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Appellate Body

**INDIA - PATENT PROTECTION FOR PHARMACEUTICAL
AND AGRICULTURAL CHEMICAL PRODUCTS**

AB-1997-5

Report of the Appellate Body

WORLD TRADE ORGANIZATION
APPELLATE BODY

**India - Patent Protection for Pharmaceutical
and Agricultural Chemical Products**

AB-1997-5

Present:

India, *Appellant*

Lacarte-Muró, Presiding Member

United States, *Appellee*

Bacchus, Member

European Communities, *Third Participant*

Beeby, Member

I. Introduction

1. India appeals from certain issues of law and legal interpretations in the Panel Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*¹ (the "Panel Report"). The Panel was established to consider a complaint by the United States against India concerning the absence in India of either patent protection for pharmaceutical and agricultural chemical products under Article 27 of the *Agreement on Trade-Related Aspects of Intellectual Property* (the "*TRIPS Agreement*"), or of a means for the filing of patent applications for pharmaceutical and agricultural chemical products pursuant to Article 70.8 of the *TRIPS Agreement* and of legal authority for the granting of exclusive marketing rights for such products pursuant to Article 70.9 of the *TRIPS Agreement*. The relevant factual aspects of India's "legal regime"² for patent protection for pharmaceutical and agricultural chemical products are described at paragraphs 2.1 to 2.12 of the Panel Report.

¹WT/DS50/R, 5 September 1997.

²WT/DS50/4, 8 November 1996.

2. The Panel Report was circulated to the Members of the World Trade Organization (the "WTO") on 5 September 1997. The Panel reached the following conclusions:

On the basis of the findings set out above, the Panel concludes that India has not complied with its obligations under Article 70.8(a) and, in the alternative, paragraphs 1 and 2 of Article 63 of the TRIPS Agreement, because it has failed to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period to which it is entitled under Article 65 of the Agreement, and to publish and notify adequately information about such a mechanism; and that India has not complied with its obligations under Article 70.9 of the TRIPS Agreement, because it has failed to establish a system for the grant of exclusive marketing rights.³

The Panel made the following recommendation:

The Panel recommends that the Dispute Settlement Body request India to bring its transitional regime for patent protection of pharmaceutical and agricultural chemical products into conformity with its obligations under the TRIPS Agreement ...⁴

3. On 15 October 1997, India notified the Dispute Settlement Body⁵ (the "DSB") of its intention to appeal certain issues of law covered in the Panel Report and legal interpretations developed by the Panel, pursuant to paragraph 4 of Article 16 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"), and filed a Notice of Appeal with the Appellate Body, pursuant to Rule 20 of the *Working Procedures for Appellate Review* (the "*Working Procedures*"). On 27 October 1997, India filed an appellant's submission.⁶ On 10 November 1997, the United States filed an appellee's submission pursuant to Rule 22 of the *Working Procedures*. That same day, the European Communities filed a third participant's submission pursuant to Rule 24 of the *Working Procedures*. The oral hearing provided for in Rule 27 of the *Working Procedures* was held on 14 November 1997. At the oral hearing, the participants and third participant presented their arguments and answered questions from the Division of the Appellate Body hearing the appeal.

³Panel Report, para. 8.1.

⁴Panel Report, para. 8.2.

⁵WT/DS50/6, 16 October 1997.

⁶Pursuant to Rule 21(1) of the *Working Procedures*.

II. Arguments of the Participants

A. Appellant - India

4. India appeals certain aspects of the legal findings and conclusions of the Panel relating to Articles 70.8, 70.9 and 63 of the *TRIPS Agreement*. India asserts that it has established, through "administrative instructions"⁷, "a means" by which applications for patents for pharmaceutical and agricultural chemical products (often referred to as "mailbox applications") can be filed and filing dates assigned to them. India contends that, as of 15 October 1997, 1924 such applications had been received, of which 531 were by United States' applicants. Upon receipt, the particulars of these applications, including serial number, date, name of applicant, and the title of the invention were published in the Official Gazette of India. None of these applications had been taken up for examination, and none had been rejected. On 2 August 1996, the Government had stated in Parliament: "The Patent Offices have received 893 patent applications in the field of drug or medicine from Indian or foreign companies/institutions until 15 July 1996. The applications for patents will be taken up for examination after 1 January 2005, as per the World Trade Organization (WTO) Agreement which came into force on 1 January 1995".⁸

5. India argues that the function of Article 70.8(a) of the *TRIPS Agreement* is to ensure that the Member concerned receives patent applications as from 1 January 1995 and maintains a record of them on the basis of which patent protection can be granted as from 2005. India asserts that the Panel ruled that Article 70.8(a) comprises two obligations: first, to establish a mailbox to receive patent applications for pharmaceutical and agricultural chemical products and to allot filing and priority dates to them; and second, to create legal certainty that the patent applications and the patents based on them will not be rejected or invalidated in the future. India maintains that the second obligation is a creation of the Panel.

6. India asserts that the Panel justified the creation of this second obligation by invoking the concept of predictability of competitive relationships that was developed by panels in the context of Articles III and XI of the GATT 1947. India contends that this concept cannot be unquestioningly imported into the *TRIPS Agreement*. Furthermore, the Panel used this concept to advance the date on which India must give substantive rights to inventors of pharmaceutical and agricultural chemical products. Thus, India concludes, the Panel incorporated into the procedural requirements of Article

⁷India's appellant's submission, p. 10.

⁸See Panel Report, Annex 2.

70.8(a) the substantive obligations set out in paragraphs (b) and (c) of Article 70.8 and turned an obligation to be carried out in the future into a current obligation.

7. India asserts that the means of filing provided by India ensures that patents can be granted when they are due. According to India, there is absolute certainty that India can, when patents are due in accordance with paragraphs (b) and (c) of Article 70.8, decide to grant such patents on the basis of the applications currently submitted and determine the novelty and priority of the inventions in accordance with the date of these applications. India insists that there is no logical link between the theoretical refusal of a mailbox application under current law and the grant of a patent in accordance with paragraphs (b) and (c) of Article 70.8 in the future.

8. According to India, the Panel interpreted into the *TRIPS Agreement* the requirement that a Member must eliminate any reasonable doubts that it has met the requirements set out in that Agreement. To India, the Panel's interpretation of Article 70.8(a) entails a violation of established principles governing the burden of proof.

9. India argues that the effect of the Panel's shift in the burden of proof from the complainant to the defendant was exacerbated by the standard of proof which the Panel applied to the evidence submitted by India to demonstrate that the United States' assertion was based on an incorrect interpretation of Indian law. In India's view, the Panel did not assess the Indian law as a fact to be established by the United States, but as a law to be interpreted by the Panel. According to India, the Panel's initiative contrasts with the cautious approach of previous panels to issues of municipal law.⁹ The Panel should have followed GATT practice and given India, as the author of the mailbox system, the benefit of the doubt as to the status of that system under its domestic law. The Panel also should have sought guidance on the manner in which the Indian authorities interpreted that law. India contends that the assertion by a Member that a mailbox system exists, and that it has been set up in accordance with its domestic law, may be displaced only by compelling evidence that the mailbox is illegal in domestic law: it is essentially for the Member itself to determine the methodology by which it sets out the mailbox system in terms of its municipal laws.

10. India argues that the text of Article 70.9 establishes the obligation to provide exclusive marketing rights to a pharmaceutical or agricultural chemical product for which a patent application has

⁹India cites Panel Report, *Canada - Measures Affecting the Sale of Gold Coins*, L/5863, 17 September 1985, unadopted, paras. 58 and 59; and Panel Report, *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco*, adopted 4 October 1994, DS44/R, para. 75.

been made only after the events specified in the provision have occurred. India maintains that there is nothing in the text of Article 70.9 that creates an obligation to make a system for the grant of exclusive marketing rights system generally available in the domestic law before the events listed in Article 70.9 have occurred.

