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The *Dispute Settlement Reports* of the World Trade Organization (the "WTO") include panel and Appellate Body reports, as well as arbitration awards, in disputes concerning the rights and obligations of WTO Members under the provisions of the *Marrakesh Agreement Establishing the World Trade Organization*. The *Dispute Settlement Reports* are available in English, French and Spanish.

This volume may be cited as DSR 1998:I

TABLE OF CONTENTS

Page

EUROPEAN COMMUNITIES - REGIME FOR THE IMPORTATION, SALE AND DISTRIBUTION OF BANANAS

Arbitration under Article 21.3(c) of the Understanding on Rules and Procedures Governing the Settlement of Disputes

Award of the Arbitrator
Said El-Naggar
WT/DS27/15

Circulated to Members on 7 January 1998

I. INTRODUCTION

1. On 25 September 1997, the Dispute Settlement Body (the "DSB") adopted the Appellate Body Report[1] and the Panel Reports[2], as modified, in *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, complaint by Ecuador, Guatemala, Honduras, Mexico and the United States (the "Complaining Parties"). On 16 October 1997, the European Communities informed the DSB, pursuant to Article 21.3 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (the "DSU"), that it would fully respect its international obligations with regard to this matter.[3] At the same meeting, the European Communities stated that - while intending to act expeditiously - it would, in view of the complexity of the matter at issue, require a reasonable period of time in which to examine all the options to meet its international obligations.[4]

2. On 24 October 1997, the European Communities requested consultations with the Complaining Parties in order to reach agreement on a "reasonable period of time" for the implementation of the recommendations and rulings of the DSB adopted on 25 September 1997. These consultations, however, did not lead to an agreement. The Complaining Parties therefore requested, on 17 November 1997,

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1 WT/DS27/AB/R.
2 Complaint by Ecuador, WT/DS27/R/ECU; Complaint by Guatemala and Honduras, WT/DS27/R/GTM, WT/DS27/R/HND; Complaint by Mexico, WT/DS27/R/MEX; Complaint by the United States, WT/DS27/R/USA.
3 WT/DSB/M/38, p. 3.
4 *Ibid*.

that the "reasonable period of time" be determined by binding arbitration pursuant to Article 21.3(c) of the DSU.[5]

3. In the absence of an agreement between the parties on the appointment of an arbitrator within 10 days after referring the matter to arbitration, the Complaining Parties requested, on 1 December 1997, the Director-General of the World Trade Organization ("WTO") to appoint the arbitrator, as provided for in footnote 12 to Article 21.3(c) of the DSU. After consultation with the parties, the Director-General decided, on 8 December 1997, to appoint me as the Arbitrator.[6] He indicated to the parties that, as a Member of the Appellate Body, I would consult with the other Members of the Appellate Body in accordance with its practice of collegiality.

4. Written submissions were received from the European Communities and the Complaining Parties on 15 December 1997, and an oral hearing was held on 17 December 1997. Consultations with the other Members of the Appellate Body took place on 19 December 1997.

II. ARGUMENTS OF THE PARTIES

A. European Communities

5. In its written submission of 15 December 1997, the European Communities requests the Arbitrator to set a "reasonable period of time", under Article 21.3(c) of the DSU, which would not expire before 1 January 1999, i.e. a period of 15 months and one week. In justification of this request, the European Communities notes that amending the existing EC import regime for bananas, as required by the recommendations and rulings of the DSB, will be a difficult and complex task for a number of reasons.

6. First, the European Communities points out that in amending its import regime for bananas, it will have to strike a difficult balance between the co-existing international obligations under the *Marrakesh Agreement Establishing the World Trade Organization* (the "*WTO Agreement*") and the Fourth ACP-EC Convention of Lomé (the "Lomé Convention")[7] with the aim of respecting both. Furthermore, the European Communities notes that amending its import regime for bananas will re-open the lengthy discussion between the Member States of the European Union on many of the issues that had been agreed in 1993 when the different national banana markets were transformed into a single Community-wide market.

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5 WT/DS27/13, G/L/209, 20 November 1997.
6 WT/DS27/14, 12 December 1997.
7 Signed in Lomé, 15 December 1989, as revised by the Agreement signed in Mauritius, 4 November 1995.

7. Secondly, the European Communities explains that the amendment of its banana import regime will require setting in motion a complex legislative procedure involving: the European Commission, which has to submit a proposal for the necessary changes; the European Parliament, which will need to give its opinion on the proposed changes; and the Council of the European Union, which will decide on the changes, either by qualified majority or by unanimity, depending on whether or not it follows the proposal of the Commission. The European Communities also notes that once the amended basic legislation is adopted by the Council, the European Commission will still need to adopt implementing legislation to make the new import regime operational.

8. Thirdly, the European Communities refers to the fact that Article 12 of the Lomé Convention imposes a legal obligation on the European Communities to consult the ACP States[8] "where [it] intends ... to take a measure which might affect the interests of the ACP States as far as this Convention's objectives are concerned". This obligation to consult certainly applies, in the view of the European Communities, to an amendment of the banana import regime. The European Communities maintains that its legislative procedure will therefore have to allow enough time to consider the observations made by the ACP States before any final decision on the new banana import regime is taken.

9. Fourthly, the European Communities notes that under its administrative practice, any change in legislation which directly affects the customs treatment of products in connection with importation or exportation, enters into force either on 1 January or 1 July of the relevant year. This practice reflects, according to the European Communities, internal management needs and the economic interests of the operators on the market to operate under orderly and predictable procedures.

10. Finally, the European Communities argues that an advance notice with a reasonable lead time of any major changes in legislation should be given to permit those involved in the banana supply chain to make the necessary adjustments to their planning and logistics.

11. The European Communities notes that, for all the above reasons, the "reasonable period of time" it proposes is already a tight schedule that will require a great deal of discipline and cooperation together with a constructive approach at all levels.

12. At the oral hearing on 17 December 1997, the European Communities made it clear that the "reasonable period of time" it requests, i.e. until 1 January 1999, is for the purpose of implementing all the recommendations and rulings of the DSB adopted on 25 September 1997 in *European Communities - Regime for the Importation, Sale and Distribution of Bananas*.

[8] The term "ACP States" refers to the African, Caribbean and Pacific States which are parties to the Lomé Convention.

B. Complaining Parties

13. The Complaining Parties note that their request to determine the "reasonable period of time" through binding arbitration followed extensive attempts to reach an agreement with the European Communities on this matter, and that these attempts failed because the European Communities was unwilling to confirm that it intends to use the "reasonable period" in order to fully implement the recommendations and rulings of the DSB. The Complaining Parties argue that a "reasonable period of time", within the meaning of Article 21.3(c), is a limited right that arises only for the purpose of implementation. In their opinion, a defending Member which refuses to state its intention to implement the relevant DSB recommendations and rulings should not be entitled to a "reasonable period of time". The Complaining Parties believe that of all the "particular circumstances" which an arbitrator should consider when deciding on a "reasonable period of time", the most important must be whether a Member has stated its intention to comply with the recommendations and rulings of the DSB. Accordingly, the Complaining Parties argue that the Arbitrator should conclude that the European Communities is not entitled to the "reasonable period of time", provided for in Article 21.3(c), since it has not clearly indicated its intention to fully implement the recommendations and rulings of the DSB.

14. In their written submission of 15 December 1997, the Complaining Parties argue, in the alternative, that even if in the course of the arbitration proceedings the European Communities would state its intention to implement the recommendations and rulings of the DSB, the "reasonable period of time" of 15 months and one week, requested by the European Communities, is excessive. They submit that the European Communities overstates the period of time needed to implement the recommendations and rulings of the DSB. The Complaining Parties note that most banana measures found to be WTO-inconsistent were implemented through Commission regulations, which can be amended through simple and rapid procedures, separate from the amendment of Regulation 404/93 on the common organization of the market in bananas, which requires action by the Council. Furthermore, the Complaining Parties note that it took the European Communities less than six months to adopt Council Regulation 404/93 after the European Commission had submitted its proposal to the Council. According to them, the current task of amending Regulation 404/93 to make it WTO-consistent is far less challenging than it was to adopt that Regulation in 1993 in the first place. Finally, the Complaining Parties submit that the European Commission often prepares implementing legislation while its proposal for basic legislation is still pending before the Council. Thus, the adoption of implementing legislation by the Commission, they argue, can be carried out shortly after the adoption of the basic legislation by the Council.

15. The Complaining Parties submit that the assertion by the European Communities that the "controversial" nature of the issue requires a more prolonged procedure should be disregarded. In their opinion, an arbitrator's enquiry must avoid the issue of what implementation period would be acceptable to domestic political constituencies, and examine instead the "practicable" time needed to

accomplish the legislative and regulatory changes involved. Under the circumstances of this case, the Complaining Parties argue that full implementation of the recommendations and rulings of the DSB is "practicable" by 1 July 1998, i.e. within nine months.

16. Ecuador, Guatemala, Honduras and Mexico also argue that Articles 21.2, 21.7 and 21.8 of the DSU require that special attention be paid to matters affecting the interests of complaining developing country Members with respect to measures that have been subject to dispute settlement. In their reply to my question, whether the interests of other developing countries, and in particular the banana producing ACP States, were not also affected, Ecuador, Guatemala, Honduras and Mexico maintained that their interests carry greater weight since they are requesting the implementation of a WTO-consistent import regime. Finally, the developing country Complaining Parties point out that the country allocations and export certificates provided for in the Framework Agreement on Bananas[9] were implemented by Commission, not Council, regulation and could, therefore, be amended easily.

17. In its closing remarks at the oral hearing, the United States, speaking on behalf of the Complaining Parties, noted the statement made by the European Communities during the oral hearing that it intends to implement all the recommendations and rulings of the DSB within the "reasonable period of time" it has requested, i.e. by 1 January 1999.

III. AWARD

18. Article 21.1 of the DSU stipulates that "prompt compliance with recommendations or rulings of the DSB is essential in order to ensure effective resolution of disputes to the benefit of all Members". This obligation is further elaborated in Article 21.3 of the DSU, where it is provided that "[i]f it is impracticable to comply immediately with the recommendations and rulings, the Member concerned shall have a reasonable period of time in which to do so". When the "reasonable period of time" is determined through binding arbitration, as provided for under Article 21.3(c) of the DSU, this provision states that a "guideline" for the arbitrator should be that the "reasonable period of time" should not exceed 15 months from the date of the adoption of a panel or Appellate Body report. Article 21.3(c) of the DSU also provides, however, that the "reasonable period of time" may be shorter or longer than 15 months, depending upon the "particular circumstances".

19. The Complaining Parties have not persuaded me that there are "particular circumstances" in this case to justify a shorter period of time than stipulated by the guideline in Article 21.3(c) of the DSU. At the same time, the complexity of

[9] *Marrakesh Protocol to the General Agreement on Tariffs and Trade 1994*, Schedule LXXX - European Communities, pp. 16373-16377.

the implementation process, demonstrated by the European Communities, would suggest adherence to the guideline, with a slight modification, so that the "reasonable period" of time for implementation would expire by 1 January 1999.

20. Therefore, I conclude that, pursuant to Article 21.3(c), the "reasonable period of time" for the European Communities to implement the recommendations and rulings of the DSB adopted on 25 September 1997 in *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, shall be the period from 25 September 1997 to 1 January 1999.

