

2: Nature and Scope of Obligations

Article 1 Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

1. Introduction: terminology, definition and scope

The requirement to implement an international agreement is implicit in the obligation to perform it in good faith. The obligation to perform in good faith (*pacta sunt servanda*) is established by Article 26 of the Vienna Convention on the Law of Treaties (VCLT), which substantially codifies customary international law. Article 1.1 of TRIPS provides that Members will “give effect to the provisions” of the Agreement, restating the basic international legal obligation.

Article 1.1 adds two rules to this basic affirmation of the law of treaties. First, Members may, but need not, adopt more extensive protection of intellectual property (IP) than is required by the agreement and, second, “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.

By stating that Members may adopt protection “more extensive” than that provided for in the agreement, Article 1.1 establishes its rules as the base (or floor) of protection often referred to as TRIPS “minimum standards”. Article 1.1 makes clear that Members are not obligated to adopt more extensive than TRIPS Agreement standards, so-called “TRIPS-plus” levels of protection.

The third sentence of Article 1.1 concerning freedom of implementation method is important in at least two senses. First, in addressing the relationship between TRIPS and domestic legal systems of Members, it does not establish an express rule regarding “direct effect” or “self-executing effect”, leaving this to a determination by each Member. Each Member decides whether it will adopt specific statutes or administrative rules to implement TRIPS, or instead rely on the text of the Agreement as part of national law (see below, Section 3).

Second, it acknowledges the flexibility inherent in the express text of the TRIPS Agreement and intellectual property law more generally, authorizing each Member to implement the rules in the manner most appropriate for itself, provided that implementation is in accord with the terms of the agreement.

2. History of the provision

2.1 Situation pre-TRIPS

2.1.1 “Give effect”

Prior to TRIPS the rules governing the protection of intellectual property at the multilateral level were established primarily by the World Intellectual Property Organization (WIPO) conventions.³⁰ The factors that led certain governments to propose the negotiation of the TRIPS Agreement are considered in Chapter 6 regarding the objectives and principles of the Agreement.

As noted above, international law requires state parties to a treaty or international agreement to “give effect” to that agreement as a matter of good faith performance. The VCLT, recognizing the obligation to perform in good faith, was adopted in 1969, and entered into force in 1980. Thus prior to the TRIPS Agreement negotiations the obligation to “give effect” to a treaty was accepted in international law.

2.1.2 Minimum standards and more extensive protections

A treaty or international agreement might provide that its rules are intended to embody the sole set of norms for a particular subject matter, and effectively preclude a state party from adopting an alternative set of rules with more (or less) extensive protection. The parties negotiating the TRIPS Agreement had the option to decide that a uniform set of negotiated rules would represent the upper and lower boundary of IPR protection. Whether or not a treaty is intended to be the sole source of norms is determined by applying general principles of treaty interpretation. It is not the subject of a general rule. It bears noting that states are sovereign within their own territories and generally have the right to legislate in the manner they consider appropriate, unless discretion has been limited by a treaty or other rule of international law.³¹

The General Agreement on Tariffs and Trade 1947 (GATT 1947) provided the rules for the multilateral trading system prior to entry into force of the WTO Agreement. The GATT 1947 set certain maximum or upper boundaries in areas such as tariffs and quotas. Thus, under Article II, GATT 1947, Contracting Parties committed themselves to tariff bindings that constituted the upper threshold they might impose (on an MFN basis). It was not left to the discretion of each

³⁰ These treaties, principally the Paris Convention on the Protection of Industrial Property and the Berne Convention on the Protection of Literary and Artistic Works, are introduced in Chapter 3.

³¹ Article 1.1, TRIPS Agreement, recognizes that, absent an agreed upon restriction or peremptory norm, states retain sovereign rights to govern within their territories. In this case, they retain the right to adopt more extensive protection.

2. History of the provision

19

Contracting Party to adopt more extensive tariff protection than that to which it bound itself, but it was open to each Contracting Party to provide less tariff protection.

The WIPO Conventions did not attempt to establish the sole set of norms for the protection of IPRs, although they limited state discretion in a number of ways (for example, by requiring national treatment). Generally speaking, state parties to the WIPO conventions remained free to adopt more extensive protections than those specifically mandated by the agreements. While the Berne Convention established minimum standards of copyright protection, the Paris Convention did not define the principal substantive standards of patent protection, essentially leaving this to each state party.

IPRs may act as trade barriers and/or cause trade distortions.³² If a government grants patents without adequate attention to whether true novelty and inventive step are involved, it may create unjustified impediments to market entry for products both of local and foreign origin. The U.S. Federal Trade Commission has observed that weak patents pose a threat to competitive markets and has urged greater vigilance on the part of patent officials, as well as improved mechanisms for challenging such patents.³³ Although concern about potential overprotection of IPRs was evidenced by various WTO Members throughout the TRIPS Agreement negotiations, and the potential problem of overprotection is referred to in the preamble, upper boundaries of protection are not well defined by the agreement.

2.1.3 Determining method of implementation

The VCLT and customary international law regarding treaties do not mandate particular means by which state parties should implement their obligations. The national (or regional) constitution of each state provides the interface between treaty obligations and domestic law. There are significant differences between the ways that national constitutions treat the relationship between treaties and domestic law.³⁴

³² As acknowledged in the first recital of the TRIPS preamble: “[...], and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade; [...]”

³³ A 2003 Federal Trade Commission (FTC) study of competition and patents in the United States focused on anticompetitive risks of overprotection, including through grant of patents of suspect quality. Proliferation of patents may threaten innovation by creating obstacles to competitive R & D, and impose costs on consumers. Recommendations included creation of opposition procedure, reducing litigation presumptions favouring patent holders, tightening standards and increasing resources for examining patent applications, exercising caution in expanding scope of patentable subject matter, and increasing federal agency competition vigilance regarding operation of patent system. U.S. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, October 2003.