11. In India's view, the Panel did not examine the context of Article 70.9 fully. There are many provisions in the *TRIPS Agreement* -- including Articles 22.2, 25.1, 39.2, 42-48 and 51 -- which explicitly oblige Members to change their domestic law to authorize their domestic authorities to take certain actions before the need to take such actions actually arises. India also notes that a comparison of the terms of Article 70.9 with those of Article 27, according to which "patents shall be available" for inventions, is revealing. According to India, the Panel examines Article 70.9 only in the context of Article 27, and dismisses the relevance of the distinction between "shall be available" and "shall be granted" in the wording of these related provisions because "an exclusive marketing right cannot be 'granted' in a specific case unless it is 'available' in the first place".¹⁰

12. India maintains that Article 70.9 is part of the transitional arrangements of the *TRIPS Agreement* whose very function is to enable developing countries to postpone legislative changes. Patent protection for pharmaceutical and agricultural chemical products is the most sensitive TRIPS issue in many developing countries. To India, the Panel's interpretation of Article 70.9 has the consequence that the transitional arrangements would allow developing countries to postpone legislative changes in all fields of technology except in the most sensitive ones.

13. In India's view, the Panel did not base its interpretation on the terms of Article 70.9, nor did it take into account the context and the transitional object and purpose of this provision; instead, the Panel justified its expansive approach with the need to establish predictable conditions of competition. India contends that this notion turns an obligation to take actions in the future into an obligation to take action immediately. India notes that there are numerous transitional provisions in the *Marrakesh Agreement Establishing the World Trade Organization* (the "*WTO Agreement*")¹¹ that require action at some point in the future, either when a date has arrived or an event has occurred. These are all obligations that are, just like those under Article 70.8 and 70.9 of the *TRIPS Agreement*, contingent upon a date or event. While it would be desirable if all Members were immediately to enable their executive authorities to take the required actions even before the dates or events requiring those actions have occurred, India asserts

¹⁰Panel Report, para. 7.56 and note 112.

¹¹Done at Marrakesh, Morocco, 15 April 1994.

that these provisions cannot reasonably be interpreted to imply the obligation to provide for such conditions in the domestic law in advance of that date or event.

14. India asserts that, under Articles 3, 7 and 11 of the DSU, panels are to make findings and recommendations only on matters submitted to them by the parties to the dispute. India therefore contends that the Panel exceeded its authority under the DSU by ruling on the subsidiary claim by the United States relating to Article 63 after accepting its principal claim under Article 70.8. If the Appellate Body were to conclude that the Panel was entitled to present findings on the United States' Article 63 claim, India asks whether the Panel was entitled to recommend simultaneously that India bring its mailbox system into conformity with Article 70.8(a) and Article 63 of the *TRIPS Agreement*. If the Panel was so entitled, India further asks the Appellate Body to what the recommendation relating to Article 63 refers.

B. *Appellee - United States*

15. The United States endorses the legal findings and conclusions of the Panel relating to Articles 70.8, 70.9 and 63 of the *TRIPS Agreement*. The United States asserts that the Panel correctly analyzed the text and context of Article 70.8, and focused on the failure of the system described by India to achieve the object and purpose of this provision. The United States contends that the concept of the importance of creating the predictability needed to plan future trade was developed in the context of Articles III and XI of the GATT 1947, as the Panel observed. However, it does not follow that the objectives of ensuring minimum standards of treatment and regulating competitive relationships are mutually exclusive. Protecting legitimate expectations of WTO Members regarding conditions of competition is as central to trade relating to intellectual property as it is to trade in goods that do not relate to intellectual property.

16. According to the United States, under Article 70.8, reasonable assurances of treatment must be provided for mailbox applications. The United States deems that the Panel correctly interpreted Article 70.8 to require a mailbox system under which patent applications have a secure legal status. This interpretation respects the relationship between paragraphs (a), (b) and (c) of Article 70.8, and the purpose of the mailbox system. The United States insists that the administrative system described by India does not provide a sound legal basis for filing mailbox applications. According to the United States, the Panel correctly placed the burden of proof on the United States, consistent with the Appellate Body Report in *United States - Measure Affecting Woven Wool Shirts and Blouses from India*

("United States - Shirts and Blouses").¹² The United States argues that nothing in the Panel's analysis had the effect of shifting the burden of proof from the United States to India, and that the Panel applied the correct standard of proof. In the view of the United States, the Panel did not require India to prove that its administrative instructions to patent offices were immune from challenge, but rather found that India had not rebutted the evidence presented by the United States regarding the likelihood that mailbox applications and patents ultimately based on them would be invalidated by such a challenge.

17. The United States asserts that the Panel appropriately considered India's factual arguments regarding the operation of the Act to Amend and Consolidate the Law Relating to Patents (the "Patents Act"), and that India's arguments represent an attempt to turn a factual question into a legal issue. While the United States acknowledges the propriety of seeking guidance from Members regarding their domestic laws, it argues that giving a Member the benefit of the doubt regarding matters of interpretation of its domestic law is not equivalent to unquestioning acceptance of the Member's position. In the view of the United States, India's argument is inconsistent with the requirement in Article 11 of the DSU that a panel make "an objective assessment" of the facts of the case. On this point, the United States recalls that the panel in *United States - Restrictions on Imports of Cotton and Man-Made Fibre Underwear* stated, "a policy of total deference to the findings of the national authorities could not ensure an "objective assessment" as foreseen by Article 11".¹³

¹²Adopted 23 May 1997, WT/DS33/AB/R.

¹³Adopted 25 February 1997, WT/DS24/R, para. 7.10.

18. The United States contends that the Panel correctly found that India has failed to comply with Article 70.9. According to the United States, the text of Article 70.9 indicates that the obligation to establish exclusive marketing rights became effective upon the entry into force of the *WTO Agreement*. The ordinary meaning of the term "granted" is to "give (rights, property, etc.) formally; transfer legally".¹⁴ The definition implies that availability and authority are necessary, but not sufficient, conditions for "granting" something. The United States asserts that the Panel correctly stated: "an exclusive marketing right cannot be "granted" in a specific case unless it is "available" in the first place".¹⁵ Moreover, the terms used in other Articles of the *TRIPS Agreement* reflect the context of each Article, and do not support the conclusion that there is no obligation under Article 70.9 to provide a system for granting exclusive marketing rights before a particular case arises.

19. The United States maintains that the context, object and purpose of Article 70.9 indicate that it imposes a current, not future, obligation. In the view of the United States, the Panel correctly found that the average period of time required to satisfy the conditions set forth in Article 70.9 is not relevant to the analysis. The United States further argues that India's argument is factually incorrect: the Panel found that at least one United States' company had satisfied the steps required for the grant of exclusive marketing rights, but had not applied for them in India because it could not obtain information regarding the appropriate procedure for doing so. In addition, the United States presented evidence regarding the likelihood that various products designed to treat serious medical conditions would be ready for introduction to the Indian market in advance of the timeframe described by India.

20. The United States argues that the consequence of India's view of Article 70.9 is that a national of another WTO Member would have to apply for exclusive marketing rights that did not exist under Indian law, and only at that time would India be obligated to enact legislation providing such rights. There would be at least a temporary violation of a Member's rights because that Member's national would have to wait for India to enact legislation making these rights available. According to the United States, such a result is inconsistent with the principle of fostering predictable conditions of competition and does not protect the legitimate expectations of Members under Article 70.9.

21. In the view of the United States, the Panel's finding on Article 70.9 does not imply that all future obligations under the *WTO Agreement* should be implemented immediately in Members' domestic law. Requiring a system for granting exclusive marketing rights protects the core balance of the *TRIPS*

¹⁴The United States cites H.W. Fowler and F.G. Fowler (eds.), *The Concise Oxford English Dictionary* (1990), p. 514.

¹⁵Panel Report, para. 7.56, note 112.

Agreement with respect to pharmaceutical and agricultural chemical product patents. Under the *TRIPS Agreement*, the *quid pro quo* for taking advantage of the extended transition period for granting product patents for pharmaceutical and agricultural chemical inventions was the grant of exclusive marketing rights.

