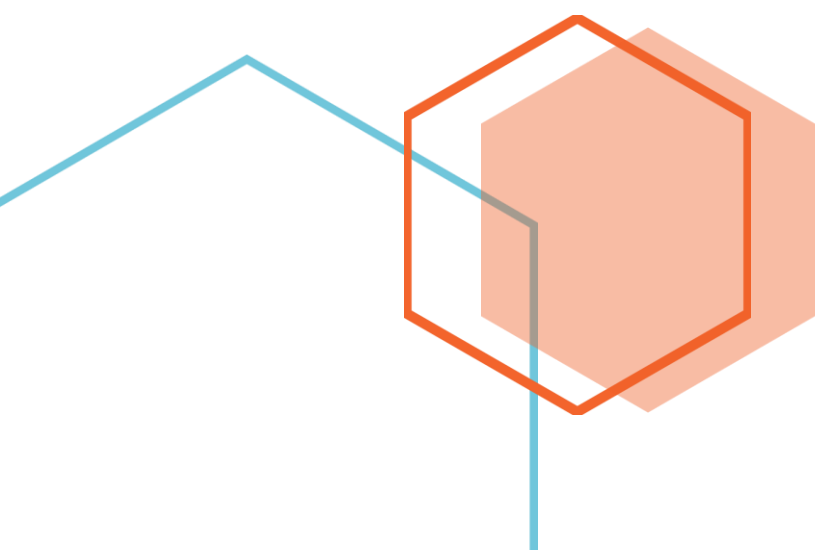




TRIPS Flexibilities relating to Enforcement





Part III of the TRIPS Agreement lays down detailed provisions relating to enforcement of IP rights, with the objective of ensuring that WTO members adopt obligations to permit the effective exercise of intellectual property (IP) rights covered under the Agreement. However, the Preamble of the TRIPS Agreement recognizes the need for effective enforcement, taking into account differences in national legal systems. The flexibility available to WTO members under Article 1.1 to determine the appropriate method of implementing the provisions of TRIPS within their own legal system and practice also applies to implementation of the obligations relating to enforcement under Part III.

In general, the TRIPS Agreement requires WTO members to make available judicial and administrative enforcement procedures, in accordance with their legal systems, with the requirement that such procedures should meet some general standards of fairness, equity and due process. In addition, the TRIPS Agreement requires WTO members to ensure that judicial or administrative authorities, as the case may be, have the authority to order certain remedies, including provisional or interim remedies. However, TRIPS Agreement does not mandate that specific remedies must be granted in particular cases.

The TRIPS Agreement does not require States to provide criminal procedures or penalties for IP enforcement except in cases of willful trademark counterfeiting or copyright piracy on a commercial scale as stated in Article 61. There is no obligation therefore, to apply criminal procedures and remedies for the enforcement of other types of IP rights, including cases of patent infringement.

General Obligations

Article 41 of TRIPS sets forth the general obligation of members to ensure that the different types of proceedings relating to IP enforcement as specified in Part III of the Agreement shall be available under the respective national laws. These general obligations are applicable to both judicial as well as administrative enforcement procedures. These general obligations are further elaborated upon in respect of specific types of enforcement procedures (civil and administrative procedures, procedures for application of provisional measures, border measures, criminal measures) as well as procedures relating to acquisition and maintenance of IP rights under Part IV, Article 62.

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.

The following general obligations are enshrined in article 41 and expanded upon in other provisions in Part III of TRIPS.

To make effective enforcement procedures available under the national laws

Article 41.1 specifies a general standard that enforcement proceedings should be such as to permit effective action against any act of infringement of the covered IP rights. The determination of what constitutes IP infringement is subject to the substantive national laws and the exceptions and defences available under the law. This general obligation applies to both judicial procedures as well as administrative procedures.

To prevent abuse of enforcement procedures

Second, part of the general obligation under Article 41.1 is that members must establish safeguards against the possibility of using enforcement procedures to prevent legitimate trade or the abuse of enforcement procedures e.g., to distort competition through sham litigation. Article 48 expands on this principle and requires judicial authorities to have the authority to award adequate compensation for injury suffered by a defendant for abuse of enforcement proceedings by the right holder, along with costs.



Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.
2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

This is an important safeguard that could be applied in the context of pharmaceutical patents to prevent abuse of enforcement procedures through strategic litigation to exclude competitors from the market. For example, in Australia, a legislation has been introduced to allow the authorities to impose penalties of up to 10 million Australian dollars on pharmaceutical patent-holders that are found to have filed frivolous suits to extend their patents and prevent entry of generic competitors in the market.

To ensure fair and equitable procedures

Article 41.2 requires enforcement procedures to be fair and equitable. These principles embody that due process standards of providing the parties an opportunity of being heard, as well as equitable considerations of legitimate interests of the defendant against the right holder should be taken into consideration in the implementation of enforcement proceedings. Such equitable considerations, for instance, can be important mitigating factors in the determination of the relief granted in an enforcement proceeding (e.g., granting a declaratory judgment, or awarding damages instead of an injunction in view of the public interest).

The principles of procedural fairness and equity are further substantiated by the requirement under article 41.3 that a decision on the merits of a case should preferably be in writing and reasoned and made available to the parties without undue. Furthermore, the principle of due process requirements are expounded by stating that the decision must be based on evidence in respect of which the parties had an opportunity of being heard. Moreover, article 41.4 requires that parties must have an opportunity to seek judicial review of final administrative decisions relating to enforcement (e.g., a decision by customs authorities relating to seizure of goods at the border on suspicion of IP infringement) or review of initial judicial decisions relating to enforcement.



The principle of fair and equitable procedures is more specifically elaborated under articles 42 and 43 in relation to defendants in civil and administrative procedures (timely and sufficient written notice, opportunity of legal representation, non-imposition of overly burdensome mandatory personal appearance, opportunity to substantiate claims and present evidence, and protection of confidential information).

Article 42

Fair and Equitable Procedures

Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 43

Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.
2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

No obligation to put in place a separate distinct/special system for IP enforcement

The TRIPS provisions relating to enforcement define the objectives that is to be achieved through the different types of enforcement measures and does not mandate specific means to be used to achieve that objective. This approach has left WTO members with considerable leeway to maintain or adopt new enforcement measures in accordance



with the peculiarities of their national legal systems. TRIPS does not require States to make available special systems of IP enforcement (such as *special* IP courts or tribunals) distinct from the general system of law enforcement. Article 41.5 makes it clear that Members are not obliged to establish a *special* court to deal with intellectual property issues, nor allocate special funds to this area.

While special IP courts may be important to address complex technical issues involved in IP cases, there would be need for avoiding unintended consequences that could derive from the establishment of special courts, through appropriate safeguards. Evidence from the United States, e.g., suggest creation of the special court in the form of the Court of Appeal of the Federal Circuit has increased the rate of growth of patent litigation and almost doubling of favourable decisions upholding the validity of challenged patents. Moreover, appellate and review procedures before higher judicial authorities from specialized courts could increase judicial burden in developing countries with long pending caseloads. For developing countries some critical issues to consider in respect of specialized IP courts could include:

- a) how to avoid a narrow tunnel vision relating to patent rights and ensure that broader public policy and public interest considerations, e.g., relating to public health, are taken into account in decision-making;
- b) address funding and sustainability for sustaining specialized IP courts (additional financial resources may be needed for specialized courts to function); and
- c) depending on the appeal's system/institutional framework, whether specialized courts will have the impact of augmenting the rate of pendency of disputes and the burden of the judiciary due, e.g., to necessary appellate and review procedures before higher judiciary authorities.

Remedies

Part III, Section 2 of TRIPS requires judicial authorities, or as the case may be, administrative authorities, to have the authority to grant the following remedies:

- a) Injunctions
- b) Damages
- c) Disposal of infringing goods outside the channels of commerce, or destruction of infringing goods.