INDIA - PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS

Report of the Appellate Body
WT/DS50/AB/R

Adopted by the Dispute Settlement Body
on 16 January 1998

India, *Appellant*	Present:
United States, *Appellee*	Lacarte-Muró, Presiding Member
European Communities, *Third Participant*	Bacchus, Member
	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.

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 appli-

[1] WT/DS50/R, 5 September 1997.
[2] WT/DS50/4, 8 November 1996.

> cations 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 Body[5] (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.

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.

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3 Panel Report, para. 8.1.
4 Panel Report, para. 8.2.
5 WT/DS50/6, 16 October 1997.
6 Pursuant to Rule 21(1) of the *Working Procedures.*
7 India's appellant's submission, p. 10.

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 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

[8] See Panel Report, Annex 2.

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 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

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[9] India 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.

[10] Panel Report, para. 7.56 and note 112.

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 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.

[11] Done at Marrakesh, Morocco, 15 April 1994.

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]

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

[12] Adopted 23 May 1997, WT/DS33/AB/R.
[13] Adopted 25 February 1997, WT/DS24/R, para. 7.10.

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 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.

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

[15] Panel Report, para. 7.56, note 112.

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 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 Arti-

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

cle 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 agree-

ments, 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 para-

> graph 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.
>
> ...
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> 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]

The Panel also referred to certain GATT 1947 panel reports[20] 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

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17 Panel Report, para. 7.22.

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

19 Panel Report, para. 7.20.

20 In 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.

21 Panel Report, para. 7.21.

> 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.

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

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[22] Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, DSR 1996:I, 97 at 107-108.

[23] Article 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.

[24] Article XXIII:1 of the GATT 1994.

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 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.

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[25] Previous 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.

[26] See, 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.

[27] See, 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.

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 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:

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

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

> 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 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

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[30] Panel Report, para. 7.18.

[31] Adopted 20 May 1996, WT/DS2/AB/R, DSR 1996:I, 3 at 15-16.

> diminish the rights and obligations provided in the covered agreements.

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:
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> (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 periods[35], 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 arrangements" exist for the obligations in Article 70.8.

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[32] Panel Report, para. 7.31.

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

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

[35] Pursuant 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.

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]

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

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[36] Panel Report, para. 7.25.
[37] Panel Report, para. 7.28.
[38] Preamble to the *TRIPS Agreement*.
[39] Panel Report, para. 7.31.

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.

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

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[40] Panel Report, para. 7.31.
[41] *Ibid.*
[42] This is India's term for its measure. India's appellant's submission, p. 10.

to India, these "administrative instructions" are legally valid in Indian law[43], 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. 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]

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43 Response by India to questioning at the oral hearing.
44 Panel Report, Annex 2.
45 India's appellant's submission, p. 8.
46 IP/N/1/IND/1, 8 March 1995.
47 We 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.
48 Response of India to questioning at the oral hearing.

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 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

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[49] Panel Report, para. 7.35.
[50] Panel Report, para. 7.37.
[51] India's appellant's submission, pp. 13 and 15.
[52] See, for example, I. Brownlie, *Principles of Public International Law*, 4th ed. (Clarendon Press, 1990), pp. 40-42.
[53] [1926], PCIJ Rep., Series A, No. 7, p. 19.

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.

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

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[54] Adopted 7 November 1989, BISD 36S/345.
[55] Panel Report, para. 7.35.
[56] Panel Report, para. 7.37.

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 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 evi-

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[57] India's appellant's submission, p. 12.
[58] Panel Report, para. 7.40.
[59] Adopted 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 337-338.

dence 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*.

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

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[60] Panel Report, para. 7.60.

[61] India'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

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]

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*.

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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.

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

[64] IP/N/1/IND/1, 8 March 1995.

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. 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 reference[66] 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 - Bananas*"), we found that "[i]t is the panel's terms of reference, governed by Article 7 of the DSU,

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65 India's appellant's submission, p. 24.
66 WT/DS50/5, 5 February 1997.
67 WT/DS50/4, 8 November 1996.
68 *Ibid*.
69 Adopted 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*".

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:

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[70] Adopted 25 September 1997, WT/DS27/AB/R, para. 145.
[71] Adopted 20 March 1997, WT/DS22/AB/R, DSR 1997:I, 167 at 186.
[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 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

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[74] WT/DS50/4, 8 November 1996.

[75] Adopted 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.

[76] Panel Report, para. 7.9.

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 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

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

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*.

INDIA - PATENT PROTECTION FOR PHARMACEUTICAL AND AGRICULTURAL CHEMICAL PRODUCTS

Report of the Panel

WT/DS50/R

Adopted by the Dispute Settlement Body on 16 January 1998
as modified by the Appellate Body Report

TABLE OF CONTENTS

Page

Page

Page

I. INTRODUCTION

1.1 On 2 July 1996, the United States requested India to hold consultations pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Article 64 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding the absence in India of either patent protection for pharmaceutical and agricultural chemical products or formal systems that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that provide exclusive marketing rights in such products (WT/DS50/1). No mutually satisfactory solution was reached in these consultations, held on 27 July 1996. The United States requested the Dispute Settlement Body (DSB), in a communication dated 7 November 1996, to establish a panel to examine the matter (WT/DS50/4). At its meeting of 20 November 1996, the DSB agreed to establish a panel with standard terms of reference in accordance with Article 6 of the DSU.

1.2 In document WT/DS50/5 of 5 February 1997, the DSB was informed that the terms of reference and the composition of the Panel were as follows:

Terms of Reference

"To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS50/4, the matter referred to the DSB by the United States in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."

Composition

Chairman: Mr. Thomas Cottier

Panelists: Mr. Douglas Chester

Mr. Yanyong Phuangrach

1.3 The Panel heard the parties to the dispute on 15 April and 13 May 1997. The Panel decided to give the parties the chance to comment, after the second session, in writing on each other's arguments related to the United States' claim based on Article 63, which claim had been made for the first time at the first session. The

interim report was issued to the parties on 27 June 1997. Only India requested the Panel to review parts of the interim report and no request was received to hold an additional meeting.

II. FACTUAL ASPECTS

2.1 The questions before this Panel concern the obligations India has as a WTO Member by virtue of certain transitional provisions of the TRIPS Agreement and are to be divided into questions related to the provisions of Article 70.8 of the TRIPS Agreement and questions related to the provisions of Article 70.9 of that Agreement. In respect of these questions, issues were also raised relating to the publication and notification provisions of Article 63.

2.2 Obligations arising under international agreements or treaties are not, by their own force, binding in Indian domestic law. Appropriate legislative or executive action has to be taken for bringing them into force.

2.3 On 31 December 1994, the President of India promulgated the Patents (Amendment) Ordinance 1994, to amend the Patents Act 1970 to provide a means in the Act for the filing and handling of patent applications for pharmaceutical or agricultural chemical products (as required by subparagraph (a) of Article 70.8 of the TRIPS Agreement) and for the grant of exclusive marketing rights with respect to the products that are the subject of such patent applications (as required by Article 70.9 of the Agreement).[1] This Ordinance was issued in exercise of the powers conferred upon the President by clause (1) of Article 123 of the Indian Constitution, which enables the President to legislate when Parliament (either House or both Houses) is not in session and the President "is satisfied that circumstances exist which render it necessary for him to take immediate action". The Ordinance became effective on 1 January 1995 and lapsed on 26 March 1995, since legislation of this kind ceases to apply at the expiration of six weeks from the re-assembly of Parliament.

2.4 At the time of the promulgation of the Patents (Amendment) Ordinance 1994, a Press Note was issued providing an explanation of its background and purposes. According to paragraph 4 of this Press Note, the Indian Government had set up an Expert Group which had been entrusted with the task of suggesting specific amendments necessary in Indian laws to comply with India's obligations under the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement and also to safeguard India's interests in this regard; this Expert Group had recommended a set of meas-

[1] The Patents (Amendment) Ordinance 1994 stipulated, in essence, that applications claiming patent protection for pharmaceutical and agricultural chemical product inventions could be made, although such inventions were not patentable, and that their handling would be postponed until 1 January 2005 or until an application for the grant of an exclusive marketing right for the product in question was made, if such would occur earlier; the Ordinance also laid down the procedures for applications for the grant of exclusive marketing rights, the scope of these rights and their enforcement.

ures on which decisions had been taken by the Government. The Ordinance was also notified by India to the Council for TRIPS under Article 63.2 of the TRIPS Agreement (which notification had been distributed as document IP/N/1/IND/1). During this period, 125 applications had been received and filed.

2.5 A Patents (Amendment) Bill 1995, which was intended to give permanent legislative effect to the provisions of the Ordinance, was introduced in the Lok Sabha (Lower House) of the Indian Parliament in March 1995. This Bill was passed by the Lok Sabha and was then introduced in the Rajya Sabha (Upper House). In the Rajya Sabha, the Bill was referred to a Select Committee of the House for examination and report. The Select Committee started its work but could not present its report before the dissolution of the Lok Sabha on 10 May 1996. The Patents (Amendment) Bill 1995 lapsed with the dissolution of the 10th Lok Sabha on that date.

(a) Article 70.8

2.6 At the time that the period of validity of the Ordinance expired, the Patents (Amendment) Bill 1995 was still being debated. India informed the Panel that, in the light of this situation, the Indian executive authorities decided, in April 1995, to instruct the patent offices in India to continue to receive patent applications for pharmaceutical and agricultural chemical products and to store them separately for processing as and when the change in the Indian patent law to make such subject matter patentable would take effect. No record of this decision or of any administrative guidelines issued to or within the patent offices of India to this effect was made available to the Panel.

2.7 No public notice was given at that time of this administrative decision and no notification concerning it was made to the Council for TRIPS. However, on 2 August 1996, the Indian Minister of Industry responded to a question asked by a member of the Lok Sabha concerning whether applications for product patents in the pharmaceutical, food and agricultural chemical areas had been received in anticipation of changes in the Indian Patents Act 1970 in accordance with the requirements of the World Trade Organization; as reflected at Annex 2 of this report, the Minister responded by stating that the patent offices had received 893 patent applications in the field of drug or medicine from Indian as well as foreign companies/institutions up to 15 July 1996 and that applications for patents would be taken up for examination after 1 January 2005 as per the WTO Agreement.

2.8 Under Indian patent law, patent applications for pharmaceutical or agricultural chemical products made by any person entitled to apply under Section 6 of the Patents Act 1970 are subject to the same fee as any other patent application being received and allotted a filing date and advertised in the Official Gazette with serial number, filing date, name of applicant and title of invention. Under the administrative arrangements of the Indian patent offices pursuant to the decision taken in April 1995, such applications are, however, unlike other patent applications, being stored separately and not referred by the Controller to an examiner as specified in Section 12 of the Act.

2.9 The legal authority for these administrative arrangements that has been cited by India is Article 73(1)(a) of the Indian Constitution in conjunction with the Indian Patents Act 1970. Article 73(1) reads as follows:

> "*Extent of executive power of the Union*. (1) Subject to the provisions of this Constitution, the executive power of the Union shall extend
>
> (a) to the matters with respect to which Parliament has power to make laws; and
>
> (b) to the exercise of such rights, authority and jurisdiction as are exercisable by the Government of India by virtue of any treaty or agreement:
>
> Provided that the executive power referred to in sub-clause (a) shall not, save as expressly provided in this Constitution or in any law made by Parliament, extend in any State to matters with respect to which the Legislature of the State has also power to make laws."