22. The United States asks the Appellate Body to affirm the Panel's decision to make findings on the Article 63 issue submitted to it by the United States. In the view of the United States, the Panel correctly addressed both the issue of India's failure to comply with Article 70.8 and its failure to comply with Article 63. The United States asserts that Articles 3, 7, and 11 of the DSU establish that the Panel acted within its authority in addressing the United States' claim: the United States submitted this issue to the Panel in both written and oral submissions and India had an abundant opportunity to respond; and the United States' characterization of its Article 63 claim is not determinative of the Panel's authority to address it.

C. *Third Participant - European Communities*

23. The European Communities endorses the Panel's findings concerning the failure by India to take the action necessary to implement its obligations under Article 70.8 of the *TRIPS Agreement* and agrees with the Panel's interpretation of Article 70.9 of the *TRIPS Agreement*. The European Communities supports the Panel's finding that India failed to take the action necessary to implement its obligations under Article 70.8 of the *TRIPS Agreement*. In the view of the European Communities, India's arguments about the Panel's interpretation of municipal law are unfounded: there is nothing in the ruling of the Panel which suggests that it did anything other than treat domestic law as a question of fact to be proved by the party asserting a breach of Article 70.8. The European Communities asserts that the Panel's findings show that the Panel treated the question of municipal law as a matter of evidence. Moreover, India's submission that the Panel's interpretation on this point be treated as a question of fact would result in it being excluded from the remit of the Appellate Body.

24. The European Communities maintains that the Panel's approach in interpreting Article 70.8(a) was consistent with the provisions of Article 31 of the *Vienna Convention on the Law of Treaties* ("the *Vienna Convention*").¹⁶ Accordingly, in analyzing the meaning to be given to the term "means" in paragraph (a) of Article 70.8, the Panel considered that term in its context and in the light of the object and purpose of Article 70.8. The European Communities asserts that the setting up of such a mailbox

¹⁶Done at Vienna, 23 May 1969, 1155 U.N.T.S. 331; 8 International Legal Materials 679.

mechanism is clearly not an end in itself. The objective of the mechanism cannot simply be to permit the filing of applications: such a mechanism would serve no useful purpose. The objective is rather to ensure that the novelty and priority of such applications is preserved and made available as from the date of application of the Agreement for developing countries.

25. With respect to India's claims that the Panel effectively relieved the United States of the burden of proof of adducing evidence that a breach of Article 70.8 had occurred, the European Communities asserts that the Panel's reasoning is correct. According to the European Communities, it is clear, from paragraph 7.37 of the Panel's findings, that India was not able to discharge the burden of proof upon it to demonstrate that its system for mailbox applications was not tainted with a degree of legal insecurity. In the view of the European Communities, this question relates to the Panel's appreciation of the evidence before it and is therefore not a question of law. In consequence, it falls outside the scope of the remit of the Appellate Body.

26. The European Communities supports the Panel's interpretation of Article 70.9 of the *TRIPS Agreement*. The European Communities maintains that Article 70.9 provides for the granting of a residual right (the exclusive marketing right) to applicants as long as the products are not patentable during the transitional period available to developing country Members. For that purpose, applicants must be able to identify the authority to whom they have to address a request for the granting of an exclusive marketing right. They must also be given the opportunity to know what their rights are with regard to other potential applicants who might request exclusive marketing rights for the same product. In the view of the European Communities, India's proposed reading of Article 70.9 disregards this aspect of the law on intellectual property rights that concerns the relationship between different actual or potential applicants. It is not possible to regulate this relationship by legislative or administrative action only after the relevant events have occurred, since such subsequent action would not be capable of determining the relationship between several actual or potential applicants. The European Communities insists that the protection of the exclusivity of the exclusive marketing right is a necessary component of the mechanism that is required under Article 70.9.

27. The European Communities contends that India's attempt to deny the need for a mechanism for the grant of exclusive marketing rights cannot be considered as a good faith interpretation of Article 70.9. According to the European Communities, India's reference to the sensitivity of the question of exclusive rights for the marketing of pharmaceuticals and agricultural chemical products in developing countries is not relevant. The European Communities contends that the basic rule of international treaty law is "*pacta sunt servanda*", that is, that treaties must be observed. Moreover, treaty

provisions must be read in context and treaty interpretation must be carried out in good faith. In the view of the European Communities, the *TRIPS Agreement* contains many provisions concerning the rights of applicants and right holders with regard to third parties; the context of the *TRIPS Agreement* requires developing country Members that invoke the transitional period to allow, in advance, the grant of exclusive marketing rights under Article 70.9 and to provide the relevant mechanism for the grant of such exclusive marketing rights in order to define the position of applicants and right holders with regard to other persons. According to the European Communities, India's argument that this reading of Article 70.9 is not consistent with the general understanding of the kind of action that is required by Members during transitional periods, provided for in a number of other multilateral trade agreements, is misleading: it neglects that Article 70.9 deals with an obligation arising during the transitional period, not after its expiry.

III. Issues Raised In This Appeal

28. The appellant, India, raises the following issues in this appeal:

- (a) What is the proper interpretation to be given to the requirement in Article 70.8(a) of the *TRIPS Agreement* that a Member shall provide "a means" by which applications for patents for inventions relating to pharmaceutical or agricultural chemical products can be filed?
- (b) Did the Panel err in its treatment of Indian municipal law, or in its application of the burden of proof, in examining whether India had complied with its obligations under Article 70.8(a) of the *TRIPS Agreement*?
- (c) Does Article 70.9 of the *TRIPS Agreement* require that there must be a "mechanism" in place to provide for the grant of exclusive marketing rights effective as from the date of entry into force of the *WTO Agreement*?
- (d) Did the Panel, after having accepted the principal claim of the United States under Article 70.8 of the *TRIPS Agreement*, err by making conclusions on the alternative claim by the United States under Article 63 of the *TRIPS Agreement*?

IV. The *TRIPS Agreement*

29. The *TRIPS Agreement* is one of the new agreements negotiated and concluded in the Uruguay Round of multilateral trade negotiations. The *TRIPS Agreement* brings intellectual property within the world trading system for the first time by imposing certain obligations on Members in the area of trade-related intellectual property rights. As one of the covered agreements under the DSU, the *TRIPS Agreement* is subject to the dispute settlement rules and procedures of that Understanding. The dispute that gives rise to this case represents the first time the *TRIPS Agreement* has been submitted to the scrutiny of the WTO dispute settlement system.

30. Among the many provisions of the *TRIPS Agreement* are certain specific obligations relating to patent protection for pharmaceutical and agricultural chemical products. With respect to patentable subject matter, Article 27.1 of the *TRIPS Agreement* provides generally:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. (footnote deleted)

31. However, Article 65 of the *TRIPS Agreement* provides, in pertinent part:

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

...

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

32. With respect to patent protection for pharmaceutical and agricultural chemical products, certain specific obligations are found in Articles 70.8 and 70.9 of the *TRIPS Agreement*. The interpretation of these specific obligations is the subject of this dispute. Our task is to address the legal issues arising from this dispute that are raised in this appeal.

V. Interpretation of the *TRIPS Agreement*

33. As one of the fundamental issues in this appeal, India has questioned the Panel's enunciation and application of a general interpretative principle which, the Panel stated, "must be taken into account" in interpreting the provisions of the *TRIPS Agreement*. The Panel found that:

... when interpreting the text of the TRIPS Agreement, the legitimate expectations of WTO Members concerning the TRIPS Agreement must be taken into account, as well as standards of interpretation developed in past panel reports in the GATT framework, in particular those laying down the principle of the protection of conditions of competition flowing from multilateral trade agreements.¹⁷

India argues that the Panel's invocation of this principle caused the Panel to misinterpret both Article 70.8 and Article 70.9 and led the Panel to err in determining whether India had complied with those obligations.¹⁸

34. The Panel stated that:

The protection of legitimate expectations of Members regarding the conditions of competition is a well-established GATT principle, which derives in part from Article XXIII, the basic dispute settlement provisions of GATT (and the WTO).¹⁹

¹⁷Panel Report, para. 7.22.

¹⁸India's appellant's submission, pp. 5-8 and 21.

