for border measures with regard to the suspected infringement of the intellectual property right, if, “*under the laws of the country of importation, there is prima facie an infringement of the right holders intellectual property right*”.

In evaluating the consistency of the EC-Regulation with the TRIPS, there are two possible approaches. The first approach consists in a comparison of the definitions of infringement of an intellectual property rights under the EC-Regulation and the TRIPS Agreement. This approach will be analysed in solution 1. The second approach consists in comparing the possible interpretations of the criteria of Article 52 TRIPS related to the law of the country of importation as presented in Section 3.3. This approach will lead to two different conclusions, which will be analysed in solution 2 and 3.

Solution 1 based on the definition of the infringement of intellectual property rights under the EC-Regulation and under TRIPS

Article 52 TRIPS allows for border measures with regard to the suspected infringement of the intellectual property right, if, “*under the laws of the country of importation, there is prima facie an infringement of the right holders intellectual property right*”. By contrast, the EC-Regulation under Article 2(1c) (i) allows such measures if the goods “*in the Member State in which the application for customs action is made, infringe: (i) a patent under that Member State’s Law; [...]*”.

Due to the different standards applied on the definition of infringement of intellectual property rights under the TRIPS Agreement and the EC-Regulation in Article 2(1c) (i), the EC-Regulation allows to circumvent the requirements contained in Article 52 TRIPS, according to which the laws of the country of importation are decisive in determining whether an intellectual property right has been infringed.

By applying its definition of “goods infringing an intellectual property right” on goods which do not infringe an intellectual property right according to the criteria set out in the TRIPS Agreement, the Regulation of the EC is not consistent with the requirements in Article 52

TRIPS, after which the laws of the country of importation are decisive in determining whether an intellectual property had been infringed.

Solution 2 based on the interpretation of the infringement of intellectual property rights under TRIPS differing from the definition in the EC-Regulation

Another way to assess the consistency of the EC-Regulation with the TRIPS Agreement would be based on the interpretation of the “*law of the country of importation*” defined under Article 52 TRIPS. Literal interpretation of this criterion would suggest, that the law defining an infringement of intellectual property rights is the law of the country of final destination of the goods. Therefore, the EU in defining an infringement of intellectual property rights pursuant to the law of the EU Member State in which the application for customs action is made, would impose its own intellectual property standards on goods which do not infringe intellectual property rights under the law of the country of importation (or in other words, the country of final destination).

Such an interpretation of Article 52 leads to different results as compared to the definition under the EC-Regulation. Under this approach it could be argued, that the EC-Regulation is not in consistency with Article 52 TRIPS.

Solution 3 based on the interpretation of the infringement of intellectual property rights under TRIPS having effects similar to the definition in the EC-Regulation

Another possible interpretation of the “*law of the country of importation*” defined under Article 52 TRIPS read in context of Article 51 first sentence would define the applicable law as the law of the country of suspected importation.

In this case, the applicable law to determine the infringement of the intellectual property rights would be the Dutch patent law according to this interpretation of Article 52. The EC-Regulation would therefore have similar effect defining the Dutch patent law to determine if the infringement of the intellectual property rights took place.

Under this third interpretation, the action of the Dutch customs authorities would not have violated the TRIPS provisions.

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

The “Doha Declaration on the TRIPS Agreement and Public Health” and the “Decision of the General Council of 30 August 2003 concerning the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health” both deal with the compulsory licensing-mechanism which was established under Article 31 TRIPS. The chapeau of Article 31 TRIPS states the following:

“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected [...]”

Compulsory licensing means that a license for the manufacturing of the patented product is granted without the authorization of the right holder. The manufacturing of products under compulsory license is generally permissible under Article 31 TRIPS.

Before the permission for compulsory licensing however, certain criteria have to be satisfied, which are enumerated in the sub-paragraphs of Article 31 TRIPS. Amongst others, prior efforts must have been made to obtain authorization from the right holder on reasonable commercial terms and conditions. Only if such efforts have not been successful within a reasonable period of time, authorization for compulsory licensing can be granted. This requirement of “reasonable period of time” can only be waived in the case of national emergency or other cases of extreme urgency (para. (b)) In addition, “the right holder shall be paid adequate remuneration in the circumstances of each case” (para.(h)) and the authorization for compulsory licensing must be “predominantly for the supply of the domestic market”(para.(h)).