Section 3, Article 50 of TRIPS also requires that judicial authorities, and where applicable, administrative authorities, shall have the authority to adopt provisional measures and



lays down the procedural requirement for the same. However, it does not prescribe particular provisional measures that should be ordered, leaving considerable discretion to determine the same to the members and determine the requirements to be imposed in accordance with each national legal system.

Injunctions

The TRIPS Agreement does not require WTO members to grant permanent or preliminary/provisional/interim/temporary injunctions in all cases of IP infringement. Rather, the TRIPS Agreement contemplates that countries may sometimes limit remedies to the payment of adequate remuneration, and may justify even categorical exclusions of injunctive relief for specific types of infringing conduct. Specifically, the TRIPS Agreement in Articles 44.1 and 50.1 only requires that countries provide authority for their judiciary to issue injunctions that terminate or prevent infringement.

Article 44

Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 44.1 mentions one of the possible objectives of an injunction, the prevention of entry into the channels of commerce of imported goods that involve infringement of an intellectual property right immediately after customs clearance of such goods. However, this is only an illustration. Judicial authorities are generally required under article 44.1 to have the authority to grant injunction in any case of IP infringement. The authority to grant injunction may be denied in case of bona fide use of an IP protected product by a third party without the knowledge or reasonable grounds of knowing that the use of the product could constitute infringement.

It should be noted that TRIPS does not require judicial authorities to grant injunction but to only have the authority to do so. As held by the US Supreme Court in *Ebay Inc. et al v Mercexchange LLC* "the decision whether to grant or deny injunctive relief rests within



the equitable discretion of the ... courts.” This means that any infringement may not necessarily lead to an injunction, if the court is convinced, based on equity considerations, that it is not justified. As expounded in this decision

[...] When the patented invention is but a small component of the product the companies seek to produce and the threat of an injunction is employed simply for undue leverage in negotiations, legal damages may well be sufficient to compensate for the infringement and an injunction may not serve the public interest [...].

As observed by the Court, in some cases judicial authorities may decide to grant damages instead of injunction. Indeed, the authority grant damages is also a requirement under article 45 of TRIPS (see below). The newly approved revision of the German Patent Law codifies a proportionality test for injunctions under Section 139 (1): if the injunction leads to an undue hardship for the defendant or third party (e.g. for access to essential medicines) that is disproportionate to the patent rights, the injunction may not be issued – opting instead for compensation or other measures.¹ This amendment reflects a prior judicial decision by the German Federal Court in the same sense. Other European jurisdictions have also adopted proportionality tests in their own case law. This means that automatically granting injunctions as the only available remedy is not even a contemporary practice in many jurisdictions of well-consolidated IP systems. Article 44.2 allows WTO members to deny injunctions in cases of compulsory licensing or government use, and limit liabilities to payment of remuneration in accordance with the provisions of Article 31 (h).

Damages

Article 45

Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 45 requires judicial authorities to also have the authority to order the infringer to pay damages that should be adequate to compensate the right holder for the injury suffered due to the act of infringement. Members may determine when compensation is deemed to be adequate. However, a bona fide infringer who did not know or have reasonable grounds to know that he engaged in an infringing activity is not required to

¹ See: <http://patentblog.kluweriplaw.com/2021/06/22/changes-to-the-german-patent-act/>



pay damages (the remedy of injunction may also be denied in such cases in terms of article 44).

In terms of article 45.2, judicial authorities are also required to have the authority to order the infringer to pay the costs along with damages. However, this could be limited to expenses in relation to the judicial action, e.g., associated court fees. There is no obligation to include lawyer's fees in the costs to be paid. There is also no obligation to set the level of damages to allow for recovery of profits, or set pre-established damages, though States may choose voluntarily to do so.