¹⁹Panel Report, para. 7.20

The Panel also referred to certain GATT 1947 panel reports²⁰ as authority for this principle. The Panel noted that whereas the "disciplines formed under GATT 1947 (so-called GATT *acquis*) were primarily directed at the treatment of the goods of other countries", "the concept of the protection of legitimate expectations" in relation to the *TRIPS Agreement* applies to "the competitive relationship between a Member's own nationals and those of other Members (rather than between domestically produced goods and the goods of other Members, as in the goods area)".²¹

35. In *Japan - Taxes on Alcoholic Beverages*, on the status of adopted panel reports, we acknowledged:

Article XVI:1 of the *WTO Agreement* and paragraph 1(b)(iv) of the language of Annex 1A incorporating the GATT 1994 into the *WTO Agreement* bring the legal history and experience under the GATT 1947 into the new realm of the WTO in a way that ensures continuity and consistency in a smooth transition from the GATT 1947 system. This affirms the importance to the Members of the WTO of the experience acquired by the CONTRACTING PARTIES to the GATT 1947 -- and acknowledges the continuing relevance of that experience to the new trading system served by the WTO. Adopted panel reports are an important part of the GATT *acquis*.²²

36. Although the Panel states that it is merely applying a "well-established GATT principle", the Panel's reasoning does not accurately reflect GATT/WTO practice. In developing its interpretative principle, the Panel merges, and thereby confuses, two different concepts from previous GATT practice. One is the concept of protecting the expectations of contracting parties as to the competitive relationship between their products and the products of other contracting parties. This is a concept that was developed in the context of *violation* complaints involving Articles III and XI, brought under Article XXIII:1(a), of the GATT 1947. The other is the concept of the protection of the reasonable expectations of contracting parties relating to market access concessions. This is a concept that was developed in the context of *non-violation* complaints brought under Article XXIII:1(b) of the GATT.

²⁰In particular: Panel Report, *Italian Discrimination Against Imported Agricultural Machinery*, adopted 23 October 1958, BISD 7S/60, paras. 12-13; Panel Report, *United States - Taxes on Petroleum and Certain Imported Substances*, adopted 17 June 1987, BISD 34S/136, para. 5.22; and Panel Report, *United States - Section 337 of the Tariff Act of 1930*, adopted 7 November 1989, BISD 36S/345, para. 5.13.

²¹Panel Report, para. 7.21.

²²Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, p. 14.

37. Article 64.1 of the *TRIPS Agreement* incorporates by reference Article XXIII of the GATT 1994 as the general dispute settlement provision governing the *TRIPS Agreement*.²³ Thus, we have no quarrel in principle with the notion that past GATT practice with respect to Article XXIII is pertinent to interpretation of the *TRIPS Agreement*. However, such interpretation must show proper appreciation of the different bases for action under Article XXIII.

38. Article XXIII:1 of the GATT 1994 sets out the various causes of action on which a Member may base a complaint. A Member may have recourse to dispute settlement under Article XXIII when it considers that:

... any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of

- (a) the failure of another contracting party to carry out its obligations under this Agreement, or
- (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or
- (c) the existence of any other situation.²⁴

39. Article XXIII:1(a) involves so-called "violation" complaints. These are disputes that arise from an alleged failure by a Member to carry out its obligations. During nearly fifty years of experience, Article XXIII:1(a) has formed the basis of almost all disputes under the GATT 1947 and the *WTO Agreement*. In contrast, Article XXIII:1(b) involves so-called "non-violation" complaints. These are disputes that do not require an allegation of a violation of an obligation. The basis of a cause of action under Article XXIII:1(b) is not necessarily a violation of the rules, but rather the nullification or impairment of a benefit accruing to a Member under a covered agreement. In the history of the GATT/WTO, there have been only a handful of "non-violation" cases arising under Article XXIII:1(b).²⁵ Article XXIII:1(c), covering what are commonly called "situation" complaints, has never been the

²³Article 64.1 of the *TRIPS Agreement* reads:

The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

²⁴Article XXIII:1 of the GATT 1994.

²⁵Previous panels have found "non-violation" nullification or impairment in only four of 14 cases where it was alleged: Working Party Report, *Australia - Subsidy on Ammonium Sulphate*, adopted 3 April 1950, BISD II/188; Panel Report, *Germany - Imports of Sardines*, adopted 31 October 1952, BISD IS/53; Panel Report, *Germany - Import Duties on Starch and Potato Flour*, noted 16 February 1955, BISD 3S/77; and Panel Report, *European Communities - Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins*, adopted 25 January 1990, BISD 37S/86.

foundation for a recommendation or ruling of the GATT CONTRACTING PARTIES or the Dispute Settlement Body, although it has formed the basis for parties' arguments before panels in a small number of cases.²⁶

40. In the context of violation complaints made under Article XXIII:1(a), it is true that panels examining claims under Articles III and XI of the GATT have frequently stated that the purpose of these articles is to protect the expectations of Members concerning the competitive relationship between imported and domestic products, as opposed to expectations concerning trade volumes. However, this statement is often made *after* a panel has found a violation of, for example, Article III or Article XI that establishes a *prima facie* case of nullification or impairment.²⁷ At that point in its reasoning, the panel is examining whether the defending party has been able to rebut the charge of nullification or impairment. It is in this context that panels have referred to the expectations of Members concerning the conditions of competition.

41. The doctrine of protecting the "reasonable expectations" of contracting parties developed in the context of "non-violation" complaints brought under Article XXIII:1(b) of the GATT 1947. Some of the rules and procedures concerning "non-violation" cases have been codified in Article 26.1 of the DSU. "Non-violation" complaints are rooted in the GATT's origins as an agreement intended to protect the reciprocal tariff concessions negotiated among the contracting parties under Article II.²⁸ In the absence of substantive legal rules in many areas relating to international trade, the "non-violation" provision of Article XXIII:1(b) was aimed at preventing contracting parties from using non-tariff barriers or other policy measures to negate the benefits of negotiated tariff concessions. Under Article XXIII:1(b) of the GATT 1994, a Member can bring a "non-violation" complaint when the negotiated balance of concessions between Members is upset by the application of a measure, whether or not this measure is inconsistent with the provisions of the covered agreement. The ultimate goal is not the withdrawal of the

²⁶See, generally, F. Roessler, "The Concept of Nullification and Impairment in the Legal System of the World Trade Organization" in E.-U. Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System* (Kluwer, 1997), pp. 123-142; and E.-U. Petersmann, *The GATT/WTO Dispute Settlement System: International Law, International Organizations and Dispute Settlement* (Kluwer, 1997), pp. 170-176.

²⁷See, for example: Working Party Report, *Brazilian Internal Taxes*, adopted 30 June 1949, BISD II/181, para. 16; Panel Report, *United States - Taxes on Petroleum and Certain Imported Substances*, adopted 17 June 1987, BISD 34S/136, para. 5.1.9; Panel Report, *Canada - Administration of the Foreign Investment Review Act*, adopted 7 February 1984, BISD 30S/140, para. 6.6; Panel Report, *Japanese Measures on Imports of Leather*, adopted 15/16 May 1984, BISD 31S/94, para. 55; Panel Report, *Japan - Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted 10 November 1987, BISD 34S/83, para. 5.11; Panel Report, *European Economic Community - Restrictions on Imports of Apples*, adopted 22 June 1989, BISD 36S/135, para. 5.25; and Panel Report, *United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco*, adopted 4 October 1994, DS44/R, para. 99.