³⁴ There are generally three approaches. Under the “monist” approach the treaty is essentially treated as part of national law without any action needed by the national government other than to accept the treaty (*e.g.*, in Argentina, France and the Netherlands). Under the “dualist” approach the treaty and national law are considered separate, except to the extent that the national government takes specific steps to transform all or part of the treaty into national law (*e.g.*, in the United Kingdom). There is a middle ground approach in which treaties may be given direct effect, but the rights and obligations may also be modified by the legislature (*e.g.*, in the United States).

2.1.3.1 Direct effect. A treaty may or may not be intended to have “direct effect” (or “self-executing effect”) in the domestic law of states that are parties to it and whose national constitutions allow for this possibility. Generally speaking, if a treaty is directly effective, persons (whether natural persons, i.e. individuals, or enterprises) may rely on it as a source of law before national courts. If a treaty is directly effective, the national government does not need to take additional steps to implement it beyond those involved in approving or adhering to the treaty. If the national government does not alter the terms of a directly effective treaty in the implementation process, this may limit the range of options open to the executive or legislative authorities in controlling how it is implemented.³⁵ Interpretation moves into the hands of judges who are called upon to apply it in specific cases or controversies.

The WIPO conventions do not expressly address the issue of direct application. Some national courts have directly applied the Berne³⁶ and Paris³⁷ Conventions as domestic law.

The GATT 1947 did not expressly state whether it was intended to be directly effective. The question was left for national authorities to decide based on interpreting its terms and context, and this question remained controversial throughout the GATT 1947 period. In a series of decisions addressing this question, the European Court of Justice (ECJ) decided that it was not, based on the general nature of its obligations and the fact that Contracting Parties often settled disputes by political negotiation rather than through the more legalized dispute settlement process.³⁸

The negotiators of the TRIPS Agreement had the option to expressly indicate whether or not its terms would be directly effective, or to leave this as a matter for interpretation by national authorities or subject to constitutional law.

2.1.3.2 Legal systems and practice. As with ordinary domestic legislation, the terms of a treaty may be more or less detailed or precise. When legislation is drafted in general terms, it often requires more specific regulations in order to

³⁵ The law concerning direct effect of treaties is complex. If a treaty is directly effective, this does not necessarily preclude the government from adopting legislation to implement it, or even to modify its terms for domestic legal purposes. In the U.S. constitutional system, for example, the Congress may adopt “later in time” legislation that modifies the terms of the treaty for domestic purposes, even though this may not be consistent with U.S. international legal obligations. On the other hand, in the Netherlands, a directly effective treaty adopted by the legislative body may not be modified by subsequent legislation. If domestic law is to be altered, the treaty must be amended, or adherence withdrawn. See generally, *Parliamentary Participation in the Making and Operation of Treaties: A Comparative Study* (S.A. Riesenfeld & F.M. Abbott, eds. 1994: Martinus Nijhoff/Kluwer), and country chapters therein [hereinafter “Parliamentary Participation”].

³⁶ See, e.g., *SUISA v. Rediffusion AG*, Bundesgericht (Switzerland), [1982] ECC 481, Jan. 20, 1981, referring also to other European judgments. In the SUIISA decision, the court refers to both Swiss federal law and the Berne Convention as the source of applicable legal rules.

³⁷ See, e.g., *Cuno v. Pall*, 729 F. Supp. 234 (EDNY 1989), U.S. federal district court applying Article 4bis of the Paris Convention directly.

³⁸ Beginning with Joined Cases 21 to 24/72 *Internationale Fruit Company N.V. v. Produktschap voor Groenten en Fruit* (No. 3) [1972], ECR 1219. As to the ECJ’s jurisprudence with respect to a possible direct effect of the *WTO Agreements*, see below, Section 6.3; as well as Chapter 32.

2. History of the provision

21

give it effect. Similarly, when treaties are drafted in more general terms, they may require more specific national legislation to produce effects in local law.

The WIPO conventions did not provide specific rules regarding how state parties should implement them in national law. Each state party was left to determine the appropriate method of implementation in the domestic legal system.

The level of specificity in the GATT 1947 varied among its provisions, though most of its rules were stated in a fairly general way. The Tokyo Round Codes added substantial specificity in areas such as regulation of dumping and subsidies, in part to address a perception that the more general rules of the GATT 1947 provided too much flexibility regarding the manner in which Contracting Parties interpreted those rules.

Intellectual property has traditionally been a highly sensitive policy area, and prior to the Uruguay Round states took rather different approaches to IPR regulation, even when addressing the same subject matter. In approaching the TRIPS negotiations, GATT Contracting Parties had the option of adopting very specific rules intended to remove discretion that states traditionally enjoyed in regulating IPRs, or adopt more general rules and leave greater discretion in the method of implementation. On the whole, the TRIPS Agreement that was concluded allows substantial flexibility in the specific implementation of IPR rules, while broadly demanding subject matter coverage for traditionally sensitive areas. The result is thus a mixed one: flexibility as to the finer aspects of implementation, yet starting from a broad scope of coverage.

2.2 Negotiating history

2.2.1 The 1987 U.S. proposal

Discussions concerning the extent to which TRIPS would provide more general guidelines or instead seek to “harmonize” national IPR legislation are evident throughout the negotiating history. In its initial 1987 proposal, the United States suggested consistency with a defined set of standards, stating:

“In adhering to a GATT Agreement on trade-related aspects of intellectual property rights, Parties would agree to provide in their national laws for the protection of intellectual property at a level consistent with agreed norms attached in an annex to the Agreement.”³⁹

2.2.2 The 1988 E.C. proposal

The European Community stressed in 1988 the importance of allowing for different national approaches:

“[Negotiations] should address trade-related substantive standards in respect of issues where the growing importance of intellectual property rights for international

³⁹ Suggestion by the United States for Achieving the Negotiating Objective, United States Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/14, 20 Oct. 1987, Nov. 3, 1987, at Norms.