Other Remedies

Article 46

Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

Article 46 requires judicial authorities to have additional powers to create an effective deterrent to infringement where goods have been found to be infringing by ordering the following measures without compensation of any sort

- a) Disposal outside the channels of commerce in such a manner as to avoid harm to the right holder. Thus, disposal outside the channels of commerce may not be ordered in situations that do not harm the right holder, e.g., where the local market for a medicine is not supplied by the patent holder.
- b) Destruction of the infringing goods unless this would be contrary to constitutional requirements.
- c) Disposal of materials and implements used in the creation of infringing goods outside the channels of commerce, where they are predominantly used in creation of the infringing goods and where it is necessary for minimizing the risk of further infringements

These remedies under article 46 are subject to a proportionality test under which the seriousness of the infringement and the remedies ordered, as well as the interest of third parties, need to be taken into account. This means that judicial authorities need to



balance the interests at stake, and at their discretion, they may refuse both disposal outside the channels of commerce or destruction of the infringing goods.

Provisional Measures

Article 50

1. 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 customs clearance;

(b) to preserve relevant evidence in regard to the alleged infringement.

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.

4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. 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 after the notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.



Article 50 is the sole provision in Part III of TRIPS on provisional measures. It requires judicial authorities to have the power to order “prompt and effective” provisional measures. The specific type of provisional measures is not defined. Hence, this article applies to procedures to be applicable in case of provisional measures, which includes preliminary injunctions.

These provisional measures are required to be available to the judicial authorities to prevent an infringement from occurring, and particularly prevent the entry of the infringing goods into the channels of commerce within the country. Hence, this is not applicable to goods destined for export out of the country.

Secondly, provisional measures could be applied to preserve the evidence with regard to the alleged infringement.

Article 50.2 also requires that judicial authorities should be empowered to adopt provisional measures *ex parte* where appropriate, particularly where any delay in adopting provisional measures is likely to cause *irreparable harm* to the right holder, or if there is demonstrable risk of evidence being destroyed. However, it is up to the members to determine whether the conditions for *ex parte*. In a number of countries *ex parte* measures are granted very exceptionally. Thus, the patent holder could be required to demonstrate that any possible harm cannot be redressed through adequate compensation or establish that the risk of evidence being destroyed is demonstrable.

Articles 50.3 establishes procedural safeguards by requiring the applicant for a provisional measure to demonstrate that the applicant is the right holder and that the applicant's rights have been infringed or infringement is imminent. The applicant is also required to provide a security deposit or equivalent assurance sufficient to protect the defendant and prevent abuse. This amount can be determined by the national authority. The amount must be sufficient not only to compensate the defendant for losses generated, but also prevent abusive use of provisional measures to interfere with legitimate competition.

Article 50.4 requires that where provisional measures are adopted *ex parte*, the parties affected by the measure (alleged, infringer, distributors, etc.) shall be given notice of the same without delay. In the latest after the execution of the measures. Members may require in their laws that such notice be given before the execution of the provisional measure, as the TRIPS provision sets a maximum time limit for such notice. Moreover, the defendant has a right to a review of the measures within a reasonable period after their notification, with a view to modification, revocation or confirmation of the measure.

Articles 50.6 and 50.7 provide detailed obligations that must be imposed on the applicant of provisional measures. If proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, the party affected by a provisional



measure may request that the measure be revoked or otherwise cease to have effect. The period within which proceedings on the merits must be initiated is to be determined by the judicial authority ordering the measures where a Member's law permits, and in the absence of such a determination, the period shall not exceed 20 working days or 31 calendar days, whichever is longer. The judicial authority or the national law may set a shorter period within which proceedings must be commenced.

Article 50.7 requires judicial authorities to be vested with the power to order the applicant, upon request of the defendant, to provide appropriate compensation for any injury caused by a provisional measure where the measures are revoked, or the measures lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement.

Special Requirements Relating to Border Measures

Section IV of Part III of the TRIPS Agreement introduces the first set of international rules on counterfeiting and copyright piracy. These provisions lay down the procedures to be followed by customs authorities in relation to infringing products in respect of which border measures by customs authorities are applicable. These provisions are mandatorily applicable in terms of the TRIPS Agreement only in respect of counterfeit trademark or pirated copyright goods. There is no requirement under TRIPS to extend such measures to other forms of IP infringement, including patents, though members may opt to apply border measures to other forms of IP infringement. In such a situation, the requirements under this section will apply to such other forms of IP infringement to which border measures are made applicable.