²⁸See, in general, E.-U. Petersmann, "Violation Complaints and Non-violation Complaints in International Law" (1991) *German Yearbook of International Law* 175.

measure concerned, but rather achieving a mutually satisfactory adjustment, usually by means of compensation.²⁹

42. Article 64.2 of the *TRIPS Agreement* states:

Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

The meaning of this provision is clear: the *only* cause of action permitted under the *TRIPS Agreement* during the first five years after the entry into force of the *WTO Agreement* is a "violation" complaint under Article XXIII:1(a) of the GATT 1994. This case involves allegations of violation of obligations under the *TRIPS Agreement*. However, the Panel's invocation of the "legitimate expectations" of Members relating to conditions of competition melds the legally-distinct bases for "violation" and "non-violation" complaints under Article XXIII of the GATT 1994 into one uniform cause of action. This is not consistent with either Article XXIII of the GATT 1994 or Article 64 of the *TRIPS Agreement*. Whether or not "non-violation" complaints should be available for disputes under the *TRIPS Agreement* is a matter that remains to be determined by the Council for Trade-Related Aspects of Intellectual Property (the "Council for TRIPS") pursuant to Article 64.3 of the *TRIPS Agreement*. It is *not* a matter to be resolved through interpretation by panels or by the Appellate Body.

43. In addition to relying on the GATT *acquis*, the Panel relies also on the customary rules of interpretation of public international law as a basis for the interpretative principle it offers for the *TRIPS Agreement*. Specifically, the Panel relies on Article 31 of the *Vienna Convention*, which provides in part:

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

44. With this customary rule of interpretation in mind, the Panel stated that:

In our view, good faith interpretation requires the protection of legitimate expectations derived from the protection of intellectual

²⁹This is codified in Article 26.1(b) of the DSU.

property rights provided for in the Agreement.³⁰

45. The Panel misapplies Article 31 of the *Vienna Convention*. The Panel misunderstands the concept of legitimate expectations in the context of the customary rules of interpretation of public international law. The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself. The duty of a treaty interpreter is to examine the words of the treaty to determine the intentions of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the *Vienna Convention*. But these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended.

46. In *United States - Standards for Reformulated and Conventional Gasoline*³¹, we set out the proper approach to be applied in interpreting the *WTO Agreement* in accordance with the rules in Article 31 of the *Vienna Convention*. These rules must be respected and applied in interpreting the *TRIPS Agreement* or any other covered agreement. The Panel in this case has created its own interpretative principle, which is consistent with neither the customary rules of interpretation of public international law nor established GATT/WTO practice. Both panels and the Appellate Body must be guided by the rules of treaty interpretation set out in the *Vienna Convention*, and must not add to or diminish rights and obligations provided in the *WTO Agreement*.

47. This conclusion is dictated by two separate and very specific provisions of the DSU. Article 3.2 of the DSU provides that the dispute settlement system of the WTO:

... serves to preserve the rights and obligations of the Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

Furthermore, Article 19.2 of the DSU provides:

In accordance with paragraph 2 of Article 3, in their findings and recommendations, the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements.

³⁰Panel Report, para. 7.18.

³¹Adopted 20 May 1996, WT/DS2/AB/R, pp. 16-17.

These provisions speak for themselves. Unquestionably, both panels and the Appellate Body are bound by them.

48. For these reasons, we do not agree with the Panel that the legitimate expectations of Members *and* private rights holders concerning conditions of competition must always be taken into account in interpreting the *TRIPS Agreement*.

VI. Article 70.8

49. Article 70.8 states:

Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

50. With respect to Article 70.8(a), the Panel found that:

... Article 70.8(a) requires the Members in question to establish a means that not only appropriately allows for the entitlement to file mailbox applications and the allocation of filing and priority dates to them, but also provides a sound legal basis to preserve novelty and priority as of those dates, 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.³²

51. In India's view, the obligations in Article 70.8(a) are met by a developing country Member where it establishes a mailbox for receiving, dating and storing patent applications for pharmaceutical and agricultural chemical products in a manner that properly allots filing and priority dates to those applications in accordance with paragraphs (b) and (c) of Article 70.8.³³ India asserts that the Panel established an additional obligation "to create legal certainty that the patent applications and the eventual patents based on them will not be rejected or invalidated in the future".³⁴ This, India argues, is a legal error by the Panel.

52. The introductory clause to Article 70.8 provides that it applies "[w]here a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27 ..." of the *TRIPS Agreement*. Article 27 requires that patents be made available "for any inventions, whether products or processes, in all fields of technology", subject to certain exceptions. However, pursuant to paragraphs 1, 2 and 4 of Article 65, a developing country Member may delay providing product patent protection in areas of technology not protectable in its territory on the general date of application of the *TRIPS Agreement* for that Member until 1 January 2005. Article 70.8 relates specifically and exclusively to situations where a Member does not provide, as of 1 January 1995, patent protection for pharmaceutical and agricultural chemical products.

53. By its terms, Article 70.8(a) applies "notwithstanding the provisions of Part VI" of the *TRIPS Agreement*. Part VI of the *TRIPS Agreement*, consisting of Articles 65, 66 and 67, allows for certain "transitional arrangements" in the application of certain provisions of the *TRIPS Agreement*. These "transitional arrangements", which allow a Member to delay the application of some of the obligations in the *TRIPS Agreement* for certain specified periods³⁵, do not apply to Article 70.8. Thus, although there are "transitional arrangements" which allow developing country Members, in particular, more time to implement certain of their obligations under the *TRIPS Agreement*, no such "transitional

³²Panel Report, para. 7.31.

³³India's appellant's submission, pp. 4-5.

³⁴India's appellant's submission, p. 5.

³⁵Pursuant to Article 65.1, all Members were entitled to delay the application of most of the provisions of the *TRIPS Agreement* for one year after the date of entry into force of the *WTO Agreement*. Pursuant to Article 65.2, developing country Members are generally entitled to a delay of a further four years. Where a developing country Member is obliged to extend patent protection to areas of technology to which it did not extend such protection on the general date of application of the *TRIPS Agreement* for that Member, Article 65.4 states that that developing country Member may delay the application of the provisions on product patents to such areas of technology for an additional period of five years.

arrangements" exist for the obligations in Article 70.8.

54. Article 70.8(a) imposes an obligation on Members to provide "a means" by which mailbox applications can be filed "from the date of entry into force of the WTO Agreement". Thus, this obligation has been in force since 1 January 1995. The issue before us in this appeal is not whether this obligation exists or whether this obligation is now in force. Clearly, it exists, and, equally clearly, it is in force now. The issue before us in this appeal is: what precisely is the "means" for filing mailbox applications that is contemplated and required by Article 70.8(a)? To answer this question, we must interpret the terms of Article 70.8(a).

55. We agree with the Panel that "[t]he analysis of the ordinary meaning of these terms alone does not lead to a definitive interpretation as to what sort of 'means' is required by this subparagraph".³⁶ Therefore, in accordance with the general rules of treaty interpretation set out in Article 31 of the *Vienna Convention*, to discern the meaning of the terms in Article 70.8(a), we must also read this provision in its context, and in light of the object and purpose of the *TRIPS Agreement*.

56. Paragraphs (b) and (c) of Article 70.8 constitute part of the context for interpreting Article 70.8(a). Paragraphs (b) and (c) of Article 70.8 require that the "means" provided by a Member under Article 70.8(a) must allow the filing of applications for patents for pharmaceutical and agricultural chemical products from 1 January 1995 and preserve the dates of filing and priority of those applications, so that the criteria for patentability may be applied as of those dates, and so that the patent protection eventually granted is dated back to the filing date. In this respect, we agree with the Panel that,

... in order to prevent the loss of the novelty of an invention ... filing and priority dates need to have a sound legal basis if the provisions of Article 70.8 are to fulfil their purpose. Moreover, if available, a filing must entitle the applicant to claim priority on the basis of an earlier filing in respect of the claimed invention over applications with subsequent filing or priority dates. Without legally sound filing and priority dates, the mechanism to be established on the basis of Article 70.8 will be rendered inoperational.³⁷

³⁶Panel Report, para. 7.25.

³⁷Panel Report, para. 7.28.

57. On this, the Panel is clearly correct. The Panel's interpretation here is consistent also with the object and purpose of the *TRIPS Agreement*. The Agreement takes into account, *inter alia*, "the need to promote effective and adequate protection of intellectual property rights".³⁸ We believe the Panel was correct in finding that the "means" that the Member concerned is obliged to provide under Article 70.8(a) must allow for "the entitlement to file mailbox applications and the allocation of filing and priority dates to them".³⁹ Furthermore, the Panel was correct in finding that the "means" established under Article 70.8(a) must also provide "a sound legal basis to preserve novelty and priority as of those dates".⁴⁰ These findings flow inescapably from the necessary operation of paragraphs (b) and (c) of Article 70.8.