The Doha Declaration on the TRIPS Agreement and Public Health reaffirms WTO Members right, to use the flexibilities built into the TRIPS Agreement for public health purposes. Its preambular provisions recognize the “*gravity of the public health problems afflicting many*

developing countries [...], especially those resultion from HIV/AIDS, tuberculosis, malaria and other epidemics” and the concerns about the effect of intellectual property protection on the prices of medicaments. The main paragraph dealing with the problems arising under the TRIPS Agreement is paragraph 5, which aims at clarifying the interpretation of disputed provisions under the TRIPS Agreement. The criteria of “domestic use” under Article 31 (f) TRIPS and the problems related to it are dealt with in Paragraph 6 of the TRIPS Agreement. This paragraph contains a provision requiring action by the TRIPS Council to find a solution for countries with insufficient or no manufacturing capacities that would allow them to make effective use of compulsory licensing under the TRIPS Agreement.

The Declaration states that *“each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”*. Furthermore,

“each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency”. As a consequence of this, a state can now declare a “national emergency” at its sole discretion in case of public health problems, without priorly having fulfilled the requirement *“to have made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time”* under Article 31 (b) TRIPS.

The main problem under Article 31 TRIPS nevertheless has not been addressed by this Declaration. By limiting compulsory licensing predominantly to the supply of the domestic market, Article 31 (f) of the TRIPS Agreement is disallowing the export from states with manufacturing facilities to those states that do not have manufacturing capacities.

In order to adress the issue of WTO Members with insufficient manufacturing capacity to make use of the compulsory licensing mechanism under Article 31 TRIPS Agreement, the Decision concerning the implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health was issued.

Paragraph 2 of the Decision says the following:

“The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing

Member(s) in accordance with the terms set out below in this paragraph [...]”.

Apart from the requirement of notification to the TRIPS Council, the requirements related to the compulsory license of the exporting members are the following:

“(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence [...],

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking.

(iii) before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination as referred to in indent (i) above and - the distinguishing features of the product(s) referred to in indent (ii) above”.

Both, the Doha Declaration and the 2003 Decision as whole create a system, under which member states are allowed to export pharmaceuticals, produced according to these criteria, to other countries. Nevertheless, in order to do so, specific requirements have to be met. Before assuming that any exportation of generic drugs therefore would be justified under these provisions, it is important to consider whether the specific circumstances of the case do in fact indicate such an assumption. With regard to the present case, no specific facts could be established which indicate that the export of these generic drugs would have been one under the compulsory licensing mechanism. For this reason, any assessment of the present case must be based on the assumption that the export from India to Brazil had been a “normal” export of these pharmaceuticals, which means that it would not fall under the exceptions of the Declaration. Furthermore, the compulsory licensing mechanism is only applicable if a patent had been conferred in the respective country. In this case, the specific product had neither been patented under Indian nor under Brazilian law. Therefore, the application of Article 31 TRIPS and the related Declaration and Decision is not possible in the case at hand.

4. Conclusion

Answers to the specific questions as provided by Oxfam

Question 1

Is there a breach of the provisions of the TRIPS Agreement? Which ones and why?

The legal assessment of a possible violation of provisions under the TRIPS Agreement under Section 3.3 contains an assessment of Articles 28, 50, 51, 52, 55 TRIPS.

Due to different interpretations under these provisions, only Article 52 has been found to be violated by the customs action. According to the literal interpretation of the criteria of “country of importation” under Article 52 TRIPS, the action by the Dutch authorities amounts to a violation of this provision. Nevertheless, as had been argued under the relevant part, a different reading of the respective criteria under Article 52 TRIPS and the reading of Article 52 TRIPS in context with Article 51 first sentence would lead to the conclusion that the action by the Dutch authorities has not violated Article 52 GATT.

Question 2

Is there a breach of GATT Article V? Does GATT Article XX provide a basis for the EU action? How do Article V and Article XX operate in relation to one another and what effect does it have upon the EU regulation?

Based on the arguments in Section 3.4, no violation of Article V GATT with regard to traffic in transit has been found. Due to the fact that Article XX (d) GATT can only be invoked in cases where other GATT obligations have been violated, there is no need for the EU to justify its measure under Article XX GATT.

Question 3

Can the EU rely on the provisions of Article 50 and 51 to justify this claim?

Article 50. 1 (a) of the TRIPS Agreement allows for “prompt and effective provisional measures to prevent an infringement of any intellectual property right from occurring”, in particular to “*prevent the entry into the channels of commerce*” including “*imported goods*”

immediately after customs clearance". Since, however, Article 50 TRIPS does not discipline custom measures but internal measures, in particular "after customs clearance" as stipulated in the last sentence of 1.(a), the EU can not rely on this Article to justify its action.

The second reason why the EU can not rely on Article 50 TRIPS to justify this claim is the fact that Article 50 TRIPS, in contrast to Article 51 TRIPS, does not apply to goods in transit. By contrast, the EU can rely on Article 51 TRIPS to justify its claim. As elaborated already under Section 3.3, this Article applies on goods infringing a patent right. Footnote 13 under Article 51 furthermore allows member states to extend their boarder measures on goods in transit.