trade requires a basic degree of convergence as regards the principles and the basic features of protection; GATT negotiations on trade related aspects of substantive standards of intellectual property rights should not attempt to elaborate rules which would substitute for existing specific conventions on intellectual property matters; contracting parties could, however, when this was deemed necessary, elaborate further principles in order to reduce trade distortions or impediments. *The exercise should largely be limited to an identification of and agreement on the principles of protection which should be respected by all parties; the negotiations should not aim at the harmonization of national laws.*"⁴⁰ [italics added]

2.2.3 The 1989 Australian proposal

Other industrialized country delegations highlighted that the TRIPS negotiations should focus on basic principles and trade effects. For example, in 1989, the Australian delegation adopted the following approach:

"Introducing his country's proposal (NG11/W/35), the representative of Australia said that the paper was intended to address the key issue of what standards and principles concerning the availability, scope and use of IPRs were appropriate to avoid inadequate or excessive protection of intellectual property in trade. Noting the use of the word "adequate" in paragraph 4(b) of the April TNC decision, he said that this suggested to his authorities that the Group was not necessarily looking for the highest possible standards or the broadest scope of protection."⁴¹

2.2.4 The 1988 Swiss proposal

The Swiss proposal for a TRIPS Agreement was centred on the notion that governments would maintain flexibility to adopt IPR laws they considered appropriate, provided that those laws did not conflict with an indicative list of practices that would be presumed to nullify or impair GATT rights.⁴²

2.2.5 The Indian position in 1989

Reflecting the importance that the Indian delegation attached to the question of discretion regarding standards, in 1989 its delegate observed:

"Recognising the extraordinary rights granted by the system and their implications, international conventions on this subject incorporated, as a central philosophy, the freedom of member States to attune their intellectual property protection system to their own needs and conditions. *This freedom of host countries should be recognised as a fundamental principle and should guide all of the discussions in the Negotiating Group.*"⁴³ [italics added]

⁴⁰ Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/W/26, July 1988, at II.

⁴¹ Note by the Secretariat, Meeting of Negotiating Group of 12-14 July 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/14, 12 September 1989, at para. 6 [hereinafter July 1989 meeting].

⁴² Proposition de la Suisse, MTN.GNG/NG11/W/25, 29 June 1988.

⁴³ Note on July 1989 meeting, at para. 5.

3. Possible interpretations

23

2.2.6 The Anell Draft

At the meeting of TRIPS negotiators in October – November 1989, a number of interventions by delegations indicated a widely held perception that TRIPS should reflect a set of minimum substantive standards that would not be intended to harmonize national law.⁴⁴

The composite text circulated by the Chairman (Lars E. R. Anell) of the TRIPS Negotiating Group in a July 23 1990 report on the status of work referred to implementation in the following way:

“3A. Unless expressly stated otherwise, nothing in Parts III-V of this agreement shall prevent PARTIES from granting more extensive protection to intellectual property rights than that provided in this agreement.”

2.2.7 The Brussels and Dunkel Drafts

Article 1.1 appeared in the draft text transmitted on the Chairman’s initiative to the Brussels Ministerial Conference in December 1990, and in its final form in the Dunkel Draft text. Both texts were essentially similar to the current provision under TRIPS.

The years during which the TRIPS negotiations took place witnessed a great deal of attention among trade scholars to the question whether the GATT 1947, and the ultimately adopted WTO Agreement, should be given “direct effect” by Members.⁴⁵ The focus of this inquiry was on whether persons (individual or enterprise) should be given the right to invoke WTO rights and obligations before their national courts. Despite this substantial amount of activity in the academic arena, and bearing in mind that a number of leading trade scholars substantially influenced the Uruguay Round negotiations, the question of direct effect was not a subject that drew the express attention of the TRIPS negotiators, at least as reflected in the minutes of the negotiating sessions.

3. Possible interpretations

3.1 Article 1.1, First sentence

Members shall give effect to the provisions of this Agreement.

The interpretation of the first sentence of Article 1.1 that Members shall “give effect” to its provisions, is not a likely subject of dispute, in light of the third

⁴⁴ For example, the delegate from New Zealand said that the New Zealand proposal was presented as a basis for adequate minimum standards; it did not seek to constrain countries from going further than the minimum standards. Given the limited amount of time left for negotiation, his delegation felt that the Group should not attempt to be over-ambitious, either in the level of detail of commitments or through attempting to invent a whole new system. Note by the Secretariat, Meeting of Negotiating Group of 30 October-2 November 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MTN.GNG/NG11/16, 4 December 1989, at para. 3.

⁴⁵ See generally, *National Constitutions and International Economic Law, Studies in Transnational Economic Law* (M. Hilf, E.-U. Petersmann, ed.), Deventer, 1993.

sentence that elaborates on the “method” for giving effect. In the absence of the third sentence, argument might well be had over how the giving of effect is to be accomplished. Since the question is more specifically addressed by the third sentence, the first should be understood as serving to state the general treaty obligation to perform in good faith.

As stated above (Section 1), the obligation to “give effect” may be discharged not only through the adoption of specific statutes or administrative rules to implement TRIPS, but also where a Member elects to rely directly on the text of the Agreement as part of national law. In this case, however, it should be noted that some of the TRIPS provisions, in order to be applied to a particular case, require further concretisation through domestic legislation or case law.⁴⁶

3.2 Article 1.1, Second sentence

Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.

There are several interpretative issues raised by this sentence.

It appears reasonable to conclude that this provision signifies that the rules of TRIPS are intended as “minimum” standards of IPR protection. Members may adopt more extensive protection, but not less extensive protection. Note, however, that the minimum standard of protection is that “required” by the Agreement, and that the express requirements of the Agreement are often framed in rather flexible terms. In this sense, the minimum standards are subject to differential application.

The second sentence also provides that Members “shall not be obliged to” implement more extensive protection. Some Members have made demands in the context of bilateral or regional negotiations that other Members adopt so-called “TRIPS-plus” standards of protection. The express language of this second sentence makes clear that no Member is obligated by the TRIPS Agreement to adopt such TRIPS-plus standards.