58. However, we 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".⁴¹ India is *entitled*, by the "transitional arrangements" in paragraphs 1, 2 and 4 of Article 65, to delay application of Article 27 for patents for pharmaceutical and agricultural chemical products until 1 January 2005. 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.

³⁸Preamble to the *TRIPS Agreement*.

³⁹Panel Report, para. 7.31.

⁴⁰*Ibid.*

⁴¹*Ibid.*

60. India insists that it has done that. India contends that it has established, through "administrative instructions"⁴², 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 to preserve the novelty of the inventions and the priority of the applications as of the relevant filing and priority dates consistent with Article 70.8(a) of the *TRIPS Agreement*. According to India, pursuant to these "administrative instructions", the Patent Office has been directed to store applications for patents for pharmaceutical and agricultural chemical products separately for future action pursuant to Article 70.8, and the Controller General of Patents Designs and Trademarks ("the Controller") has been instructed not to refer them to an examiner until 1 January 2005. According to India, these "administrative instructions" are legally valid in Indian law⁴³, as they are reflected in the Minister's Statement to Parliament of 2 August 1996.⁴⁴ And, according to India:

There is ... *absolute certainty* that India can, when patents are due in accordance with subparagraphs (b) and (c) of Article 70.8, decide to grant such patents on the basis of the applications currently submitted and determine the novelty and priority of the inventions in accordance with the date of these applications.⁴⁵ (emphasis added)

61. India has not provided any text of these "administrative instructions" either to the Panel or to us.

62. Whatever their substance or their import, these "administrative instructions" were not the initial "means" chosen by the Government of India to meet India's obligations under Article 70.8(a) of the *TRIPS Agreement*. The Government of India's initial preference for establishing a "means" for filing mailbox applications under Article 70.8(a) was the Patents (Amendment) Ordinance (the "Ordinance"), promulgated by the President of India on 31 December 1994 pursuant to Article 123 of India's Constitution. Article 123 enables the President to promulgate an ordinance when Parliament is not in session, and when the President is satisfied "that circumstances exist which render it necessary for him to take immediate action". India notified the Ordinance to the Council for TRIPS, pursuant to Article 63.2 of the *TRIPS Agreement*, on 6 March 1995.⁴⁶ In accordance with the terms of Article 123 of India's Constitution, the Ordinance expired on 26 March 1995, six weeks after the reassembly of Parliament.

⁴²This is India's term for its measure. India's appellant's submission, p. 10.

⁴³Response by India to questioning at the oral hearing.

⁴⁴Panel Report, Annex 2.

⁴⁵India's appellant's submission, p. 8.

⁴⁶IP/N/1/IND/1, 8 March 1995.

This was followed by an unsuccessful effort to enact the Patents (Amendment) Bill 1995 to implement the contents of the Ordinance on a permanent basis.⁴⁷ This Bill was introduced in the Lok Sabha (Lower House) in March 1995. After being passed by the Lok Sabha, it was referred to a Select Committee of the Rajya Sabha (Upper House) for examination and report. However, the Bill was subsequently not enacted due to the dissolution of Parliament on 10 May 1996. From these actions, it is apparent that the Government of India initially considered the enactment of amending legislation to be necessary in order to implement its obligations under Article 70.8(a). However, India maintains that the "administrative instructions" issued in April 1995 effectively continued the mailbox system established by the Ordinance, thus obviating the need for a formal amendment to the Patents Act or for a new notification to the Council for TRIPS.⁴⁸

63. With respect to India's "administrative instructions", the Panel found that "the current administrative practice creates a certain degree of legal insecurity in that it requires Indian officials to ignore certain mandatory provisions of the Patents Act"⁴⁹; and that "even if Patent Office officials do not examine and reject mailbox applications, a competitor might seek a judicial order to do so in order to obtain rejection of a patent claim".⁵⁰

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.⁵¹

65. In public international law, an international tribunal may treat municipal law in several ways.⁵² 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

⁴⁷We note that an Expert Group advised the Indian Government that a formal legal basis was required to make the mailbox system valid under Indian law. See Panel Report, para. 7.36.

⁴⁸Response of India to questioning at the oral hearing.

⁴⁹Panel Report, para. 7.35.

⁵⁰Panel Report, para. 7.37.

⁵¹India's appellant's submission, pp. 13 and 15.

⁵²See, for example, I. Brownlie, *Principles of Public International Law*, 4th ed. (Clarendon Press, 1990), pp. 40-42.

obligations. For example, in *Certain German Interests in Polish Upper Silesia*, the Permanent Court of International Justice observed:

It might be asked whether a difficulty does not arise from the fact that the Court would have to deal with the Polish law of July 14th, 1920. This, however, does not appear to be the case. From the standpoint of International Law and of the Court which is its organ, municipal laws are merely facts which express the will and constitute the activities of States, in the same manner as do legal decisions and administrative measures. *The Court is certainly not called upon to interpret the Polish law as such; but there is nothing to prevent the Court's giving judgment on the question whether or not, in applying that law, Poland is acting in conformity with its obligations towards Germany under the Geneva Convention.*⁵³ (emphasis added)

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.

67. Previous GATT/WTO panels also have conducted a detailed examination of the domestic law of a Member in assessing the conformity of that domestic law with the relevant GATT/WTO obligations. For example, in *United States - Section 337 of the Tariff Act of 1930*⁵⁴, the panel conducted a detailed examination of the relevant United States' legislation and practice, including the remedies available under Section 337 as well as the differences between patent-based Section 337 proceedings and federal district court proceedings, in order to determine whether Section 337 was inconsistent with Article III:4 of the GATT 1947. This seems to us to be a comparable case.

⁵³[1926], PCIJ Rep., Series A, No. 7, p. 19.

⁵⁴Adopted 7 November 1989, BISD 36S/345.

68. And, just as it was necessary for the Panel in this case to seek a detailed understanding of the operation of the Patents Act as it relates to the "administrative instructions" in order to assess whether India had complied with Article 70.8(a), so, too, is it necessary for us in this appeal to review the Panel's examination of the same Indian domestic law.

69. To do so, we must look at the specific provisions of the Patents Act. Section 5(a) of the Patents Act provides that substances "intended for use, or capable of being used, as food or as medicine or drug" are not patentable. "When the complete specification has been led in respect of an application for a patent", section 12(1) *requires* the Controller to refer that application and that specification to an examiner. Moreover, section 15(2) of the Patents Act states that the Controller "shall refuse" an application in respect of a substance that is not patentable. We agree with the Panel that these provisions of the Patents Act are mandatory.⁵⁵ And, like the Panel, we are not persuaded that India's "administrative instructions" would prevail over the contradictory mandatory provisions of the Patents Act.⁵⁶ We note also that, in issuing these "administrative instructions", the Government of India did not avail itself of the provisions of section 159 of the Patents Act, which allows the Central Government "to make rules for carrying out the provisions of [the] Act" or section 160 of the Patents Act, which requires that such rules be laid before each House of the Indian Parliament. We are told by India that such rulemaking was not required for the "administrative instructions" at issue here. But this, too, seems to be inconsistent with the mandatory provisions of the Patents Act.

70. We are not persuaded by India's explanation of these 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.

71. For these reasons, we agree with the Panel's conclusion that India's "administrative instructions" for receiving mailbox applications are inconsistent with Article 70.8(a) of the *TRIPS Agreement*.

72. India raises the additional argument that the Panel erred in its application of the burden of proof in assessing Indian municipal law. In particular, India alleges that the Panel, after having required the United States merely to raise "reasonable doubts" suggesting a violation of Article 70.8, placed the

⁵⁵Panel Report, para. 7.35.