Question 4

What is the scope of acceptable situations in which countries can rely on Article 50 and 51?

Both, Article 50 and Article 51 TRIPS Agreement aim to prevent infringements of intellectual property rights. Generally, Article 50 and Article 51 TRIPS Agreement seem to be complementary provisions. Only if the right holder has failed to lodge an application for suspension by customs authorities under Article 51 and the goods suspected to infringe an intellectual property right are already about to enter into the channels of commerce of the respective country, then provisional measures under Article 50 TRIPS can be applied.

Article 50 TRIPS therefore is applicable on goods suspected to infringe an intellectual property right which are no more under customs clearance in order to prevent their entry into the channels of commerce. Due to the context of the TRIPS Agreement and the provision of specific measures applied to boarder measures Article 50 TRIPS can not be applied to goods which are still under customs clearance and therefore is also not applicable to goods in transit.

Article 51 TRIPS by contrast defines the requirements for the suspension of the release of goods which are suspected to infringe an intellectual property right by customs authorities. The requirements of Article 51 TRIPS especially apply to measures at the border before the respective goods can enter into the channels of commerce. This means that Article 51 TRIPS applies to goods which are still under customs clearance in contrast to the requirement of "imported goods immediately after customs clearance" under Article 50 TRIPS.

A more detailed legal assessment of Articles 50 and 51 TRIPS can be found under Section 3.3 of the present document.

Question 5

Does the EU action have any bearing on the 2001 Doha Declaration on TRIPS and Public health and implementation of decision to deal with the “paragraph 6 problem”? What are the legal issues involved in the link between this Declaration and the EU action and how can these be best articulated from a legal stand point?

As had been pointed out under Section 1 concerning the facts of the present case, the seized products were neither patented in India nor in Brazil. In addition, Section 4, dealing with the Doha Declaration, provides a detailed explanation of the problems under Article 31 TRIPS which are addressed in the related “Doha Declaration on the TRIPS Agreement and Public Health” and the “Decision concerning the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”.

Article 31 refers to situations in which a country grants “compulsory licensing” of a product without the authorization of the right holder. Due to the fact that there had been no patent protection of the respective product in India, the requirements for compulsory licensing under Article 31 do not have to be met by the country before producing a similar pharmaceutical product. Consequently, the relevant provision concerning the compulsory mechanism under the TRIPS, including the Doha Declaration and the 2003 Decision, are not applicable to the present case.

Even though there is no direct relation between the Doha Declaration and its related 2003 Decision on the implementation of paragraph 6 and the export of India to Brazil in the present case, both, the Doha Declaration as well as the present case, can be related to the problem of export of generic drugs,.

It could therefore be argued that, based on the spirit of the Doha Declaration, India and Brazil might articulate a proposal for a measure to prevent the recurrences of such custom seizure. In this proposal, any custom cannot block the transit of legitimate (meaning not patented in both exporting and importing countries) generic medicines as long as the package of such generic clearly indicates that the package is under transit and it does not contain any illegal product, for example a big stamp saying "TRANSIT OF UNPATENTED GENERIC".

Question 6

What is the law on enforcement of patents? Is it only territorial? Or can it apply to goods in transit?

This question has been elaborated in detail under Section 3.3 of the present paper. Generally, The rights of patent holders are defined by the national jurisdiction and are conferred within the borders of national jurisdiction. Patent rights are traditionally enforced on the national level. It is the national jurisdiction that decides whether a patent right was effectively infringed. Nevertheless, due to the wording of Article 41 TRIPS, it had been argued that the law on enforcement of patents is not only territorial but also applies to goods in transit as long as the law of the country of final destination is respected in determining the infringement of a patent right.

Question 7

Can the EU claim that (European) community law protects them in the midst of inconsistency with international law obligations? What takes precedence in this case?

According to the arguments put forward under Section 3.2 the EU has not the possibility to invoke its own regulations to justify a deviation from its obligations under the TRIPS Agreement. Rather, the EU, as an separate member of the WTO has to bring its regulation and laws into accordance with the obligations under existing WTO Agreements. The inconsistency of the EC-Regulation 1383/2003 with obligations under the TRIPS Agreement therefore does not find any justification under the applicable provisions.

Due to Article 1 (1) of the Agreement Establishing the WTO, the WTO obligations of the EU clearly take precedence in the case where WTO obligations and obligations under EU law or regulations conflict with each other.

Question 8

If India and Brazil brought a case to the dispute panel what would be the arguments used by the EU to counter the case?

The main argument brought forward by the EU in its statement had been the consistency of the action by Dutch authorities with the EC-Regulation 1383/2003 and with Article 51 TRIPS. It is therefore very likely that the EU would base its arguments on the relevant provisions of the EC-Regulation. The action of the Dutch authorities had been based on EU-Customs Regulation 1383/2003. The EU might argue that under Article 9 (1) of the Regulation, customs authorities are allowed to suspend release of goods if they are suspected to infringe an intellectual property right under a member states patent law.