An important interpretative question is whether a Member that *demand*s the adoption of TRIPS-plus standards in the bilateral or regional context might be failing to perform its TRIPS Agreement obligations in good faith. The argument on behalf of a Member’s being subjected to such demands would be that it accepted its TRIPS obligations as part of a set of reciprocally negotiated commitments that represent a balance of rights and obligations on which that Member is entitled to rely. Bilateral pressure to exceed the agreed upon commitments is contrary to

⁴⁶ For instance, the TRIPS provisions on exceptions to exclusive rights, such as Article 30 with respect to patents, which reads: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” For details on Article 30 see below, Chapter 23.

3. Possible interpretations

25

the object and purpose of the WTO Agreement and TRIPS Agreement to provide a secure framework for the conduct of international trade relations.

A counter-argument is that each Member is sovereign and free to accept or reject additional commitments in the bilateral or regional context. Diplomacy often involves the application of pressure in some form, and the application of pressure cannot inherently be ruled out in international relations.

The WTO Appellate Body and Dispute Settlement Body (DSB) might well have to consider whether there are forms of bilateral or regional pressure that exceed the limits of good faith performance of TRIPS. Recall that in negotiations surrounding the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, developing countries sought a commitment from developed Members that bilateral and regional pressures to forego TRIPS Agreement options, and to adopt TRIPS-plus measures, would be halted.⁴⁷ The question from a TRIPS Agreement interpretative standpoint is the threshold at which a Member would be considered “obliged” to adopt more extensive protection as the result of bilateral pressure. At what point would the pressured Member be relinquishing its sovereign capacity to freely bargain?⁴⁸

Another important interpretative question raised by Article 1.1, second sentence, is at what stage more extensive protection contravenes TRIPS? The preamble of the Agreement, discussed in Chapter 1, recognizes that “measures and procedures to enforce intellectual property rights” may constitute “barriers to legitimate trade”. Yet the express text of TRIPS on substantive matters is largely devoted to setting forth minimum standards of protection, not maximum levels or upper limits. In this sense, the text of the Agreement appears to provide limited guidance regarding the kinds of more extensive IPRs substantive measures that might “contravene the Agreement”. On the other hand, the enforcement provisions of TRIPS provide that certain rights must be accorded to parties alleged to be engaged in infringing acts. So, for example, Article 42 prescribes that defendants be accorded due process rights in IPR enforcement proceedings. The adoption of more extensive protection that diminished these due process rights would contravene TRIPS. In this regard, more extensive protections should not include reducing the rights of those asserted to be engaged in infringing acts. Since the reduction of procedural rights would contravene specific provisions of TRIPS, the reference in Article 1.1 may not add very much in this regard.

3.3 Article 1.1, Third sentence

Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

⁴⁷ See Non-paper (Africa Group et al.), “Ministerial Declaration on the TRIPS Agreement and Public Health”, 19 Sept. 2001.

⁴⁸ There is an analogy to the common law contract doctrine of “unconscionability” that examines whether a bargain should be voided because of undue pressure placed by one party on another.

A narrow construction of this provision might suggest that the words “appropriate method”⁴⁹ refer only to the legal procedure by which a Member implements its TRIPS obligations. So, for example, a Member could choose to implement TRIPS by adopting either a statute or administrative regulation, or allow the TRIPS Agreement direct effect and rely on judicial application of the Agreement.

A broader construction of this provision acknowledges the flexibility inherent in the text of TRIPS. It refers not only to method, but also to the “legal system and practice” of each Member. The method of implementation therefore may take into account each Member’s system of laws, and its practice regarding the application of those laws. Throughout the historical development of IPR law, countries have taken different approaches within their legal systems and practice to basic issues such as the scope of permissible exceptions, including the means by which exceptions are recognized. In some countries, for example, exceptions to patent rights are adopted as part of the statutory framework. In others, courts have crafted the exceptions as a matter of judicial application.⁵⁰ The acknowledgement that courts may be responsible for determining the permissible scope of exceptions is an inherent acknowledgement that IPR protection will vary among Members, and that Members maintain flexibility in implementing TRIPS.

There are limits to TRIPS Agreement flexibility in the sense that its rules cannot be stretched beyond reasonable good faith interpretation.⁵¹

In acknowledging the freedom of each Member to determine the appropriate method of implementing the Agreement, Article 1.1, third sentence, does not mandate that Members give it “direct” or “self-executing” effect. At the same time, that sentence does not appear to indicate that the Agreement should not be considered directly effective in countries where this is permitted. Instead, the matter is left to the constitutional system and practice of each Member state to determine.

It might be argued that because all Members need not apply TRIPS directly, it is not intended to be applied directly by any Member. This argument, which is based on reciprocity of obligation, has not traditionally persuaded courts where direct effect is practiced. Some states, such as the United Kingdom, do not allow direct effect for any treaty, and if reciprocity determined the directly applicable character of a treaty, then no treaty to which the UK is a party could be directly effective. This is not the accepted practice. The most reasonable interpretation of Article 1.1, third sentence, would appear to be that each Member is free to determine whether it will apply the Agreement directly, and that this will depend on its legal system and practice.

Where direct effect is possible, courts tend to look at whether the terms of the agreement are sufficiently precise to be applied by a court in a concrete case or controversy, and in light of the object and purpose of the agreement. The question of direct effect thus involves a “contextual analysis”. If TRIPS is given direct effect, this will provide entitlements to right holders, as well as entitlements to those

⁴⁹ The New Shorter Oxford English Dictionary defines “method” as a noun as “I Procedure for attaining an object.”

⁵⁰ See, e.g., Annex 5 to the *Canada-Generics* decision describing national approaches to regulatory review exceptions. (Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, 17 March 2000.)

⁵¹ See discussion of the *India-Mailbox* case, Section 4, below.

4. WTO jurisprudence

27

defending against claims brought by right holders (for example, by allowing “fair use” defences). If the national legislature wants to exercise greater control over the way the TRIPS Agreement is locally applied, it may well decide not to rely on principles of direct effect that leaves issues of specific implementation up to the courts.