2.10 The full text of the provisions of the Patents Act of relevance to the case in hand can be found at Annex 1 of this report. For the purposes of the case in hand, the main aspects of these provisions that are of relevance are as follows:

- Chapter III (Sections 6 through 11) deals with applications for patents. These provisions do not require that applications for patents must be limited to patentable subject matter. In respect of the subject matter of the claims, they only require that such applications should be for inventions.
- Inventions are defined in Section 2(1)(j) as, *inter alia*, any new and useful substance produced by manufacture, including any new and useful improvement of such a substance.
- Section 5 makes it clear that inventions claiming substances intended for use, or capable of being used, as a food, medicine or drug or relating to substances prepared or produced by chemical processes are not in themselves patentable, but methods or processes for their manufacture are. Under Section 2(1)(l)(iv) the term 'medicine or drug' includes insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants.
- Chapter IV of the Patents Act concerns the examination of applications. Section 12 requires that, when the complete specification has been filed[2] in respect of an application for a patent the applica-

[2] Pursuant to Section 9, the complete specification must normally be filed within 12 months of the date of the filing of the application, which can be extended to 15 months, failing which the application is deemed abandoned.

tion shall be referred by the Controller General of Patents, Designs and Trademarks to an examiner. The examiner shall ordinarily report to the Controller within a period of 18 months on, *inter alia*, whether the application and the specification are in accordance with the requirements of the Act and whether there is any lawful ground for objecting to the grant of the patent under the Act.

- Paragraph 2 of Section 15 states that, if it appears to the Controller that the invention claimed in the specification is not patentable under the Act, he shall refuse the application.

2.11 India informed the Panel that, between 1 January 1995 and 15 February 1997, a total of 1,339 applications for pharmaceutical and agricultural chemical products had been received and registered. Of these applications, United States' companies had filed 318 applications for pharmaceutical product patents and 45 applications for agricultural chemical product patents. On the day the Patents (Amendment) Ordinance 1994 had lapsed, 125 applications had been received and filed (41 made by US companies); prior to 15 February 1997, out of the other 1,214 applications (322 by US companies), 605 had been received and filed prior to the day the Patents (Amendment) Bill 1995 had lapsed.

(b) Article 70.9

2.12 The Indian executive authorities do not have the legal powers under present Indian law to accord exclusive marketing rights in accordance with the provisions of Article 70.9. No request for the grant of exclusive marketing rights has so far been submitted to the Indian authorities.

III. FINDINGS AND RECOMMENDATIONS REQUESTED BY THE PARTIES

3.1 The United States requested the Panel to make the following rulings, findings and recommendations:

Article 70.8

(a) India has failed to implement the obligation in Article 70.8 to establish a mechanism that preserves the novelty of applications for pharmaceutical and agricultural chemical product patents during the TRIPS transition period, regardless of when those applications are filed during that period.

(b) Article 70.8 of the TRIPS Agreement requires India to ensure that persons who filed or would have filed "mailbox"[3] applications had

[3] For an explanation of the term "mailbox system", see footnote 4 below.

the "mailbox" been in place on time and maintained can file such applications and receive the filing date they would have received.

Article 63

(c) In the alternative, if the Panel finds that India has had a valid mailbox system[4] in place, India has failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement.

Article 70.9

(d) The obligation to establish an exclusive marketing rights system arose on 1 January 1995, based on the text of Article 70.9. Because India has failed to implement an exclusive marketing rights system legislatively, it is currently out of compliance with this obligation under the TRIPS Agreement.

(e) India has failed to implement the obligation in Article 70.9 that marketing rights be granted so that competitors of the owner of such right will not be permitted on the market absent the owner's consent.

Article 70.8 and 70.9

(f) That the Panel recommend that India bring its measures into conformity with its obligations under the TRIPS Agreement.

(g) That the Panel suggest that India implement its obligations under Article 70.8 and 70.9 in a manner similar to the way in which Pakistan has indicated it is implementing these obligations.

3.2 India requested the Panel to reject the United States complaints on the basis of the following findings:

Article 70.8

(a) India is providing a means for filing patent applications for pharmaceutical and agricultural chemical products consistently with Article 70.8 of the TRIPS Agreement. This means is capable of attaining the objectives of Article 70.8 of the TRIPS Agreement.

(b) The United States' request, referred to under 3.1(b) above, is a request for a ruling on how India should eliminate the consequences of an alleged violation of Article 70.8 of the TRIPS Agreement. Article 19.1 of the DSU does not permit the Panel to make a ruling

[4] The term "mailbox system" is used as shorthand for provisions to be put in place which allow for the filing of patent applications for pharmaceutical and agricultural chemical products as required by Article 70.8.

on how India should eliminate the consequences of the alleged violation of Article 70.8 of the TRIPS Agreement.

Article 63

(c) The United States' request for findings based on Article 63 should not be considered by the Panel, since the Panel's terms of reference do not cover the United States' Article 63 claim and the scope of factual and legal claims cannot be expanded after the first written submission.

(d) In the alternative, if the Panel were to consider that it can examine the United States' claim:

  (i) Article 63 does not apply to developing countries until 1 January 2000;

  (ii) if the Panel were to consider that Article 63 already applies to India, India has published the elements of its means of filing that are subject to the transparency requirements of Article 63.1.

Article 70.9

(e) Since there has not been any request for exclusive marketing rights in India, India has not failed to accord exclusive marketing rights to any product entitled to such rights under Article 70.9 of the TRIPS Agreement.

(f) Since the issue of the scope of exclusive marketing rights was not an issue relating to an existing measure, the United States' request, referred to under 3.1(e) above, amounts to a request for a declaratory judgement, which type of finding does not fall within the competence of panels because Article XXIII of GATT 1994 and the DSU permit only complaints on measures actually taken.

Article 70.8 and 70.9

(g) The United States' request that the Panel suggest that India implement its obligations under Article 70.8 and 70.9 in a manner similar to the way in which Pakistan has indicated it is implementing these obligations should be rejected as procedurally and legally inappropriate.

IV. ARGUMENTS OF THE PARTIES

Article 70.8

(a) The United States' Claim that India Does Not Have in Place a Mailbox System that Corresponds to the Requirements of Article 70.8

4.1 In its first written submission, the **United States** argued that, since the Patents (Amendment) Ordinance 1994 ceased to have effect in early 1995, no formal mailbox system existed today in India and that India, therefore, had failed to comply with its obligations under Article 70.8 of the TRIPS Agreement to establish a mailbox system in its law which permitted the filing of mailbox applications.

4.2 **India** responded by stating that applications for the grant of patent protection for pharmaceutical and agricultural chemical products were being filed, registered and stored in India and that the system, which was consistent with the provisions of the Patents Act 1970, was operating effectively. India argued that the system fulfilled the requirements of Article 70.8 of the TRIPS Agreement for the following reasons:

- The Patents Act and the administrative practices governing patent applications permitted the filing of a patent application for a pharmaceutical or agricultural chemical product notwithstanding the fact that such products were currently not patentable. Section 6 of the Act provided for the receipt of applications for a patent for inventions. It was not a precondition of Section 6 that the application should relate to a patentable invention. The Patents Act of 1970 defined "invention" in Section 2(1)(j) and further provided in Section 3 that certain subject matters were not inventions. In Section 5, the Act recognized that there might be an invention in relation to pharmaceutical products and chemical products, but provided that such inventions were not patentable in respect of the product itself while being patentable for the methods or processes of manufacture.
- It was true that, should an application be examined under the provisions of Section 12, the examiner would be duty-bound to apply the provisions of Section 5 and at this stage raise objections to the patentability of a pharmaceutical and agricultural chemical product. However, applications for patents for pharmaceutical and agricultural chemical products were not being referred by the Controller General of Patents, Trademarks and Designs for examination. Therefore, the question of their rejection did not arise, since that question could only arise after examination and the application of Section 5. Thus, patent applications for pharmaceutical or agricultural chemical products would not be refused and withdrawn from consideration prior to the date when such protection would become

available. Once patent protection or exclusive marketing rights for pharmaceutical and agricultural chemical products must be granted in accordance with Article 70.8(c) and 70.9, a complete record going back to the date of entry into force of the WTO Agreement of all patent applications for pharmaceutical and agricultural chemical products, including the date and the sequence of the applications, would thus be available.

- Article 70.8(a) of the TRIPS Agreement created, at present, only one obligation for India in respect of pharmaceutical and agricultural chemical products, namely "to 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*" (*emphasis added by India*). A method of filing applications for pharmaceutical and agricultural chemical products had been made available and was being used.
- WTO Members were free to determine the means by which patent applications could be filed. Article 70.8(a) required Members to provide "a means" for filing; it did not prescribe the choice of a particular method. This was explicitly recognized in Article 1.1 of the TRIPS Agreement which made clear that "Members shall be *free to determine the appropriate method* of implementing the provisions of this Agreement within their own legal *system and practice*" (*emphasis added by India*). India had initially decided to provide for a means for the filing of applications through an ordinance by the President and, when this ordinance had lapsed, through administrative action by instructing the patent offices to continue to receive applications and to store them separately for future action in accordance with Article 70.8. Both the legislative and the administrative approaches were available to India under Articles 1 and 70 of the TRIPS Agreement. It was therefore not correct for the United States to claim that India must create a mailbox *system* in its *law* for the filing of patent applications (*emphasis by India*). WTO Members were free to determine the means by which patent applications could be filed and India was free to choose an administrative method pending the change in legislation.
- The means currently provided by India was capable of attaining the objectives of Article 70.8. The main rationale of the requirement of subparagraph (a) of Article 70.8 was to ensure that the WTO Member, when it eventually granted patents for pharmaceutical and agricultural chemical products, was able to assign a filing date to the patent for the purpose of determining the remaining patent term. Any method of filing, registration and storage of applications that enabled the Member to assign a filing date to patent applications must, therefore, be regarded as a proper means for filing within the meaning of Article 70.8.

- The number of filings submitted under this system indicated that the companies concerned did not experience or anticipate any difficulty in the matter of filing their applications.[5]

4.3 The **United States** argued that the Indian claim that a mailbox system had been put in place in India was contrary to its laws, its statements and its actions:

- India had made it clear that changes to its laws were necessary to establish a mailbox system consistent with the requirements of Article 70.8. India had done so through statements and actions surrounding its issuance and notification of the Patents (Amendment) Ordinance 1994 and its attempt to get the Patents (Amendment) Bill 1995 adopted by Parliament. The text of the Patents Ordinance made it clear that the relatively automatic system for the rejection of pharmaceutical and agricultural chemical product patent applications must be modified to establish a legally defensible mailbox system. The Patents Ordinance had, temporarily, amended Section 5 of the Patents Act by the insertion of a Chapter IVA stipulating special rules for the handling of mailbox applications, which overrode the operation of Section 12 of the Patents Act and prohibited the Controller to forward mailbox applications to examiners. India thus had thought that it was *necessary* to modify the Indian Patents Act with respect to the handling of applications for pharmaceutical and agricultural chemical products (*emphasis by the United States*). The Patents Ordinance would not have been issued unless the President, presumably acting on the advice of his legal experts, had determined that it was "necessary" to take "immediate action" under Article 123 of the Indian Constitution. The importance of issuing the Ordinance and implementing its provisions in India's laws had been restated in the context of the Indian Government's unsuccessful attempts to get the Patents (Amendment) Bill 1995 passed by Parliament. The Indian Government had also stated in its notification of 6 March 1995 of the Patents Ordinance to the Council for TRIPS that the Ordinance had been issued "with a view to meet India's obligations under paragraphs 8 and 9 of Article 70 of the [TRIPS] Agreement". These statements made perfectly clear that India knew it had to make amendments to the Patents Act to implement its Article 70.8 mailbox obligations, and that if it did not do so it would be out of compliance with its TRIPS obligations.
- As a result of the rejection by Parliament of the Patents (Amendment) Bill 1995, Sections 5, 12 and 15 of the Patents Act 1970 remained in force and continued to require that applications drawn to

[5] The numbers are reflected in paragraph 2.11 above.

pharmaceutical and agricultural chemical products be rejected. In this case, Parliament must take action to modify this statutory system before an administrative system of the type described by India could have legal effect.