Nevertheless, as had been argued under Section 3.5, the definition of the EC-Regulation concerning the infringement of intellectual property rights is not consistent with the respective TRIPS provisions. With regard to the fact and as argued under Section 3.2, the EU has the obligation to bring its laws and regulations into conformity with TRIPS. The EU therefore can not rely on the definition in the EC - Regulation to justify the action by Dutch authorities.

On the other hand, the EU could base its argument on the suspected importation of the respective goods into its territory, relying on the interpretation of the “country of importation” requirement under Article 52 read in conjunction with Article 51 first sentence of the TRIPS Agreement. As had been argued under Section 3.3, dealing with the legal assessment of the relevant TRIPS provisions, this interpretation would provide the EU with a valid argument for the action of the Dutch authorities.

5. Annex – Legal provisions

TRIPS

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

Article 51

Suspension of Release by Customs Authorities

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, 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.

Footnote 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.

Article 52

Application

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 sufficiently 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 the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

Article 55

Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

GATT

Article V

Freedom of Transit

1. Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without transshipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article "traffic in transit".
2. There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.
3. Any contracting party may require that traffic in transit through its territory be entered at the proper custom house, but, except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions and shall be exempt from

customs duties and from all transit duties or other charges imposed in respect of transit, except charges for transportation or those commensurate with administrative expenses entailed by transit or with the cost of services rendered.

4. All charges and regulations imposed by contracting parties on traffic in transit to or from the territories of other contracting parties shall be reasonable, having regard to the conditions of the traffic.

5. With respect to all charges, regulations and formalities in connection with transit, each contracting party shall accord to traffic in transit to or from the territory of any other contracting party treatment no less favourable than the treatment accorded to traffic in transit to or from any third country.

6. Each contracting party shall accord to products which have been in transit through the territory of any other contracting party treatment no less favourable than that which would have been accorded to such products had they been transported from their place of origin to their destination without going through the territory of such other contracting party. Any contracting party shall, however, be free to maintain its requirements of direct consignment existing on the date of this Agreement, in respect of any goods in regard to which such direct consignment is a requisite condition of eligibility for entry of the goods at preferential rates of duty or has relation to the contracting party's prescribed method of valuation for duty purposes.

7. The provisions of this Article shall not apply to the operation of aircraft in transit, but shall apply to air transit of goods (including baggage).

Article XX

General Exceptions

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices;

WTO Agreement

Article XI

Original Membership

1. The contracting parties to GATT 1947 as of the date of entry into force of this Agreement, and the European Communities, which accept this Agreement and the Multilateral Trade Agreements and for which Schedules of Concessions and Commitments are annexed to GATT 1994 and for which Schedules of Specific Commitments are annexed to GATS shall become original Members of the WTO.

Article XVI

Miscellaneous Provisions

4. Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.

EC-Regulation 1383/2003

Article 2

1. For the purposes of this Regulation, "goods infringing an intellectual property right" means:

(c) goods which, in the Member State in which the application for customs action is made, infringe:

(i) a patent under that Member State's law;

(ii) a supplementary protection certificate of the kind provided for in Council Regulation (EEC) No 1768/92(7) or Regulation (EC) No 1610/96 of the European Parliament and of the Council(8);

(iii) a national plant variety right under the law of that Member State or a Community plant variety right of the kind provided for in Council Regulation (EC) No 2100/94(9);

(iv) designations of origin or geographical indications under the law of that Member State or Council Regulations (EEC) No 2081/92(10) and (EC) No 1493/1999(11);

(v) geographical designations of the kind provided for in Council Regulation (EEC) No 1576/89(12).

Article 9

1. Where a customs office to which the decision granting an application by the right-holder has been forwarded pursuant to Article 8 is satisfied, after consulting the applicant where necessary, that goods in one of the situations referred to in Article 1(1) are suspected of infringing an intellectual property right covered by that decision, it shall suspend release of the goods or detain them.

The customs office shall immediately inform the competent customs department which processed the application.

Article 13

1. If, within 10 working days of receipt of the notification of suspension of release or of detention, the customs office referred to in Article 9(1) has not been notified that proceedings have been initiated to determine whether an intellectual property right has been infringed under national law in accordance with Article 10 or has not received the right-holder's agreement provided for in Article 11(1) where applicable, release of the goods shall be granted, or their detention shall be ended, as appropriate, subject to completion of all customs formalities.

This period may be extended by a maximum of 10 working days in appropriate cases.

2. In the case of perishable goods suspected of infringing an intellectual property right, the period referred to in paragraph 1 shall be three working days. That period may not be extended.