4. WTO jurisprudence

4.1 India-Mailbox

Article 1.1 was most notably discussed by the WTO Appellate Body (“AB”) in the *India-Mailbox* case.⁵² In that case, India argued that because Article 1.1 allowed it to implement the requirement of establishing a mechanism for the receipt and preservation of patent applications (the so-called “mailbox”) in the manner it determined to be appropriate, the AB should accept its representation that the mechanism it had established was adequate within its own legal system. The AB acknowledged India’s freedom to choose the appropriate method of implementation within its own legal system, but did not accept that this precluded examining whether the means chosen by India were in fact adequate to fulfil its obligation. The AB said:

“58. ... [W]e do *not* agree with the Panel that Article 70.8(a) requires a Member to establish a means ‘so as to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated because, at the filing or priority date, the matter for which protection was sought was unpatentable in the country in question’ ... In our view, India is obliged, by Article 70.8(a), to provide a legal mechanism for the filing of mailbox applications that provides a sound legal basis to preserve both the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates. No more.

59. But what constitutes such a sound legal basis in Indian law? To answer this question, we must recall first an important general rule in the *TRIPS Agreement*. Article 1.1 of the *TRIPS Agreement* states, in pertinent part:

... Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Members, therefore, are free to determine how best to meet their obligations under the *TRIPS Agreement* within the context of their own legal systems. And, as a Member, India is ‘free to determine the appropriate method of implementing’ its obligations under the *TRIPS Agreement* within the context of its own legal system.

60. India insists that it has done that. India contends that it has established, through ‘administrative instructions’, a ‘means’ consistent with Article 70.8(a) of the *TRIPS Agreement*. According to India, these ‘administrative instructions’ establish a mechanism that provides a sound legal basis ...

[...]

⁵² *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Report of the Appellate Body, WT/DS50/AB/R, 19 December 1997 (“India – Mailbox”). For more details on the factual background, see Chapter 36.

64. India asserts that the Panel erred in its treatment of India's municipal law because municipal law is a fact that must be established before an international tribunal by the party relying on it. In India's view, the Panel did not assess the Indian law as a fact to be established by the United States, but rather as a law to be interpreted by the Panel. India argues that the Panel should have given India the benefit of the doubt as to the status of its mailbox system under Indian domestic law. India claims, furthermore, that the Panel should have sought guidance from India on matters relating to the interpretation of Indian law.

65. In public international law, an international tribunal may treat municipal law in several ways. Municipal law may serve as evidence of facts and may provide evidence of state practice. However, municipal law may also constitute evidence of compliance or non-compliance with international obligations [...].

66. In this case, the Panel was simply performing its task in determining whether India's 'administrative instructions' for receiving mailbox applications were in conformity with India's obligations under Article 70.8(a) of the *TRIPS Agreement*. It is clear that an examination of the relevant aspects of Indian municipal law and, in particular, the relevant provisions of the Patents Act as they relate to the 'administrative instructions', is essential to determining whether India has complied with its obligations under Article 70.8(a). There was simply no way for the Panel to make this determination without engaging in an examination of Indian law. But, as in the case cited above before the Permanent Court of International Justice, in this case, the Panel was not interpreting Indian law 'as such'; rather, the Panel was examining Indian law solely for the purpose of determining whether India had met its obligations under the *TRIPS Agreement*. To say that the Panel should have done otherwise would be to say that only India can assess whether Indian law is consistent with India's obligations under the *WTO Agreement*. This, clearly, cannot be so.

[...]

70. We are not persuaded by India's explanation of ... seeming contradictions. Accordingly, we are not persuaded that India's 'administrative instructions' would survive a legal challenge under the Patents Act. And, consequently, we are not persuaded that India's 'administrative instructions' provide a sound legal basis to preserve novelty of inventions and priority of applications as of the relevant filing and priority dates."

The AB decided that freedom to determine appropriate method is not the equivalent of a right to self-certify compliance with TRIPS obligations. Compliance requires demonstration of a legally sound basis of implementation.

4.2 Canada-Generics

In the *Canada-Generics* case,⁵³ Canada argued that Article 1.1, third sentence, provided it with substantial discretion in determining the scope of exceptions to patent rights, particularly when read in conjunction with Articles 7 and 8.1.

⁵³ *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000 ("Canada-Generics").

4. WTO jurisprudence

29

According to the panel report, Canada argued:

“The existence of such a discretion was consistent with the provision of Article 1.1 that Members should be free to determine the appropriate method of implementing the provisions of the TRIPS Agreement, which provisions of course included Articles 7 and 30 as well as Articles 27, 28 and 33.

The provision of this discretion, in the interests of achieving an appropriate balance in each of the national legal systems, reflected Members’ desire to ensure that the limitations on the scope of patent rights that existed within – or were contemplated for – their own intellectual property laws at the time the Agreement was being negotiated would be taken into account.” (para. 4.13) (argument of Canada)

The European Communities argued in response:

“Article 1.1 of the TRIPS Agreement was invoked by Canada in order to establish that it had a broad *discretion* as to how to implement its obligations under the Agreement. However, Canada was wrong to consider that this provision provided a general discretion for Members to *adjust* obligations under the Agreement. It clearly stated that the protection of intellectual property under the TRIPS Agreement was to be considered a *minimum level of protection*. The flexibility which was allowed related to the *means* by which this minimum level of protection was secured in each Member’s legal system.” (para. 4.29)(argument of the EC)

In its determination, the Panel did not attribute significance to Article 1.1, instead focusing on Articles 7 and 8. It said:

“7.23 Canada called attention to a number of other provisions of the TRIPS Agreement as relevant to the purpose and objective of Article 30. Primary attention [footnote 385] was given to Articles 7 and 8.1 . . . [footnote 385: Attention was also called to the text of the first recital in the Preamble to the TRIPS Agreement and to part of the text of Article 1.1. The Preamble text in question reads: ‘Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;’ (emphasis added by Canada)]

[. . .]

7.25 The EC also referred to the provisions of first consideration of the Preamble and Article 1.1 as demonstrating that the basic purpose of the TRIPS Agreement was to lay down minimum requirements for the protection and enforcement of intellectual property rights.