- India's claim that the Patents Act 1970 permitted it to grant special treatment to applications drawn to pharmaceutical and agricultural chemical products because such applications allegedly were different from applications drawn to other types of unpatentable subject matter listed in Section 3 of the Patents Act had no legal or regulatory basis. The process for review of applications that dealt with subject matter listed in Sections 3 and 5 was identical to the review of any other type of subject matter - once filed with the Patent Office, these applications were to be forwarded to examiners for a review of patentability. Section 15 of the Patents Act stated that an examiner shall identify unpatentable subject matter, regardless of whether it fell within the subject matter listed in Sections 3 and 5. In any event, this alleged distinction between applications drawn to different types of unpatentable subject matter was irrelevant. The matters before this Panel related only to the fact that Sections 5, 12 and 15 of the Patents Act required the Controller to forward applications drawn to pharmaceutical and agricultural chemical products to examiners and ultimately reject them for being drawn to unpatentable subject matter. Therefore, Indian law did not permit the Indian Patent Office to treat, on an *ad hoc* basis, one set of applications any differently; once filed with the Patent Office, applications must be forwarded to the examiners for a review of patentability. India’s attempt to claim that it was able to do so was contrary to the law, and any patents granted on applications filed under this informal, unrecognized system might be subject to legal challenge based on a claim that they were filed and processed in a manner inconsistent with the current law. In such a case, a court might find that the system for handling the applications was *ultra vires* and applications filed under that system could not result in the grant of a valid patent. A group of 11 patent experts convened by the Indian Government in 1994 to discuss whether India's laws must be amended to implement Article 70.8 and 70.9 had known this. They specifically had considered the option of implementing the mailbox system administratively and rejected it, finding it far too likely to invite legal challenges to any applications filed under such a system. They had concluded that amendments to the Patents Act to disable the automatic process for forwarding applications to examiners and ultimately rejecting those drawn to pharmaceutical and agricultural chemical inventions were necessary to establish a mailbox system in accordance with Article 70.8.

- India's claim that it had a mailbox system in place was called into question by the fact that it had never notified such a system to the Council for TRIPS, as required by the TRIPS Agreement. The only notification India had made to the Council for TRIPS was the notification setting forth the text of the Patents (Amendment) Ordinance 1994. This notification made it clear to all governments and potential applicants that the system established by the Ordinance created the basis for accepting mailbox applications. In other words, without this system mailbox applications would not be processed or have the legal status required by the TRIPS Agreement. India had never sent a follow-up notification to the Council for TRIPS stating that, notwithstanding the clear requirements of its law, applications for unpatentable subject matter would not be refused and would receive the status required by the TRIPS Agreement.
- India's claim that it had implemented a mailbox system was inconsistent with its obligations under Article 63 of the TRIPS Agreement to publish or make publicly available the specific terms and provisions of its system "*in such manner as to enable governments and right holders to become acquainted with them*" (*emphasis by the United States*). This claim had been made for the first time on 8 April 1997 in a confidential document that would not be circulated to WTO Members, let alone to the public. The private sector had no idea of the existence of this system and those people who, despite all indications to the contrary, had invested time and money in filing applications claiming pharmaceutical and agricultural chemical inventions, had no idea of the legal status of their applications. This could not under any criteria be considered an acceptable implementation of India's Article 70.8 obligation, particularly in light of the transparency obligations in the TRIPS Agreement, and should create a presumption that it did not have a legally valid system in place. Article 70.8 was clear in its requirement that an open and known process be developed for accepting applications for pharmaceutical and agricultural chemical product patents and granting those applications the proper legal status. The first element of this obligation was the establishment of a system that people knew about and knew how to use. A mailbox system that was unknown to the world was useless.

4.4 The United States also argued that the Indian system, by failing to give applications the legal status necessary to protect the expectations of applicants, did not fulfil the underlying purpose of Article 70.8:

- The principal purpose of the requirement to establish a mailbox system was to ensure that applications that were filed in the transitional period would not lose their novelty and, consequently, to allow mailbox applicants to preserve their ability to obtain patent

protection for pharmaceutical and agricultural chemical products in a Member taking advantage of some or all of the transitional period. The benefit provided by the system was such that, when patent protection for pharmaceutical and agricultural chemical products was established, such protection would also be available to persons who had filed applications during the transitional period based on the effective filing date of their applications. To this end, Article 70.8 did not require the examination and grant of the patent at the time of application; rather it required that a system be established to ensure that effective filing dates were granted in anticipation of the future benefit of eligibility for product patent protection based on those dates. A mailbox applicant must have the assurance that the application *would* lead to the grant of a patent if the conditions foreseen in paragraphs (b) and (c) of Article 70.8 were met (*emphasis by the United States*). In the case of India, which had indicated its intent to take advantage of the entire transitional period, this future benefit of the mailbox system would not be available to applicants until 2005. Once a filing date had been granted and applications were given the required legal status, the applicants would be able to factor this status into their operations and business decisions.

- The mailbox system, therefore, had a rationale common to many other WTO obligations, "namely to protect expectations of the contracting parties as to the competitive relationship between their products and those of other contracting parties"[6]. The *Superfund* report had established clearly the importance of "creat[ing] the predictability needed to plan future trade"[7]. Applicants must be able to anchor, during the transitional period, their right to receive a patent at the end of the transitional period so that they could plan their business operations accordingly (e.g., where to invest, where to move operations, whom to hire, which distribution networks to establish, etc.). As regards how applicants could make informed business decisions based on the right to seek a patent in the future, it should be borne in mind that, if the particular application proved unpatentable in other WTO Members during the transitional period, then this right might not be of much value, but that, on the contrary, if an application proved to be patentable everywhere else, then it would presumably be patentable in India at the end of the transitional period; thus, the current right to seek patent protection based on the appropriate filing date was of great strategic and

[6] Panel Report on "United States - Taxes on Petroleum and Certain Imported Substances" *(Superfund)*, adopted on 17 June 1987, BISD 34S/136, at 160.
[7] *Id*.

commercial value to applicants. Article 70.8 established the expectation that through the grant of this legal status to their applications, applicants would be able to establish their competitive position in the country at issue and factor this competitive position into their business plans.

- Despite India's claim that it had decided for the moment not to enforce the mandatory provisions of Sections 5, 12 and 15 of the Patents Act 1970 (which claim was unknown to other governments and the public), that "measure continues to be mandatory legislation which may influence the decisions of economic operators"[8]. The economic operators in the present case - potential patent applicants - had no confidence that a valid mailbox system had been established, and thus would not file mailbox-eligible applications in India. To paraphrase the *Beer II* panel, a non-enforcement of a mandatory law that violated a WTO obligation did not ensure that the obligation was not being broken.[9] Here, Sections 5, 12 and 15 mandated that applications for pharmaceutical and agricultural chemical product patents be forwarded to examiners, determined to be drawn to unpatentable subject matter, and rejected. Because India had failed to establish a fully functional mailbox system that granted mailbox applications the legal status required by the TRIPS Agreement as of their priority filing date, large numbers of applications that would have been filed were currently being withheld until India established such a system. Although India would not be obligated to grant patents on such applications meeting the criteria for patentability set out in Article 27 of the TRIPS Agreement as of their appropriate filing date until the end of the transitional period, it would not be sufficient that the legal changes necessary to provide an assurance of patentability were made at the end of the transitional period. Applicants must be given the legal assurance of a current right to the conditional future benefit that they would be able to seek patent protection on the basis of those criteria as of 1 January 1995, allowing them to plan their business operations accordingly as of that time. If a valid mailbox system were established today and an applicant who would have filed in July 1995 did so tomorrow and was assigned its July 1995 filing date, that applicant would be granted the right it must have under the TRIPS Agreement, but would have lost almost two years of shaping its business plan with the knowledge that it had an application with the legal status required by Article 70.8.

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[8] Panel Report on "United States - Measures Affecting Alcoholic and Malt Beverages" *(Beer II)*, adopted on 19 June 1992, BISD 39S/206, at 290.

[9] *Id*.

4.5 The United States further contended that the number of applications filed in India for pharmaceutical and agricultural chemical products was irrelevant.

- In light of India's clear violation of the mailbox provisions of the TRIPS Agreement, a showing of actual damage was not a prerequisite to a finding that India's failure to establish a TRIPS-consistent mailbox system was nullifying or impairing benefits under the TRIPS Agreement. Article 3.8 of the DSU provided that, where there was a violation of the obligations under a covered agreement, the action was considered *prima facie* to constitute a case of nullification or impairment. In any event, during 1995 and 1996 the United States Patent and Trademark Office had received over 50,000 such applications.[10]

4.6 In response, **India** argued that the mailbox system in place in India had a sound basis in Indian law and the United States' claims that changes in Indian law were necessary were unfounded.

- Under India's legal system there was more than one method by which it could satisfy its obligations under Article 70.8 of the TRIPS Agreement. This could be done by statute, subordinate legislation, such as rules or regulations, and even by administrative instructions and practice. Initially, India had chosen the legislative route to provide a means for receiving applications for pharmaceutical and agricultural chemical products and according priority to them. At present, India administratively continued to receive applications for pharmaceutical and agricultural chemical products and was deferring their examination. Such an administrative decision was permissible under Article 73(1)(a) of the Indian Constitution which provided that "the executive power of the Union shall extend to the matters to which Parliament has the power to make law". Under this constitutional provision, the Executive could act administratively in cases in which Parliament had legislative competence. In the case of providing the necessary "means" under Article 70.8 of the TRIPS Agreement, the relevant legislative power would be Entry 49 of List I or List III of the Seventh Schedule to the Constitution which read "Patents, inventions and designs; copyright; trade marks and merchandise marks". In this connection, two Supreme Court opinions showed that administrative action was an available method for the Executive, namely *J.R. Raghupathy vs*

[10] Following India's response reflected in paragraph 4.8 below, the United States added that, given the size and importance of the Indian market, it was clear that well over 1,339 of these applications would have been filed in India had India established and maintained a valid mailbox system since 1 January 1995.