⁵⁶Panel Report, para. 7.37.

burden on India to dispel such doubts.⁵⁷

73. The Panel states:

As the Appellate Body report on *Shirts and Blouses* points out, "a party claiming a violation of a provision of the WTO Agreement by another Member must assert and prove its claim". In this case, it is the United States that claims a violation by India of Article 70.8 of the TRIPS Agreement. Therefore, it is up to the United States to put forward evidence and legal arguments sufficient to demonstrate that action by India is inconsistent with the obligations assumed by India under Article 70.8. In our view, the United States has successfully put forward such evidence and arguments. Then, ... the onus shifts to India to bring forward evidence and arguments to disprove the claim. We are not convinced that India has been able to do so (footnotes deleted).⁵⁸

74. This statement of the Panel is a legally correct characterization of the approach to burden of proof that we set out in *United States - Shirts and Blouses*.⁵⁹ However, it is not sufficient for a panel to enunciate the correct approach to burden of proof; a panel must also apply the burden of proof correctly. A careful reading of paragraphs 7.35 and 7.37 of the Panel Report reveals that the Panel has done so in this case. These paragraphs show that the United States put forward evidence and arguments that India's "administrative instructions" pertaining to mailbox applications were legally insufficient to prevail over the application of certain mandatory provisions of the Patents Act. India put forward rebuttal evidence and arguments. India misinterprets what the Panel said about "reasonable doubts". The Panel did not require the United States merely to raise "reasonable doubts" before the burden shifted to India. Rather, after properly requiring the United States to establish a *prima facie* case and after hearing India's rebuttal evidence and arguments, the Panel concluded that *it* had "reasonable doubts" that the "administrative instructions" would prevail over the mandatory provisions of the Patents Act if a challenge were brought in an Indian court.

75. For these reasons, we conclude that the Panel applied the burden of proof correctly in assessing the compliance of India's domestic law with Article 70.8(a) of the *TRIPS Agreement*.

⁵⁷India's appellant's submission, p. 12.

⁵⁸Panel Report, para. 7.40.

⁵⁹Adopted 23 May 1997, WT/DS33/AB/R, p. 16.

VII. Article 70.9

76. Article 70.9 of the *TRIPS Agreement* reads:

Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

77. With respect to Article 70.9, the Panel found:

Based on customary rules of treaty interpretation, we have reached the conclusion that under Article 70.9 there must be a mechanism ready for the grant of exclusive marketing rights at any time subsequent to the date of entry into force of the WTO Agreement.⁶⁰

78. India argues that Article 70.9 establishes an obligation to grant exclusive marketing rights for a product that is the subject of a patent application under Article 70.8(a) after all the other conditions specified in Article 70.9 have been fulfilled.⁶¹ India asserts that there are many provisions in the *TRIPS Agreement* that, unlike Article 70.9, explicitly oblige Members to change their domestic laws to authorize their domestic authorities to take certain action before the need to take such action actually arises.⁶² India maintains that the Panel's interpretation of Article 70.9 has the consequence that the transitional arrangements in Article 65 allow developing country Members to postpone legislative changes in all fields of technology except the most "sensitive" ones, pharmaceutical and agricultural chemical products. India claims that the Panel turned an obligation to take action in the future into an obligation to take action immediately.⁶³

⁶⁰Panel Report, para. 7.60.

⁶¹India's appellant's submission, p. 19.

⁶²*Ibid.*; for example, India asserts that according to Articles 42-48 of the *TRIPS Agreement*, the judicial authorities of Members "shall have the authority" to grant certain rights. Article 51 obliges Members to "adopt procedures" to enable right holders to prevent the release of counterfeited or pirated products from customs. Article 39.2 requires Members to give natural and legal persons "the possibility of preventing" the disclosure of information. According to Article 25.1 "Members shall provide for the protection" of certain industrial designs and Article 22.2 obliges Members to "provide the legal means for interested parties to prevent" certain misuses of geographical indications. India further asserts that a comparison of the terms of Article 70.9 with those of Article 27 according to which "patents shall be available" for inventions is revealing.

⁶³India's appellant's submission, p. 21.

79. India's arguments must be examined in the light of Article XVI:4 of the *WTO Agreement*, which requires that:

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

80. Moreover, India acknowledged before the Panel and in this appeal that, under Indian law, it is necessary to enact legislation in order to grant exclusive marketing rights in compliance with the provisions of Article 70.9. This was already implied in the Ordinance, which contained detailed provisions for the grant of exclusive marketing rights in India effective 1 January 1995. However, with the expiry of the Ordinance on 26 March 1995, no legal basis remained, and with the failure to enact the Patents (Amendment) Bill 1995 due to the dissolution of Parliament on 10 May 1996, no legal basis currently exists, for the grant of exclusive marketing rights in India. India notified the Council for TRIPS of the promulgation of the Ordinance pursuant to Article 63.2 of the *TRIPS Agreement*⁶⁴, but has failed as yet to notify the Council for TRIPS that the Ordinance has expired.

81. Given India's admissions that legislation is necessary in order to grant exclusive marketing rights in compliance with Article 70.9 and that it does not currently have such legislation, the issue for us to consider in this appeal is whether a failure to have in place a mechanism ready for the grant of exclusive marketing rights, effective *as from the date of entry into force* of the *WTO Agreement*, constitutes a violation of India's obligations under Article 70.9 of the *TRIPS Agreement*.

82. By its terms, Article 70.9 applies only in situations where a product patent application is filed under Article 70.8(a). Like Article 70.8(a), Article 70.9 applies "notwithstanding the provisions of Part VI". Article 70.9 specifically refers to Article 70.8(a), and they operate in tandem to provide a package of rights and obligations that apply *during* the transitional periods contemplated in Article 65. It is obvious, therefore, that both Article 70.8(a) *and* Article 70.9 are intended to apply as from the date of entry into force of the *WTO Agreement*.

83. India has an obligation to implement the provisions of Article 70.9 of the *TRIPS Agreement* effective as from the date of entry into force of the *WTO Agreement*, that is, 1 January 1995. India concedes that legislation is needed to implement this obligation. India has not enacted such legislation.

⁶⁴IP/N/1/IND/1, 8 March 1995.

To give meaning and effect to the rights and obligations under Article 70.9 of the *TRIPS Agreement*, such legislation should have been in effect since 1 January 1995.

84. For these reasons, we agree with the Panel that India should have had a mechanism in place to provide for the grant of exclusive marketing rights effective as from the date of entry into force of the *WTO Agreement*, and, therefore, we agree with the Panel that India is in violation of Article 70.9 of the *TRIPS Agreement*.

VIII. Article 63

85. India argues that, under Articles 3, 7 and 11 of the DSU, a panel may make findings only on issues that have been submitted to it by the parties to the dispute. With this in mind, India contends that the Panel exceeded its authority under the DSU by ruling on the subsidiary claim by the United States under Article 63 of the *TRIPS Agreement* after having first accepted the principal claim by the United States of a violation of Article 70.8 of the *TRIPS Agreement*.⁶⁵

86. The facts are these. The Panel's terms of reference⁶⁶ refer to the request by the United States for the establishment of a panel.⁶⁷ The United States did not include a claim under Article 63 in its request for the establishment of a panel in this case.⁶⁸ The United States did not mention Article 63 in its first written submission to the Panel. The United States did not raise Article 63 as an alternative claim for the first time until its oral statement at the first substantive meeting of the parties with the Panel.

87. In *United States - Shirts and Blouses*, we said that "[a] panel need only address those claims which must be addressed in order to resolve the matter in issue in the dispute".⁶⁹ This means that a panel has the discretion to determine the claims it must address in order to resolve the dispute between the parties -- provided that those claims are within that panel's terms of reference. We have stressed, on more than one occasion, the fundamental importance of a panel's terms of reference. In *European Communities - Regime for the Importation, Sale and Distribution of Bananas* ("*European Communities -*

⁶⁵India's appellant's submission, p. 24.

⁶⁶WT/DS50/5, 5 February 1997.

⁶⁷WT/DS50/4, 8 November 1996.

⁶⁸*Ibid.*

⁶⁹Adopted 23 May 1997, WT/DS33/AB/R, p. 19. A footnote to this statement reads: "The 'matter in issue' is the 'matter referred to the DSB' pursuant to Article 7 of the DSU".