[. . .]

7.26 Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.”

The panel in the *Canada-Generics* case did not specifically rely on Articles 7 and 8.1 or Article 1.1 in its determination regarding Canada’s stockpiling and regulatory review exceptions.

4.3 U.S. – Copyright (Homestyle Exemption)

The decision of the panel in the *U.S. – Copyright (Homestyle Exemption)* case refers to the argument of the United States in its written submission concerning Article 1.1.⁵⁴ In its written submission, the United States said:

“Article 1.1 of TRIPS also *emphasizes flexibility*, and provides that ‘Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice’.”⁵⁵ (Italics added)

It is notable that the United States acknowledged that Article 1.1 “emphasizes flexibility” in defending its implementation of Article 13, TRIPS Agreement, which deals with limitations and exceptions to copyright.

5. Relationship with other international instruments

As noted earlier, the obligation on states to implement treaties is implicit in the obligation to perform in good faith recognized in the VCLT. The manner in which each state undertakes this obligation depends on its national constitutional arrangement and on the terms, context and object and purpose of the treaty in question.

6. New developments

6.1 National laws

Article 1.1 addresses the method of implementing the Agreement. Since all WTO Members were required to implement at least certain parts of the Agreement upon its entry into force on 1 January 1995, a large body of national experience has already accumulated. Additional implementation obligations arose on 1 January 1996 and 1 January 2000, depending on the level of development of Members.⁵⁶

Inquiry regarding national experience in the implementation of TRIPS should include studying the means by which Members have chosen to give effect to the flexibility inherent in the rules, for example, in the adoption of exceptions to general obligations. Such exceptions have already been the subject of WTO dispute settlement in the fields of patent (*Canada-Generics*) and copyright (*U.S. – Copyright (Homestyle Exemption)*).⁵⁷

There have been notable instances of Members being challenged in national courts regarding compliance with TRIPS Agreement obligations. The most significant and widely reported was the case brought by 39 pharmaceutical companies against the government of South Africa regarding the Medicines and Related Substances Control Amendment Act of 1997. The legal arguments of the pharmaceutical companies included that parallel importation of medicines was not allowed

⁵⁴ *United States – Section 110(5) of the US Copyright Act*, Report of the Panel, WT/DS160/R, 15 June 2000 (“*U.S. – Copyright (Homestyle Exemption)*”), at para. 6.189, note 167.

⁵⁵ *Id.*, Annex 2.1, First Written Submission of the United States, 26 Oct. 1999, para. 21.

⁵⁶ For details on the TRIPS transitional periods, see Chapter 33.

⁵⁷ There is limited discussion of the trademark exceptions in *U.S. – Havana Club*, but that treatment was not a significant element in the AB decision.

6. New developments

31

pursuant to Article 28. The pharmaceutical companies eventually withdrew their complaint.⁵⁸

In view of the extensive national experience in implementing TRIPS, it is not feasible to provide a systematic review here. It is, however, possible to describe a few approaches Members have taken regarding whether TRIPS is directly effective (or self-executing) in domestic law. The experience of Argentina, South Africa and the United States is representative of the variety of potential approaches. The situation in the European Communities is described below in relation to regional arrangements.

6.1.1 Argentina

The Constitution of Argentina has been interpreted by courts as allowing the direct application of international treaties, provided that their particular provisions are precise and complete enough to be applied without further legislative developments. This doctrine has been applied in several cases where plaintiffs invoked provisions of the TRIPS Agreement, particularly articles 33 and 50 of the Agreement.⁵⁹ The Supreme Court confirmed this monist interpretation in several rulings,⁶⁰ indicating that in case of contradiction between a provision of the domestic law and a provision of TRIPS, the latter overrides and replaces the former.

6.1.2 South Africa

The South African Constitution has undergone several recent revisions that have affected the manner in which treaties may be given effect in national law.⁶¹ The Constitution under which the Uruguay Round Agreements were approved for ratification by the South African Parliament required that a treaty be expressly adopted as part of national law to have direct effect.⁶² The South African Parliament approved the ratification of the Uruguay Round Agreements in 1995, and did not stipulate that those agreements would have direct effect.⁶³ The subsequent

⁵⁸ For a description of the legal arguments in the South Africa pharmaceuticals case, see Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, Study Paper 2a for the British Commission on Intellectual Property Rights, Feb. 2002, available at <<http://www.iprcommission.org>>. For an analysis of the interplay of parallel imports and Article 28, TRIPS Agreement, see below, Chapter 5.

⁵⁹ See, e.g., *S.C. Johnson & Son Inc. c/Clorox Argentina S.A. s/medidas cautelares*, Cam.Fed.Civ. y Com. Sala II, 30 April 1998; *Lionel's S.R.L. s/ medidas cautelares*, Cam.Fed.Civ.y Com. Sala II, 24 November 1998.

⁶⁰ See *Unilever NV c/Instituto Nacional de la propiedad Industrial s/denegatoria de patente*, 24.10.2000; *Dr. Karl Thomae Gesellschaft mit Beschränkter Haftung c/Instituto Nacional de la Propiedad Industrial s/denegatoria de patente*, 13.2.01. See also Correa, Carlos (2001) "El régimen de patentes tras la adopción del Acuerdo sobre los Derechos de la Propiedad Intelectual Relacionados con el Comercio", *Jurisprudencia Argentina*, No. 6239, Buenos Aires.

⁶¹ See, e.g., John Dugard and Iain Currie, *International Law and Foreign Relations*, in *Annual Survey of South African Law 1995*, at 76 et seq. (Juta & Co., Limited) [hereinafter Dugard and Currie].

⁶² This text largely followed the British model and required legislative action to give treaty provisions direct effect in national law. See *Azanian Peoples Organization v. President of the Republic*, Constitutional Court of South Africa, Case CCT17/96, decided July 25, 1996, at paras. 26–27.