State of Andra Pradesh and *Union of India vs H.R. Patankar and Others*.[11]

- Advancing evidence of the decision not to take up the applications for examination until 1 January 2005, India referred to a question that had been asked in Parliament about the action taken or proposed to be taken in respect of applications for pharmaceutical and agricultural chemical products (Unstarred Question No. 2601 asked by a Member of Parliament (Lok Sabha)) and the reply given by the Government in Parliament on 2 August 1996 that "the applications for patent will be taken up for examination after 1 January 2005 as per the WTO Agreement which had come into force on 1 January 1995".[12]
- There was no requirement that Parliament should recognize an administrative practice unless explicitly required by the Constitution or statute.
- With regard to the claim of the United States with respect to Article 123 of the Constitution, India stated that Article 123 was intended to enable legislation even when Parliament (either House or both Houses) was not in session. Therefore, the determination that the President was required to make under Article 123 was that it was necessary *to take immediate action* to promulgate an Ordinance despite Parliament not being in session and not that legislation was the only means of satisfying a particular obligation (*emphasis by India*).

4.7 As regards the arguments put forward by the United States regarding publication and notification, India made the following points:

- Article 70.8 merely stated that a means of filing must be provided. It did not state that it must be made "clear to the public" through "press releases or international news reports". Article 70.8 merely stipulated that Members provide a means by which applications could be filed and that "to provide" means "to supply for use"; it did not mean "make known to the world". The usefulness of a means of filing did not depend on it being made "known to the world"; it was sufficient that individual companies that wished to submit an application could obtain the necessary information from the relevant authorities. The fact that as many United States' companies as could be expected on the basis of past trends had in fact filed applications under the means provided by India underscored this point.

[11] All India Report 1988 SC 1681 and 1984 SC 1587.

[12] The full text of the question and answer, as submitted to the Panel by India, can be found at Annex 2 of this report.

- Article 70.8 did not state that the means of filing provided must be notified to the WTO. Besides, it should be stressed that India was continuing to apply the same means of filing that it had initially provided by virtue of the Ordinance and which had been given publicity and notified to the WTO. The transparency obligations were set out in Article 63, not in Article 70.8; moreover, these obligations related in this case to the Patents Act of 1970, which had been published, and not to the administrative arrangements made under that Act. In any event, as noted above, as a practical matter, adequate publicity had been given to the means of filing which had initially been provided by India and subsequently continued administratively.

4.8 As regards the number of patent applications filed, India had compared the number of applications made in India by United States' companies and found that the proportion between applications in the United States and applications in India by United States' companies in recent years had been around 0.7 per cent. The 363 applications received from United States' companies under the Indian filing system for pharmaceutical and agricultural chemical products concurred with that trend.

4.9 India further argued that whether the means of filing provided by India conformed to the requirements set out in Article 70.8 should be considered in accordance with the principle set out in Article 31 of the Vienna Convention on the Law of Treaties that a treaty shall be interpreted 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*" (*emphasis added by India*). In this connection, India noted that the Appellate Body had, consistently with Article 3 of the DSU, determined the meaning of the terms of the WTO agreements on the basis of the principles of interpretation of the said Vienna Convention.

The terms of the TRIPS Agreement

- India maintained its argument that WTO Members were free to determine the means by which patent applications could be filed and that Article 70.8(a) required Members to provide “a means” for filing without prescribing the choice of a particular method. In this context, it also reiterated that Indian law did not require a change in law to implement these obligations and reiterated that the transparency obligations in the TRIPS Agreement could not be found in Article 70.8 but in Article 63.

Context

- Subparagraph (a) of Article 70.8 must be read in conjunction with subparagraphs (b) and (c) of that provision and the transitional arrangements set out in Article 65. Subparagraph (a) of Article 70.8

obliged Members to provide a means of filing, i.e. the first step in a procedure leading to the grant of patent protection "as from the date of entry into force of the WTO Agreement", i.e. 1 January 1995. The obligation to apply the TRIPS Agreement's criteria of patentability and to provide patent protection when those criteria were met arose only "as of the date of application of this Agreement" (subparagraphs (b) and (c)). This date was defined in Article 65. Paragraph 4 of that Article made it clear that the relevant date of application in India of the provisions on product patents in respect of pharmaceutical and agricultural chemical products was 1 January 2005. Article 70.8 thus established two different obligations that became effective on two different dates: the obligation to provide a means of filing on 1 January 1995 and the obligation to accord patent protection on 1 January 2005. Given this context, subparagraph (a) of Article 70.8 could not be interpreted to establish already now the obligation to provide for the grant of patents in the year 2005. To give this interpretation to subparagraph (a) would effectively turn an obligation that arose at the end of a transitional period into a current obligation. The rationale of Articles 65 and 70 was clearly to permit developing country Members to postpone changes in their law that other Members were required to make under Article 27 of the TRIPS Agreement. It would be inconsistent with that rationale if Article 70.8(a) were interpreted to require the establishment of a procedure that *would* lead to the granting of a patent (*emphasis by India*). The consequence of such an interpretation would be that developing country Members would have to change their law to provide for the patentability of pharmaceutical and agricultural chemical products *before* having to grant patentability to other products (*emphasis by India*) - a consequence completely at odds with the purpose of Article 65.4 which was designed to extend for these products the period of transition beyond the normal five-year period.

- The fundamental purpose of the transitional arrangements was to enable developing countries to accept the WTO Agreement without having to change their patent law at the same time. There had been a recognition among the negotiators of the TRIPS Agreement of the fact that many developing countries still needed more time to build the domestic consensus necessary to accord patent protection, in particular for products where patentability was perceived to have certain adverse implications. The United States' complaint was an attempt to eliminate this function of the transitional arrangements of the TRIPS Agreement. During the first five years of the TRIPS Agreement, during which developing countries expected to be free from the need to make *any* legislative change,

they thus would have to make such changes in the most sensitive area (*emphasis by India*). The United States' interpretation of Articles 70.8 and 70.9, therefore, effectively turned transitional arrangements designed to create a special benefit in respect of pharmaceutical and agricultural chemical products into a source of an additional burden. To the knowledge of India, no developing country had acted under Article 70 on the basis of the interpretations proposed by the United States. Examination of the notifications submitted to the TRIPS Council under Article 63.2 of the TRIPS Agreement relating to Article 70.8 showed that not one of these notifications provided for a procedure to be established under which patents for pharmaceutical and agricultural chemical products would be made available as from 2005.

- Regarding the jurisprudence of the CONTRACTING PARTIES to GATT 1947 under which certain basic obligations under GATT, such as the national treatment obligation under its Article III and the general prohibition of quantitative restrictions under its Article XI, had been interpreted as obligations "protecting expectations" of Members as to the "competitive relationship" between their products and those of other Members and that a measure could therefore be inconsistent with these provisions even if it had not yet had a trade effect, India would not suggest that the Panel apply a different principle to the basic obligations set out in the TRIPS Agreement. However, it argued that, under the transitional arrangements of the TRIPS Agreement, the date of application of the provision to which the principle developed by the CONTRACTING PARTIES could be applied in this case, i.e. Article 27 of the TRIPS Agreement, had not yet arrived.

- It would have far-reaching implications if - for the sake of creating predictable conditions of competition - the many arrangements under the WTO agreements were interpreted to entail the immediate obligation to empower the executive authorities to carry out the obligations that would have to be observed at the end of the transitional period. To give a specific example, the Agreement on Textiles and Clothing permitted the maintenance of restrictions during a transitional period. Did that Agreement imply the obligation to change any domestic law mandatorily prescribing these restrictions? A provision creating the obligation to establish certain conditions of competition as from a specified date or as from the occurrence of a certain event could not be interpreted as entailing the obligation to provide for such conditions of competition in the domestic law in advance of that date or event. The CONTRACTING PARTIES to GATT 1947 had never used the concept of conditions of competition to advance the effective date of application of an obligation.

Object and Purpose

- The purpose of subparagraph (a) of Article 70.8 emerged clearly from subparagraphs (b) and (c) of that provision and Article 70.9. According to subparagraphs (b) and (c), developing country Members must grant patents to pharmaceutical and agricultural chemical products for a period of at least 20 years "counted from the filing date" as if the criteria for patentability laid down in the TRIPS Agreement were being applied on "the date of filing". Furthermore, according to Article 70.9 only products for which a patent application had been filed in accordance with Article 70.8(a) were eligible for the grant of exclusive marketing rights. The purpose of subparagraph (a) was thus not to create a procedure ensuring that pharmaceutical and agricultural chemical products *would* become patentable or *would* be given exclusive marketing rights, but rather to ensure that each patent applicant obtained a date of filing on the basis of which patent protection *could* be granted as from the date on which Article 27 applied and that exclusive marketing rights *could* be granted to products at the point at which they were eligible for such rights (*emphasis by India*).

4.10 The **United States** commented as follows on the evidential material concerning the decision to postpone the referral of patent applications for pharmaceutical and agricultural chemical products by the Controller for their examination and the two Supreme Court opinions concerning Article 73(1)(a) of the Indian Constitution that had been advanced by India:

- The only evidence that India could muster to show that it had made a public decision to establish an administrative mailbox system was a question and answer in the Lok Sabha that apparently had taken place on 2 August 1996. However, it was interesting to note that the answer to the question: (a) did not state that the applications that had been filed had been granted the proper legal status; (b) had apparently never been made known to the public (let alone notified to other WTO Members through the Council for TRIPS); and (c) was of no apparent legal effect.
- The opinions provided by India clarified that amendments to the Patents Act were necessary to establish a mailbox system. They did not support India's assertion that it could create a mailbox system through administrative guidance. In *Union of India vs. H.R. Patankar and Others*, the Supreme Court had held that "if there are no statutory rules in force.... or even if there are statutory rules but they are silent on any particular subject, it is competent to the Government [to make appropriate rules] to fill in the lacuna in the

statutory rules"[13]. Rather than an instance of statutory silence or a gap in statutory rules, the present case concerned a specific statutory provision that directed the Controller to forward applications to the examiners, where applications drawn to pharmaceutical or agricultural chemical products would be identified as being drawn to unpatentable subject matter and ultimately rejected. By implication, *Union of India* stood for the proposition that the Government was not authorized to issue administrative guidance that was contrary to the letter of the law. In *J.R. Raghupathy vs. State of A.P.*, the Supreme Court had addressed the issue of the ability of the High Court to review the Government's exercise of discretion conferred upon it, even when that exercise of discretion was contrary to its own guidelines. Citing prior authorities, the Court had held that administrative guidelines had no statutory force and conferred no right on any citizen to complain that they were not being met.[14] Thus, even if India had issued instructions to its Controller to ignore the mandatory nature of Article 12(1) of the Patents Act 1970, which the United States doubted, those instructions would have no legal effect and a court would be unable to compel the Patent Office to follow them. The *J.R. Raghupathy* case also stood for the proposition that, where a statute was to be implemented by a designated authority, Parliament "must have assumed that the designated authority would act properly and responsibly, with a view to doing what was best in the public interest and most consistent with the policy of the statute"[15]. This language did not provide any support for the Indian Government's assertion that it was permitted to act administratively in a manner that thwarted or circumvented clear and direct statutory instruction to take a particular action. As a result, the Indian patent experts referred to earlier had been correct in their conclusion that the Patents Act 1970 must be amended if India was to fully implement the mailbox obligations under Article 70.8 of the TRIPS Agreement.