At the outset, it is important to note that the border measures applicable under TRIPS have no linkage to the quality and safety standards of the products concerned. Any conflation between IP infringement and the quality and safety of the product for consumers, e.g., in the case of medicines, should be avoided. An IP infringing product should not be assumed to be a product of compromised quality.

Need to avoid conflation between IP infringement and Quality and Safety of the Products

It is important to note that the border measures applicable under the TRIPS Agreement have nothing to do with the quality standards or the safety of the product in question. Sometimes terminology such as “counterfeit medicines” may be used in common parlance to pursue measures to prevent the entry of fake or spurious products, but that determination should be separate from the determination of IP infringement, as TRIPS uses counterfeiting in relation to trademark infringement. Moreover, the IP status of a product is not subject to a determination of the quality standards of the product. A patent is granted much before the regulatory approval of the safety and efficacy of



the drug, which is a separate determination by the drug regulator. Similarly, a trademark on a drug is not registered subject to meeting quality assurance standard. In the context of medicines, both patented and generic medicines would bear the same international non-proprietary or generic names on their package (e.g., paracetamol) which is not a trademark. Different manufacturers for the same product could adopt trademarks that relate to the generic name (e.g., paramol and cromol) which could be similar as trademarks, but may not vary in quality. Thus, the existence of a *prima facie* case of IP infringement does not imply that the infringing product is a product of substandard quality, or a fake or spurious product. In this regard, the WHO has decided to not use the term “counterfeit” in relation to quality compromised medical products, to distinguish the quality issues from IP issues.

Counterfeits (trademarks) ≠ IP infringement ≠ Quality of product ≠ Generic

The border measures under section IV are relating to the seizure and suspension of covered infringing goods by customs authorities after their importation but before their release into the channels of commerce in the domestic market. Therefore, the obligation does not apply to goods that are in transit through the customs territory but are not meant for entry into the domestic market.

Article 51

Suspension of Release by Customs Authorities

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

Moreover, there is no obligation under TRIPS for customs authorities to act on their initiative to apply the border measures. Article 51 only requires that WTO members should adopt procedures to enable a right holder to apply before competent administrative or judicial authorities to suspension of suspected infringing products by customs authorities. However, WTO members may require competent authorities to act on their own initiative in an *ex officio* capacity to suspend the release of goods. In that case, procedures under article 58 would be applicable.

Article 58



Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

- (a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;
- (b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;
- (c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

Whether the suspension of goods suspected of infringing a covered IP right is pursuant to an application by the right holder or by *ex officio* determination by the competent authorities, in both cases this must be based on a *prima facie* evidence of possible infringement.

Procedural safeguards that are applicable include the requirement of provision of notice of suspension to both the right holder (applicant) and the importer (Article 54), the deposit of security or equivalent assurance by the right holder to indemnify the defendant and the competent authorities and prevent abuse of the procedures (ensuring the amount is not a deterrent to recourse to the procedures) (Article 53). Article 55 stipulates that the goods suspended are required to be released if within 10 days of the notice of suspension to the applicant the competent authorities are not informed of initiation of proceedings on the merits of the case or the extension of the suspension through provisional measures adopted by empowered authorities. Members may extend the time limit by another 10 days, but this is not mandatory. Where proceedings on merits have been initiated, the defendant will have the right to seek a review of the border measures within a reasonable period, with a view to their modification, revocation or confirmation. There is no obligation that the suspension should continue until the conclusion of the proceedings on the merits of the case.

Where the border measures are applied in respect of other forms of IP rights, including patents, if provisional relief has not been granted by the empowered authorities within the 10-day period from notice of suspension, the owner, importer or consignee of the goods shall be entitled to their release upon the deposit of a security amount sufficient to protect the right holder from any infringement. This amount and its sufficiency may be determined by the competent authorities. Moreover, if proceedings on merits are not initiated within a reasonable time the security deposit is required to be released. This period can also be determined by competent authorities under national law. Where statutes or rules are silent on these questions, these would be left to the discretion of the competent authorities.