⁶³ See Dugard and Currie, referring to approval of ratification of "Marrakesh Final Agreement establishing the World Trade Organization and incorporating the General Agreement on Tariffs

and present text of the Constitution allows for the possibility of direct effect without express statement when a self-executing treaty provision is not inconsistent with the Constitution or an act of Parliament.⁶⁴

There is an interesting and as yet unresolved question under South African law whether a treaty adopted prior to the change in the constitutional treatment of direct effect, including TRIPS, will be evaluated under the new or old constitutional rule.

In any case, the South African Parliament adopted legislation to bring national law into compliance with the WTO Agreements, including TRIPS.⁶⁵ This is consistent with the type of dualist approach followed in the United States, which permits direct effect, but allows the legislature to control even directly effective treaties by subsequent legislation. The one approach does not exclude the other. That is, a treaty may be directly effective as to some issues, but controlled by legislation as to others.

6.1.3 United States

In the U.S. constitutional framework, the Congress has primary authority in the conduct of external trade relations, and the President and executive branch act in the field of international trade relations under both general and specific grants of authority from the Congress.⁶⁶ Congress authorized U.S. adherence to the WTO Agreement, including TRIPS, in the Uruguay Round Agreements Act (URAA), which also implemented the WTO Agreement in U.S. domestic law.⁶⁷ In connection with the congressional fast-track approval process that was used for the URAA, the executive branch submitted to the Congress a Statement of Administrative Action that was and is intended to represent the authoritative interpretation of the WTO Agreement by the executive branch both for purposes of U.S. international obligation and domestic law.⁶⁸ The Statement of Administrative Action was

and Trade (GATT) – *National Assembly Debates* col 653 (6 April 1995); *Senate Debates* col 554 (6 April 1995)", at page 77, and exclusion from list of treaties resolved to have direct effect by Parliament, at page 79.

⁶⁴ Article 231 of the Constitution of South Africa, adopted 8 May 1996, amended 11 Oct 1996 and in force from 7 Feb 1997, provides in relevant part:

Section 231 International agreements

"(4) Any international agreement becomes law in the Republic when it is enacted in law by national legislation; but a self-executing provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.

(5) The Republic is bound by international agreements which were binding on the Republic when this Constitution took effect."

⁶⁵ For a discussion of the interface between the South African Constitution, trade agreements and national trade law, see Gerhard Erasmus, *The Incorporation of International Trade Agreements into South African Law: The Extent of Constitutional Guidance*, 28 SOUTH AFRICAN YEARBOOK OF INTERNATIONAL LAW, 2003 at pgs.157–181.

⁶⁶ See generally, Riesenfeld and Abbott, *The Scope of U.S. Senate Control over the Conclusion and Operation of Treaties*, in *Parliamentary Participation* at 302.

⁶⁷ Uruguay Round Agreements Act [hereinafter URAA], Pub. L. 103-465, 108 Stat 4809 (1994), sec. 101(a)(1).

⁶⁸ Office of the U.S. Trade Representative, *The Uruguay Round Agreements Act Statement of Administrative Action*, at introduction. URAA, sec. 101(d).

6. New developments

33

approved by Congress in connection with approval of the URAA.⁶⁹ The President accepted the WTO Agreement and related Uruguay Round Agreements following approval by Congress⁷⁰ and in accordance with the procedures prescribed in Article XIV of the WTO Agreement. The WTO Agreement and related agreements entered into force for the United States on January 1, 1995.⁷¹

Congress in the URAA followed a pattern that it had established in connection with the GATT Tokyo Round Agreements, by denying self-executing or direct effect to the WTO Agreement.⁷²

The provisions of the URAA which deny the WTO Agreement self-executing or direct effect apply to all constituent components of the agreement, and so encompass TRIPS. These provisions preclude a private party's direct reliance on the WTO Agreement as the basis for civil action against a private party, or as the basis for action against the federal or state governments.

6.2 International instruments

6.3 Regional and bilateral contexts

6.3.1 Regional

In an advisory opinion of 1994, the ECJ decided that the TRIPS Agreement must be adopted jointly by the member states and the EC because the member states and EC shared competence in the regulations of IPRs.⁷³ When the Council of the European Communities subsequently approved adherence to the Uruguay Round

⁶⁹ URAA, sec. 101(a)(2).

⁷⁰ URAA, sec. 101(b).

⁷¹ See 19 USCA §3511 (1996).

⁷² Section 102 of the URAA provides "(a) Relationship of Agreements to United States Law.- (1) United States Law to Prevail in Conflict.- No provision of any of the Uruguay Round Agreements, nor the application of any such provisions to any person or circumstance, that is inconsistent with any law of the United States shall have effect." Section 102 of the URAA further provides:

"(c) Effect of Agreement With Respect to Private Remedies.-

(1) Limitations.- No person other than the United States-

(A) shall have any cause of action or defense under any of the Uruguay Round Agreements or by virtue of congressional approval of such an agreement, or

(B) may challenge, in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, any State, or any political subdivision of a State on the ground that such action or inaction is inconsistent with such agreement.

(2) Intent of congress.- It is the intention of the Congress through paragraph (1) to occupy the field with respect to any cause of action or defense under or in connection with any of the Uruguay Round Agreements, including by precluding any person other than the United States from bringing any action against any State or political subdivision thereof or raising any defense to the application of State law under or in connection with any of the Uruguay Round Agreements-

(A) on the basis of a judgment obtained by the United States in an action brought under any such agreement; or

(B) on any other basis."

The Statement of Administrative Action is perhaps more categorical than the statute concerning the preclusion of direct effect, particularly as it might relate to actions as between private parties.

It says, *inter alia*:

"A private party thus could not sue (or defend suit against) the United States, a state or a private party on grounds of consistency (or inconsistency) with those [WTO] agreements." *Id.* at 20.

⁷³ Opinion 1/94 of 15 November 1994 [1994] ECR I-5267, para 105.

Agreements, the decision expressing that approval included a recital that it was understood the WTO Agreement would not be considered directly effective for the EC.⁷⁴ A recital would not ordinarily have the same legal effect as an operative provision of a decision, but would nonetheless be expected to have some influence in the interpretation of that decision and the subject treaty by the EC organs.