4.11 The United States also responded that India could not persuasively claim that individual companies had access to the necessary information. India apparently acknowledged that a mailbox system that was totally unknown to the public was of no value, but claimed that "it is sufficient that individual companies that wish to submit an application can obtain the necessary information from the relevant authorities". Even if India's assertion of what constituted fulfilment of WTO obligations were correct (which it was not), India had not even met this low standard. India repeatedly had made clear to WTO Members, its own nationals, and the rest of

[13] Paragraph 4 of the opinion.
[14] Paragraphs 18 and 30 of the opinion.
[15] Paragraph 29 of the opinion.

the world that it would not have a valid mailbox system in place until it had amended its patent law. The United States Government had attempted for over two years to clarify the situation and had been either ignored or led to believe that India did not have a valid mailbox system in place. There was no reason to expect individual companies to receive any better treatment or information than the United States Government. Individual companies that had filed or would have filed pharmaceutical and agricultural chemical product patent applications in India continued to believe that India did not have a TRIPS-consistent mailbox system in place.[16]

4.12 **India** maintained that mailbox applications had a proper legal status under Indian law and that the filing system put in place by India had the necessary support from the provisions of the Patents Act 1970 and the provisions of Article 73 of the Indian Constitution.[17]

- The written answer from the Government to Unstarred Question No. 2601 in the Lok Sabha on 2 August 1996 put beyond any doubt that the applications received had a proper legal status. The Government had stated in this written answer that until 15 July 1996 as many as 893 applications had been received from Indian as well as foreign companies in the fields of drugs and medicine. It had further been stated that these applications would be taken up for examination after 1 January 2005 as per the WTO Agreement which had come into force on 1 January 1995. It was to be borne in mind that the Indian legal system was based upon common law systems and that any statement, more particularly written statement, made in any House of the central legislature, by the Minister who was an authorized functionary of the Government, put that Government under the obligation of the common law doctrine of "estoppel", in the sense that the Government at no stage could perform any act in contravention of the position already taken under that statement.
- As regards the United States' assertion that the answer to Unstarred Question No. 2601 had apparently never been made known to the public, all answers to questions put by Members of Parliament were given in writing and were laid on the table of the relevant House and circulated amongst all Members of that House. The national and international electronic, print and other media had open access to the answers given in the House and widely reported them. Questions and answers given were reported in the Reporters pub-

[16] In this regard, the United States submitted to the Panel a copy of a letter from Dr. Harvey E. Bale, Jr., of the US Pharmaceutical Research and Manufacturers Association, to the United States Special Trade Representative, Ambassador Barshefsky (see Annex 3 of this report).

[17] India also made a number of arguments relevant to the issues concerning Article 70.8 in the context of Article 63.

lished by the secretariat of the respective House and formed a permanent printed record which was accessible to the public.

- Regarding the United States' assertions based on the two Indian Supreme Court opinions, India stated that it was a settled proposition in Indian law that the executive power of the central government under Article 73 was co-extensive with the legislative power of the Parliament. In other words, it extended over the whole of the territory of India with respect to the matters enumerated in List I (including Entry 49 "Patents, inventions and designs; copyright, trademarks and merchandise marks") and List III of the Seventh Schedule to the Indian Constitution. In *J.R. Raghupathy vs State of Andra Pradesh*, the Supreme Court had stated that the executive powers of the Union under Article 73 were much wider than the prerogative powers in England. The provisions of Article 73 of the Constitution as interpreted in *Union of India vs H.R. Patankar and Others* and *J.R Raghupathy vs State of Andra Pradesh* were in the nature of support mechanisms for the legislative provisions in the Patents Act 1970 which formed the basis for the current filing system. The United States had quoted the *J.R.Raghupathy* opinion out of context. The essence of the Supreme Court opinion was that if there were certain deviations from the guidelines set for in-house management of the government departments, the courts did not need to interfere. However, where administrative instructions impinged upon the rights of persons, there was no way out and the courts were bound to come into active play. The explicit position taken by the Supreme Court in *Union of India vs H.R. Patankar* made it clear that even if there were any statutory rules, but they were silent on any particular subject, the Government was competent to fill in the lacunae in the statutory rules.

(b) The United States' Claim that Article 70.8 of the TRIPS Agreement Requires India to Ensure that Persons who Filed or Would Have Filed Mailbox Applications Had the Mailbox Been in Place on Time and Maintained Can File Such Applications and Receive the Filing Date b by Would Have Received

4.13 The **United States** argued that the number of applications filed in India for pharmaceutical and agricultural chemical products was far less than that which would have been filed had a valid system been in place. Any applications filed subsequent to the expiration of the Patents (Amendment) Ordinance 1994 had been filed by companies willing to take the risk that they would have the legal status required by the TRIPS Agreement. Many other applicants who would have filed had a system been in place had not filed. Under a mailbox system that had been established by 1 January 1995 and subsequently maintained in accordance with Article 70.8 of the TRIPS Agreement, ensuring that applications were assigned their effec-

tive filing date was relatively straightforward: applications were simply assigned an effective filing date of either (a) the date they had been filed with the Member, or (b) where that Member granted priority filing benefits, the priority filing date. Where, as in the case of India, a Member had failed to establish a mailbox system by 1 January 1995 and subsequently maintain it, additional steps might be necessary to ensure that applicants were assigned an effective filing date that reflected the filing date they would have received had a mailbox application system been in place.

4.14 **India** responded that the United States' request for a ruling on the retroactive allocation of filing dates was moot and inconsistent with Article 19.1 of the DSU. The administrative mechanisms which India had put into place did permit the filing of applications and enabled the patent offices to assign a filing date to each application. A substantial number of applications had been filed under these procedures. The situation that would make the finding requested by the United States meaningful therefore did not exist. The finding requested by the United States did not concern the consistency of a measure actually taken by India *but corrective actions that India allegedly would need to take subsequent to the violation of Article 70.8 of the TRIPS Agreement claimed by the United States* (*emphasis by India*). The request thus did not relate to the question of *whether* India had failed to observe its obligations but to the question of *how* India should bring itself into conformity with its obligations, in particular the steps India should take to eliminate the legal consequences of an inconsistency alleged by the United States (*emphasis by India*). The scope of the Panel's examination should remain limited to the allegation of the United States that India had not fulfilled its obligation under Article 70.8 of the TRIPS Agreement. The Panel could not and should not get into hypothetical questions as to how India should deal with the situation in the event that the United States' allegation was found to be substantiated. This was a matter entirely within the competence of the Member concerned, i.e. the Indian authorities. Article 19.1 of the DSU did not permit the Panel to make a ruling on how India should eliminate the consequences of the alleged violation of Article 70.8 of the TRIPS Agreement.

4.15 The **United States** rebutted that it was not seeking a specific remedy in this matter, but a determination by this Panel that India had failed to fulfil the Article 70.8 obligation to ensure that transitional period applicants would be able to obtain patent protection when it became available in India for pharmaceutical and agricultural chemical products, and to establish a means to ensure that applications that were filed in this transitional period would not lose their novelty. Although the number of these applicants was irrelevant since, in light of India's clear violation of the mailbox provisions of the TRIPS Agreement, a showing of actual damage was not a prerequisite to a finding that India's failure to establish a TRIPS-consistent mailbox system was nullifying or impairing benefits under the TRIPS Agreement[18],

[18] Article 3.8 of the DSU provides that where there is a violation of the obligations under a covered Agreement, the action is considered *prima facie* to constitute a case of nullification or impairment.

evidence of the fact that additional applications would have been filed had a legally valid mailbox system been in place on time could be found in the letter from Dr. Harvey E. Bale, Jr.[19,20]

Article 63

4.16 At the first substantive meeting with the parties, the **United States** stated that it had been surprised by India's statement in its first written submission to the Panel that it had established a system for the filing of applications. In response to that statement, the United States said that it was of the opinion that the administrative instructions in question did not meet the requirements of Article 70.8 but, if the Panel were to find that they did constitute a valid mailbox system in the context of Article 70.8, would argue, in the alternative, that India had failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement. In support of that alternative claim, the United States made the arguments outlined in the last two indents of paragraph 4.3 above.

4.17 India disputed the United States' requested finding on Article 63 on procedural and substantive grounds.

(a) Procedural Grounds

4.18 **India** argued that the United States' request for a finding that India had failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement had been made for the first time in its oral statement at the first meeting of the Panel and argued that to submit such an additional request for a finding after the first written submission constituted an unacceptable procedural scheme.

- The Panel's terms of reference did not cover the United States' Article 63 claim. According to Article 7.1 of the DSU, the mandate of the Panel was to examine the matter referred to the DSB in the document in which the United States had requested the establishment of a panel in accordance with Article 6 of the DSU, i.e. document WT/DS50/4. Neither that request nor, earlier, the United States' request for consultations had raised the issue of transparency or compliance with Article 63 of the TRIPS Agreement. In these requests, the United States had summarized the issues as follows: "The legal regime in India currently does not make patent protection available for inventions as specified in Article 27 of the TRIPS Agreement or provide systems that conform to obligations of the TRIPS Agreement regarding the acceptance of applications and the grant of exclusive marketing rights. As a result, India's le-

[19] The letter referred to above in paragraph 4.11 and footnote 16.

[20] In this regard, reference was also made to the arguments reflected above in paragraph 4.4, third indent.

gal regime appears to be inconsistent with the obligations of the TRIPS Agreement, including but not necessarily limited to Articles 27, 65 and 70".

- According to Article 6.2 of the DSU, the request for the establishment of a panel must meet two central requirements: it must "identify the specific measures at issue" and "provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly". The United States' request did not identify lack of transparency as a specific measure at issue. The vague reference to "obligations of the TRIPS Agreement, including but not necessarily limited to" is not sufficient to present the problem clearly. The recent WTO Panel on *European Communities - Regime for the Importation, Sale and Distribution of Bananas*[21] had concluded in a comparable situation that "reference to a WTO Agreement without mentioning any provisions or to unidentified 'other' provisions are too vague to meet the standards of Article 6.2 of the DSU".

4.19 The **United States** responded that its Article 63 claim was inexorably linked to the description of the "problem" it had with the Indian failure to implement Articles 70.8 and 70.9 of the TRIPS Agreement as articulated in its request for consultations and the establishment of a panel. It advanced the following arguments:

- Under the unusual and unfortunate circumstances of this case - where India had indicated publicly and during consultations that it had no mailbox system in place and refused to answer United States' questions regarding whether such a system existed - it would be appropriate for the Panel to provide the United States with an opportunity to identify specific legal claims regarding transparency during the first substantive meeting. The only reason that Article 63 had not been explicitly referenced previously was that India had maintained for two years that it had no mailbox system in place and first claimed that it had a mailbox system in place in its first written submission to the Panel.
- The basis for the ruling of the *Bananas* Panel was that panel procedures should not operate so as to permit surprise and prejudice of a party's interests. That concept was applicable here, where the interests of the United States would be unfairly disadvantaged if the Panel did not consider, in the alternative, its Article 63 claim.
    (i) The *Bananas* Panel had found that because of the way the panel request had been written "it is not possible at the panel request stage, even in the broadest generic terms, to describe what legal 'problem' is asserted. While a reference

[21] The report of the *Bananas* Panel was issued on 22 May 1997 and circulated as document WT/DS27/R.

to a specific provision of a specific agreement may not be essential if the problem or legal claim is otherwise clearly described, in the absence of some description of the problem, a mere reference to an entire argument or simply to 'other' unspecified agreements or provisions is inadequate under the terms of Article 6.2".[22] The Panel therefore had indicated that where a "problem" had been clearly described, a reference to a specific provision in a specific agreement might not be necessary. In this case, the United States had made abundantly clear in its panel request and in its first written submission to the Panel that the "problem" was India's failure to implement a mailbox system that (a) allowed applicants to submit applications and (b) granted those applications the required legal status. Assuming that India had a system in place, its failure to make that system known to WTO Members was necessarily part of this "problem". This transparency issue could not be separated from the central "problem" of not establishing a useful mailbox system, i.e. a system enabling applicants to know how and where to submit applications.