Bananas"), we found that "[i]t is the panel's terms of reference, governed by Article 7 of the DSU, which set out the claims of the complaining parties relating to the matter referred to the DSB".⁷⁰ In *Brazil - Measures Affecting Desiccated Coconut* ("*Brazil - Desiccated Coconut*"), we stated:

A panel's terms of reference are important for two reasons. First, terms of reference fulfil an important due process objective -- they give the parties and third parties sufficient information concerning the claims at issue in the dispute in order to allow them an opportunity to respond to the complainant's case. Second, they establish the jurisdiction of the panel by defining the precise claims at issue in the dispute.⁷¹

88. We stated also in *Brazil - Desiccated Coconut* that all claims must be included in the request for establishment of a panel in order to come within the panel's terms of reference, based on the practice of panels under the GATT 1947 and the Tokyo Round Codes.⁷² That past practice required that a claim had to be included in the documents referred to, or contained in, the terms of reference in order to form part of the "matter" referred to a panel for consideration. Following both this past practice and the provisions of the DSU, in *European Communities - Bananas*, we observed that there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions, and the first and second panel meetings with the parties as a case proceeds. There we said:

Article 6.2 of the DSU requires that the *claims*, but not the *arguments*, must all be specified sufficiently in the request for the establishment of a panel in order to allow the defending party and any third parties to know the legal basis of the complaint. If a *claim* is not specified in the request for the establishment of a panel, then a faulty request cannot be subsequently "cured" by a complaining party's argumentation in its first written submission to the panel or in any other submission or statement made later in the panel proceeding.⁷³

89. Thus, a claim *must* be included in the request for establishment of a panel in order to come within a panel's terms of reference in a given case. In this case, after describing the obligations of Articles 27, 70.8 and 70.9 of the *TRIPS Agreement*, the request for establishment of a panel by the United States reads, in pertinent part:

⁷⁰ Adopted 25 September 1997, WT/DS27/AB/R, para. 145.

⁷¹ Adopted 20 March 1997, WT/DS22/AB/R, p. 22.

⁷² *Ibid.*

⁷³ Adopted 25 September 1997, WT/DS27/AB/R, para. 143.

... India's legal regime appears to be inconsistent with the obligations of the TRIPS Agreement, including but not necessarily limited to Articles 27, 65 and 70

Accordingly, the United States respectfully requests the establishment of a panel to examine this matter in light of the TRIPS Agreement, and to find that India's legal regime fails to conform to the obligations of Articles 27, 65 and 70 of the TRIPS Agreement, and nullifies or impairs benefits accruing directly or indirectly to the United States under the TRIPS Agreement.⁷⁴

90. With respect to Article 63, the convenient phrase, "including but not necessarily limited to", is simply not adequate to "identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly" as required by Article 6.2 of the DSU. If this phrase incorporates Article 63, what article of the *TRIPS Agreement* does it not incorporate? Therefore, this phrase is not sufficient to bring a claim relating to Article 63 within the terms of reference of the Panel.

91. In *European Communities - Bananas*, we accepted the view of the panel in that case that it was "sufficient for the Complaining Parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements", and we also agreed with the panel that the request in that case was sufficiently specific to comply with the "minimum standards" established by Article 6.2 of the DSU.⁷⁵ In this case, in contrast, there is a failure to identify a specific provision of an agreement that is alleged to have been violated. This falls below the "minimum standards" that we were willing to accept in *European Communities - Bananas*.

92. We note also the Panel's statement that it "ruled, at the outset of the first substantive meeting held on 15 April 1997, that all legal claims would be considered if they were made prior to the end of that meeting; and this ruling was accepted by both parties".⁷⁶ We do not find this statement at all persuasive in advancing the argument made by the United States on this issue. Nor do we find this statement consistent with the letter and the spirit of the DSU. Although panels enjoy some discretion in establishing their own working procedures, this discretion does not extend to modifying the substantive

⁷⁴WT/DS50/4, 8 November 1996.

⁷⁵Adopted 25 September 1997, WT/DS27/AB/R, para. 141; Panel Reports, adopted 25 September 1997, WT/DS27/R/ECU, WT/DS27/R/GTM, WT/DS27/R/HND, WT/DS27/R/MEX, WT/DS27/R/USA, para. 7.29.

⁷⁶Panel Report, para. 7.9.

provisions of the DSU. To be sure, Article 12.1 of the DSU says: "Panels shall follow the Working Procedures in Appendix 3 unless the panel decides otherwise after consulting the parties to the dispute". Yet that is *all* that it says. Nothing in the DSU gives a panel the authority either to disregard or to modify other explicit provisions of the DSU. The jurisdiction of a panel is established by that panel's terms of reference, which are governed by Article 7 of the DSU. A panel may consider only those claims that it has the authority to consider under its terms of reference. A panel cannot assume jurisdiction that it does not have. In this case, Article 63 was not within the Panel's jurisdiction, as defined by its terms of reference. Therefore, the Panel had no authority to consider the alternative claim by the United States under Article 63.

93. The United States argues that, in the consultations between the parties to this dispute in this case, India had not disclosed the existence of any "administrative instructions" for the filing of mailbox applications for pharmaceutical and agricultural chemical products. Therefore, the United States asserts that it had no way of knowing that India would rely on this argument before the Panel. The United States maintains that, for this reason, it had not included a claim under Article 63 in its request for the establishment of a panel.⁷⁷ All that said, there is, nevertheless, no basis in the DSU for a complaining party to make an additional claim, outside of the scope of a panel's terms of reference, at the first substantive meeting of the panel with the parties. A panel is bound by its terms of reference.

94. All parties engaged in dispute settlement under the DSU must be fully forthcoming from the very beginning both as to the claims involved in a dispute and as to the facts relating to those claims. Claims must be stated clearly. Facts must be disclosed freely. This must be so in consultations as well as in the more formal setting of panel proceedings. In fact, the demands of due process that are implicit in the DSU make this especially necessary during consultations. For the claims that are made and the facts that are established during consultations do much to shape the substance and the scope of subsequent panel proceedings. If, in the aftermath of consultations, any party believes that all the pertinent facts relating to a claim are, for any reason, not before the panel, then that party should ask the panel in that case to engage in additional fact-finding. But this additional fact-finding cannot alter the claims that are before the panel -- because it cannot alter the panel's terms of reference. And, in the absence of the inclusion of a claim in the terms of reference, a panel must neither be expected nor permitted to modify rules in the DSU.

95. It is worth noting that, with respect to fact-finding, the dictates of due process could better be

⁷⁷Response by the United States to questioning at the oral hearing.

served if panels had standard working procedures that provided for appropriate factual discovery at an early stage in panel proceedings.

96. For these reasons, we find that the Panel erred in its findings and conclusions relating to the alternative claim by the United States under Article 63 of the *TRIPS Agreement*. In the light of this finding, it is not necessary for us to consider whether the Panel erred also in recommending simultaneously that India bring itself into compliance with its obligations under both Articles 70.8(a) and 63 of the *TRIPS Agreement*.

IX. Findings and Conclusions

97. For the reasons set out in this Report, the Appellate Body:

- (a) upholds the Panel's conclusion that India has not complied with its obligations under Article 70.8(a) to establish "a means" that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional periods provided for in Article 65 of the *TRIPS Agreement*;
- (b) upholds the Panel's conclusion that India has not complied with its obligations under Article 70.9 of the *TRIPS Agreement*; and
- (c) reverses the Panel's alternative findings that India has not complied with paragraphs 1 and 2 of Article 63 of the *TRIPS Agreement*.

98. The Appellate Body *recommends* that the Dispute Settlement Body request India to bring its legal regime for patent protection of pharmaceutical and agricultural chemical products into conformity with India's obligations under Articles 70.8 and 70.9 of the *TRIPS Agreement*.

Signed in the original at Geneva this 4th day of December 1997 by:

Julio Lacarte-Muró
Presiding Member

James Bacchus
Member

Christopher Beeby
Member