In 1999, the ECJ in *Portugal v. Council* decided that the WTO Agreements were not directly effective in the law of the EC.⁷⁵ The ECJ relied on essentially the same arguments that persuaded it in 1972 (in the *International Fruit* case) that the GATT 1947 was not directly effective in Community law.⁷⁶ In 2000, the ECJ decided in *Parfums Christian Dior v. Tuk Consultancy*⁷⁷ that its decision in *Portugal v. Council* extended to TRIPS, and that TRIPS is not directly effective as a matter of Community law.⁷⁸ The ECJ added, however, that because TRIPS is an international obligation of the EC, the courts should endeavour to interpret EC law consistently with TRIPS.⁷⁹

For the EC, the matter is complex because it does not enjoy exclusive competence *vis-à-vis* the member states in the field of IPRs. The ECJ therefore said that the question of direct effect must be resolved as a matter of member state law as to those areas in which the member state retains exclusive competence.⁸⁰

⁷⁴ Council Decision (of 22 December 1994) concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) *Official Journal of the European Communities* L 336, 23/12/1994 p. 1–2.

⁷⁵ See Case C-149/96 *Portuguese Republic v Council of the European Union*, [1999] ECR I-8395, at para. 47: “It follows from all those considerations that, having regard to their nature and structure, the WTO agreements are not in principle among the rules in the light of which the Court is to review the legality of measures adopted by the Community institutions.” [hereinafter *Portugal v Council*].

⁷⁶ See Joined Cases 21 to 24/72 *International Fruit Company N.V. v. Produktschap voor Groenten en Fruit* (No. 3) [1972] ECR 1219.

⁷⁷ See joined cases C-300/98 and C-392/98 *Parfums Christian Dior SA and Tuk Consultancy BV*, [2000] ECR I-11307. While in *Portugal v Council* the ECJ refused the *EU member states* the possibility to invoke the WTO Agreements against EC legislation, the *Christian Dior* decision concerned the denial of direct effect in favour of *individuals* (i.e. EU citizens).

⁷⁸ The ECJ said:

“44. For the same reasons as those set out by the Court in paragraphs 42 to 46 of the judgment in *Portugal v Council*, the provisions of TRIPS, an annex to the WTO Agreement, are not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law.”

⁷⁹ The ECJ said:

“49. [...] in a field to which TRIPS applies and in respect of which the Community has already legislated, the judicial authorities of the Member States are required by virtue of Community law, when called upon to apply national rules with a view to ordering provisional measures for the protection of rights falling within such a field, to do so as far as possible in the light of the wording and purpose of Article 50 of TRIPS, [...]”

⁸⁰ The ECJ said:

“49. [...] in a field in respect of which the Community has not yet legislated and which consequently falls within the competence of the Member States, the protection of intellectual property rights, and measures adopted for that purpose by the judicial authorities, do not fall within the scope of Community law. Accordingly, Community law neither requires nor forbids that the legal order of a Member State should accord to individuals the right to rely directly on the rule laid down by Article 50(6) of TRIPS or that it should oblige the courts to apply that rule of their own motion.”

7. Comments, including economic and social implications

35

In *Christian Dior*, this meant that the courts of the Netherlands would decide whether Article 50.6, TRIPS Agreement, regarding provisional measures, would be directly applied in Dutch law. The ECJ has in effect acknowledged that the question whether TRIPS is directly effective is to be determined by each WTO Member (bearing in mind that in the case of the EC the identity of that Member may differ depending on the context).

6.4 Proposals for review

As part of its authority under Article 68, TRIPS Agreement, (see Chapter 35 of this book) to monitor implementation of obligations and afford Members the opportunity to consult with respect to IPRs, the Council for TRIPS is reviewing implementation of TRIPS Agreement obligations. These reviews began with respect to developed Members following their general implementation deadline of 1 January 1996, and with respect to developing Members following their general implementation deadline of 1 January 2000.⁸¹

A number of developing Members have suggested an amendment or interpretation of TRIPS that would preclude the exercise of bilateral or regional pressure against Members that propose to act to take advantage of flexibility inherent in TRIPS, such as the right to issue compulsory licenses.⁸² This type of amendment or interpretation would address Article 1.1, second sentence, providing that Members are not obliged to adopt TRIPS-plus protection.

7. Comments, including economic and social implications

TRIPS established minimum standards of IPR protection that are consistent with the prevailing standards in the most highly industrialized countries. Highly industrialized countries such as the United States and Japan went through prolonged periods of providing weak IPR protection to achieve their present levels of development.⁸³ TRIPS to some extent precludes today's developing countries from relying on this same model of economic transformation by setting minimum standards at levels tailored for later stages of growth. Moreover, by setting minimum standards, but not maximum standards, TRIPS leaves an opening for bilateral and regional agreements that may significantly shift the balance of economic interests to the more powerful WTO Members, thereby further exacerbating problems in the global distribution of wealth. With hindsight, developing Members might have insisted more strongly that TRIPS reflect not only the minimum standards of IPR protection, but also that any increase in those standards be negotiated only within the multilateral framework of the WTO (where developing Members have a higher degree of control over outcomes). Developing Members have a certain margin of flexibility in the implementation of TRIPS Agreement standards

⁸¹ This review process is discussed in Chapter 35.

⁸² See, e.g., proposal of developing country group for a Declaration on the TRIPS Agreement and Public Health, Section 3 above.

⁸³ See UNCTAD-ICTSD Policy Discussion Paper, Chapter 1.

which they should take great care to use and preserve.⁸⁴ This may not be the optimal way to address development priorities, but it is for now the one provided by TRIPS.

⁸⁴ The importance of understanding the flexible nature of TRIPS Agreement provisions is elaborated in various works by Profs. Carlos Correa and Jerome Reichman, see, e.g., Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre 2000), and; Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After U.S. v. India*, 1 J. INT'L ECON. L. 585 (1998).