(ii) India could not realistically claim surprise, particularly because its own actions had delayed full consideration of this issue. The panel on *Brazil - Measures Affecting Desiccated Coconut* had noted regarding Brazil's refusal to consult that such a refusal was "a matter which this Panel views with the utmost seriousness. Compliance with the fundamental obligation of WTO Members to enter into consultations where a request is made under the DSU is vital to the operation of the dispute settlement system..... pursuant to Article 4.6 of the DSU, consultations are 'without prejudice to the rights of any Member in any further proceedings'. In our view, these provisions make clear that Members' duty to consult is absolute, and is not susceptible to the prior imposition of any terms and conditions by a Member".[23] It was no less serious a matter when a Member refused in consultations to provide information of which it was aware, or gave misleading information in consultations. The Panel could and must respond to this situation through a simple application of the concept of estoppel: where a party had actively refused to respond concerning information within its exclusive control, or had given misleading information in con-

[22] *Banana* Panel Report at para. 7.30.
[23] WT/DS22/R, para. 287.

> sultations, that party should be held to its earlier representations and estopped from contradicting them at a later stage in the proceeding. At the very least, the other party should be able to present arguments on that information in the ongoing proceeding. Any contrary result would act as an incentive for parties to be as uninformative as possible in consultations and would lead to a breakdown in the WTO dispute settlement process.

4.20 **India** maintained that the United States had failed to make its claim based on Article 63 within the time the procedures permitted and made the following further points:

- It was incorrect that India had only informed the United States of the mailbox system currently in place in India in its first written submission to the Panel. The United States had been informed about the means of filing in India during the consultations held on 27 July 1996 with the United States and the European Communities. The internal written record of the Indian Government on the consultations held between India and the United States and the European Communities on 27 July 1996 in Geneva indicated that the representative of India had given the following information:

  > "In the meanwhile, product patent applications in the pharmaceutical and agrochemical sector were being received under the provisions of the Patents Act of 1970. About 1,000 applications had been received so far, and are being preserved in a manner which will facilitate establishing the necessary queuing order as and when the necessary legislation is in place. The Patents Act 1970 has provided the necessary legal scope for receipt of applications for product patents even in sectors like pharmaceuticals and agrochemicals though the Patents Act 1970 does not provide for the processing of such applications or for grant of product patents in those sectors."

  The Indian record of the consultations further indicated that the United States had responded to this information as follows:

  > "The US appreciated the update given by India. It was helpful to know that around 1,000 applications had been filed."

  If the United States had been of the view that the means of filing in question should have been published in accordance with Article 63 of the TRIPS Agreement, notwithstanding the fact that the Patents Act of 1970 had been published, it could therefore easily have identified this issue in the request for the establishment of a panel.

- Under the DSU, the complainant could not expand the scope of its factual and legal claims after having made its first submission. It

was a well-established practice that the first written submission of the complainant incorporated all its legal claims and all the requests for findings and recommendations it wished to submit to the Panel. This practice was reflected in paragraphs 5 and 7 of the standard Working Procedures in Appendix 3 to the DSU which stated that "At the first meeting with the parties, the Panel shall ask the party which has brought the complaint to present its case" and that "Formal rebuttals shall be made at a second substantive meeting of the Panel". It followed from these procedures that the written submissions for the first meeting must constitute the full presentation of the case by the complainant. An indirect reflection of this principle was Article 10.3 of the DSU which stated that "third parties shall receive the submissions of the parties to the dispute to the first meeting of the Panel". This provision had obviously been drafted on the assumption that the first submission informed the third parties fully of the complainant's case. However, not only third parties' rights would be curtailed if complainants could introduce new claims and requests after the first submission, but also the rights of the respondent. This had been recognized in the recent report of the Panel on *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, which had ruled that:

> "For the purposes of determining whether a Complainant in this matter has made a claim, we have examined its *first written submission*, as we consider that document *determines the claims made by a complaining party. To allow the assertion of additional claims after that point would be unfair to the respondent*..... In our view, the failure to make a claim in the first submission cannot be remedied by later submissions....." (*emphasis added by India*)[24]

The extremely tight timetables for panel work set out in the DSU entailed the need for complainants to carefully prepare their case in advance of the proceedings and incorporate in their first submission all their factual and legal claims. According to paragraph 12 of the Working Procedures annexed to the DSU, five to eight weeks normally lapsed between the receipt of the first written submission of the complainant and the receipt of the written rebuttals. Thus, while the complainant could prepare its case without any time constraint, the respondent normally had only five to eight weeks to prepare its rebuttal, which created a significant imbalance between complainants and respondents. According to the Working Procedures, only two to three weeks normally lapsed between the first meeting of the Panel and the receipt

[24] Paragraph 7.57 of the report.

of the written rebuttals. If the complainant were permitted to make new claims at the time of the first substantive meeting, the time available to prepare the rebuttal would therefore be reduced by more than half and the existing imbalance would be exacerbated to the point of effectively curtailing the respondent's right to be given sufficient time for the preparation of its rebuttal - a right which Article 12.10 of the DSU specifically accorded to developing countries.

4.21 The **United States** responded by denying that India had told it during the consultations on this matter that it had a valid mailbox system in place and remained convinced that India did not have a valid system in place. It also argued that India had been given a reasonable opportunity to respond to the United States' transparency claim under Article 63.

- The United States had no information as to what might be in an Indian staffer's notes from the consultations held with India, but could state, as it had throughout this proceeding, that until India's first written submission to the Panel, the Indian Government had never stated that it had established a valid mailbox system. Had the Indian Government made this assertion earlier, the United States would necessarily have included a reference to Article 63 of the TRIPS Agreement in its panel request. In light of this surprise, equity demanded that the Panel be able to take up the transparency issue, in the alternative.
- India had been given three opportunities to respond to the United States' alternative transparency claim under TRIPS Article 63[25], and its last written submission on this issue had been submitted seven weeks after the first substantive meeting of the Panel with the parties. India had therefore had a reasonable opportunity to respond to this issue. Furthermore, India could not claim prejudice to third parties as a basis for refusing a claim under Article 63. Article 10.3 of the DSU stated that "[t]hird parties shall receive the submissions of the parties to the dispute to the first meeting of the Panel". The rules of the DSU provided for third parties no more than the opportunity to present views to a panel. Dispute settlement was conducted first and foremost for the benefit of the parties to the dispute, not for the benefit of third parties or possible third parties.

(b) Substantive Grounds

4.22 **India** also disputed the United States' claims regarding the transparency obligations under Article 63 on the basis of substantive grounds. It recalled the ar-

[25] Reference was made to India's second written submission to the Panel, in its oral presentation at the second Panel meeting and in its third written submission to the Panel.

guments summarised in paragraph 4.7 and 4.12 above and put forward the following additional arguments:

- Article 63 applied to developing countries only as of 1 January 2000. According to Article 65.2 of the TRIPS Agreement, developing countries were entitled to delay up to 1 January 2000 the date of application of the TRIPS Agreement except for its Articles 3, 4 and 5. Consequently, the provisions of Article 63 established obligations applicable to India only as of 1 January 2000. It was true that the minutes of meetings of the Council for TRIPS made reference to a "Working Hypothesis" according to which national laws and regulations would be notified as of the time that the corresponding substantive obligation applied[26], but this "Working Hypothesis" did not reflect a common understanding among Members on their obligations under the TRIPS Agreement. It had been elaborated because the differences of interpretation among Members on the scope of the transparency obligations during the transitional period could not be overcome. At the meeting of the Council for TRIPS of 21 September 1995, the Chairman had noted the existence of the "Working Hypothesis" but then correctly had stated that the "basic differences of interpretation had remained".[27] An informal arrangement of this type did not establish obligations binding under international law and could therefore not modify rights or obligations under a WTO agreement. The legal situation under Article 63 had not been changed as a result of the elaboration of the "Working Hypothesis".
- As regards paragraph 1 of Article 63, which was the only paragraph the United States had referred to at the first substantive meeting of the Panel with the parties while not having specified any paragraph in its written submission, India took the view that the law on which India had based its means of filing had been published. This means of filing had been established on the basis of the Patents Act 1970 which, like all other acts of Parliament, had been published in the Gazette of India. According to Article 63.1, only "laws and regulations, and final judicial decisions and administrative rulings of general application" had to be published. The decision of India to continue to receive applications for pharmaceutical and agricultural chemical product patents under the Patents Act was an administrative measure of a kind that did not need to be published under Article 63.1. Under that provision, only the law on

[26] IP/C/M/3, p. 8.
[27] *Id*.

which this measure was based was subject to the publication requirement.

4.23 The **United States** responded that India's claims were either inaccurate or irrelevant, for the following reasons:

- It was not correct that Article 63 applied to developing countries only as of 1 January 2000. The Council for TRIPS had decided on 21 November 1995 that "[a]s of the time that a Member is obliged to start applying a provision of the TRIPS Agreement, the corresponding laws and regulations shall be notified without delay (normally within 30 days, except where otherwise provided in the TRIPS Council)".[28] The TRIPS Council had also decided that amendments to laws and regulations shall be notified within 30 days where no translation is required.[29] India had participated in these decisions and had not objected to them. In fact, India had already notified the Patents (Amendment) Ordinance 1994 on 6 March 1995 well before this clarifying decision had been issued by the TRIPS Council. India was well aware of the obligation to notify any amendments to its laws or regulations regarding Article 70.8 in accordance with this decision, but had failed to do so. India's claim that it did not have to do so because its mailbox system had been created through administrative guidance was of no merit, because administrative guidance could not be used to overcome the express provisions in the Patents Act 1970 requiring the rejection of mailbox-type applications.

4.24 In response, **India** reiterated that the method of filing currently in place in India created all the conditions necessary to enable the Government of India to determine the date of filing of patent applications at the time when the products must be made patentable and, while referring to its earlier statement that this apparently also had been the conviction of the companies that had submitted 1,339 applications between 1 January 1995 and 15 February 1997, it stressed that the trend and pace of filing applications established initially had been maintained. This was a clear indication of the fact that the companies concerned did not experience any difficulty or anticipate any difficulty in the matter of filing of their applications.

Article 70.9

4.25 It was not in dispute between the parties that India was subject to the provisions of Article 70.9, given that it did not provide patent protection for pharmaceutical and agricultural chemical products as of 1 January 1995. Nor was it disputed that the Indian executive authorities did not have the legal powers under present

[28] Paragraph 2.1 of document IP/C/2.
[29] *Id*. at paragraph 2.2.

Indian law to grant exclusive marketing rights and that such legal powers would have to be obtained in order to grant exclusive marketing rights in accordance with the obligations under Article 70.9. The main issues between the parties concerned the questions of the timing of when the Indian Executive needed to have the legal authority to implement the provisions of Article 70.9 and of the scope of the term "exclusive marketing rights" as stipulated in Article 70.9.

(a) Timing

4.26 The **United States** contended that, because no formal system existed today in India governing the grant of exclusive marketing rights pursuant to Article 70.9 and this requirement was applicable in India from 1 January 1995, India was not in conformity with its obligations under Article 70.9.

4.27 **India** responded by arguing that it had not denied any requests for exclusive marketing rights and that Article 70.9 did not require WTO Members to make exclusive marketing rights available in their law prior to the events that triggered the obligation to grant an exclusive marketing right. According to the *terms* of Article 70.9 as well as its *context* and *object and purpose*, exclusive marketing rights must be accorded to specific products when these were eligible for such rights (*emphasis by India*). As with Article 70.8, India based its argumentation on the principle set out in Article 31 of the Vienna Convention on the Law of Treaties.[30]

The terms of the TRIPS Agreement

- According to Article 70.9, exclusive marketing rights must be granted by India to a pharmaceutical or agricultural chemical product for which a patent application had been made only after the product met the following conditions:
  - (a) A patent *application* had been filed in respect of that product in another Member of the WTO *after 1 January 1995*.
  - (b) The other Member of the WTO had *granted the patent*.
  - (c) The *other Member had approved the marketing* of the product.
  - (d) *India had approved the marketing* of the product.

  (emphases above by India)
- The last step in the procedures prior to eligibility - marketing approval in the Member not according patentability - was a step controlled by the Member that must subsequently grant exclusive marketing rights or patentability. It was consequently not an abstract category of products that was eligible for exclusive marketing

[30] See paragraph 4.9 above.

rights under Article 70.9; the individual products that were eligible would be known before the duty to accord exclusive marketing rights arose. Article 70.9 was a transitional provision the application of which was triggered by specified future events.[31]

- The United States had not presented evidence showing that all the above-mentioned events had occurred with respect to a particular pharmaceutical or agricultural chemical product. The principal products covered by Article 70 were drugs and medicines. It took considerable time to obtain a patent for such products and then to obtain the marketing approval first in the country of origin and then in the country in which exclusive marketing rights were sought under Article 70.9. So far, no request for exclusive marketing rights had been received by the Government of India. There was, therefore, no question of India having denied exclusive marketing rights to any product entitled to such rights under Article 70.9 of the TRIPS Agreement.
- According to the text of Article 70.9, an exclusive marketing right must be granted for a pharmaceutical or agricultural chemical product only "until a product patent is granted or rejected in that Member". The terms of Article 70.9 thus explicitly accorded developing country Members the right to choose between the grant of patentability and the grant of exclusive marketing rights with respect to each pharmaceutical or agricultural chemical product for which a patent application had been made. It would be logically inconsistent with this right to opt out of the obligation to grant exclusive marketing rights if Article 70.9 were interpreted to oblige Members to provide in their legislation for the general availability of exclusive marketing rights as from 1 January 1995.

Context

- The obligation under Article 70.9 needed to be distinguished from those under other provisions of the TRIPS Agreement. The TRIPS Agreement made a clear distinction between obligations to change the domestic law governing intellectual property rights and obligations to take, or refrain from taking, specific measures in relation to intellectual property rights. For instance, according to Article 27 of the TRIPS Agreement "*patents shall be available* for any invention". The obligation created by this provision was thus not merely to take a specific measure but to change the law to make future measures possible. The same applied to Article 42 of the TRIPS

[31] India's views on the fundamental purpose of the transitional provisions concerning Article 70.8 and 70.9 are reflected in paragraph 4.9 above.

Agreement, according to which "Members shall *make available to right holders civil judicial procedures* concerning the enforcement of any intellectual property right covered by this Agreement". Articles 27 and 42 of the TRIPS Agreement thus set out requirements to change the domestic law to create legal opportunities for inventors and right holders. These provisions were violated when the Member failed to adjust its law to create those opportunities and complaints could therefore be brought *before* the opportunity had actually been denied to a particular inventor or right holder. Most of the basic provisions of the TRIPS Agreement were of this nature, such as Articles 26.1, 28.1, 32, 36, 39.2 and 41.1. Articles 45, 46, 47, 48, 50, 53 and 56 stated that the competent authorities "*shall have the authority*" to perform certain acts. In the case of all these provisions, the drafters thus chose terms that made it explicit that the domestic law of Members must give certain persons and authorities defined rights. If the drafters had meant to do so in the case of exclusive marketing rights, they would therefore have chosen terms such as "the competent authorities shall have the authority to grant exclusive marketing rights" or "exclusive marketing rights shall be available". Instead, they had chosen terms clearly indicating that particular products shall be granted such rights after they met certain conditions. Article 70.9 of the TRIPS Agreement, therefore, did not fall into this category of norms. (*emphases above by India*)

Object and Purpose

- Article 70.9 formed part of the transitional arrangements for developing countries and its object and purpose could therefore only be ascertained in the light of these arrangements.[32] According to Article 70.9, an exclusive marketing right had to be granted only for a maximum period of five years. This five-year period corresponded to the five-year period by which developing country Members might, according to Article 65.4, delay the application of the provisions on product patents in areas of technology not protectable on 1 January 1996, i.e. the period between 1 January 2000 and 1 January 2005. The purpose of Article 70.9 was thus to give inventors of pharmaceutical and agricultural chemical products the economic privilege of an exclusive marketing right for the five-year period preceding 1 January 2005 if their products were denied patentability even beyond the normal five-year transitional period for

[32] India's views on the fundamental purpose of the transitional provisions concerning Article 70.8 and 70.9 are reflected in paragraph 4.9 above.

developing countries. It would be completely contrary to this purpose to interpret Article 70.9 as giving rise to obligations before 1 January 2000. That Article 70.9 essentially related to events that the drafters expected to take place during the period covered by Article 65.4 became obvious when one analysed the practical operation of Article 70.9. In order to be eligible for the grant of an exclusive marketing right, a United States' inventor must have filed a patent application in the United States after 1 January 1995 and have been granted the patent in the United States and marketing approval in both the United States and in India. Common sense and practical experience indicated that all these steps took a long time and normally the products in question would not get on the market in a developing country before the expiry of the ten-year transitional period. The provision had been made for the grant of exclusive marketing rights of up to five years only to tide over the gap between the obtaining of marketing approval and the grant of patent protection for the product in question in a developing country benefiting from the ten-year transitional period, so that inventions that met the criteria for patentability on or after the date of entry into force of the Agreement would become eligible for protection in such countries by the time that protection became of commercial significance, either by the grant of a patent after the expiration of the ten-year period or by an exclusive marketing right for products getting marketing approval before that time. Commentators had confirmed these practical implications.[33]

- That the object and purpose of Article 70.9 were not to oblige developing countries to make exclusive marketing rights available immediately upon the entry into force of the WTO Agreement but to tide over the gap between marketing approval and patentability during the five years preceding the end of the ten-year transitional period could also be deduced from commercial realities. In general, it simply made no commercial sense to obtain an exclusive marketing right for a five-year period unless that period was immediately followed by the grant of the exclusive rights to be conferred on patent owners under Article 28 of the TRIPS Agreement. If the inventor of a pharmaceutical product obtained an exclusive marketing right in 1997 and made his product known and widely used

[33] Reference was made to Adrian Otten, "Improving the Playing Field for Exports: The Agreements on Intellectual Property, Investment Measures and Government Procurement" in *GATT-Uruguay Round: Nine Papers*, Bern: Verlag Staempli, 1995, pp. 79-80; Marco C.E.J. Bronckers, "The Impact of TRIPS: Intellectual Property Protection in Developing Countries", *Common Market Law Review*, 1994, Vol. 31, p.1245; Adrian Otten and Hannu Wager, "Compliance with TRIPS: The Emerging World View", *Vanderbilt Journal of Transnational Law*, 1996, Vol. 29, p.408.

in India, his competitors could enter the market in the year 2002 and free-ride on the inventor's marketing efforts for three years. Only in the year 2005 could the inventor again enjoy the exclusive rights of a patent owner. Thus, even if an inventor had succeeded in obtaining a patent in the United States and marketing approval in the United States and India within a period of less than five years, he would nevertheless in most situations have a commercial interest to request exclusive marketing rights only in the year 2000 so as to ensure a seamless transition from exclusive marketing rights to the exclusive rights of a patent owner. The economic purposes of Article 70.9 would thus not be furthered if it were interpreted to give rise to obligations before 1 January 2000.

- Article 70.9 obliged a Member to grant exclusive marketing rights for a particular product only "until a product patent is granted or rejected in that Member". Under Article 70.9 developing countries were thus explicitly given the right to choose between the grant of exclusive marketing rights and the grant of patentability. The economic impact of the grant of an exclusive marketing right was very similar to that of the grant of the exclusive rights to be conferred under Article 28 on the owners of patents. Moreover, exclusive marketing rights must be granted even for those products for which a patent could be rejected consistently with the TRIPS Agreement. The function of Article 70.9 was thus not only to create rights for holders of patents in other Members but also to give developing country Members an incentive to opt for patentability. Under the United States' interpretation the provision could not fulfil this function.
- According to the United States' interpretation of Article 70.9, developing countries would be obliged to take a decision on the patentability of pharmaceutical and agricultural chemical products immediately while being able to postpone that decision with respect to all other products until 1 January 2000. This interpretation therefore frustrated the basic purpose of the transitional regime established by Articles 65 and 70, which was to give developing countries the right to postpone sensitive decisions beyond the date of entry into force of the WTO Agreement. In fact, this interpretation would turn Article 70 on its head because it would oblige developing countries to decide on the patentability of pharmaceutical and agricultural chemical products *before* having to implement the TRIPS Agreement with respect to other products (*emphasis by India*).
- Examination of the 14 notifications submitted to the TRIPS Council under Article 63.2 of the TRIPS Agreement showed that not one of these notifications provided that exclusive marketing rights were made available as from 1995 in the domestic law.

4.28 The **United States** was of the view that India had an immediate obligation to implement Article 70.9 and, since India had admitted that it had taken no steps to establish a mechanism by which persons who had filed mailbox applications could obtain and enforce exclusive marketing rights, it was out of compliance with its obligations under the Agreement. As a result, the United States was, according to Article 3.8 of the DSU, presumed to be adversely impacted. India bore the burden of rebutting the charge[34], but had failed to do so. In support of this view, the United States made the following arguments:

- As was the case with Article 70.8, India had made it clear that modifications to its intellectual property system were necessary to implement the requirements of Article 70.9.[35] While India was correct in its claim that Members were free to determine the manner in which they implemented their obligations, Members were not free to determine whether their obligations must be implemented at all. India had repeatedly made clear that, unless its laws and regulations were modified, it would not have implemented its obligations under Article 70.9. Having made this matter clear, it was unable to assert now that, because it had discretion as to the manner in which it fulfilled its Article 70.9 obligations, it could decide to do nothing.
- Regarding India's claim that it was in compliance with its obligations under Article 70.9 because no person had been denied exclusive marketing rights in India and that this was a matter for future implementation, the United States said that right holders had not been denied exclusive marketing rights because they had not sought such rights and they had not sought such rights because there were no such rights under Indian law or regulations to seek. Right holders would not even know to whom they should apply, let alone the procedures and costs involved or, since India had also failed to establish a mailbox application system, who would be eligible to request such protection had a system been in place. Even now, nearly two and a half years after the TRIPS Agreement had come into force, India had not stated where applications could be filed, what procedures would be followed, what authority would be responsible for reviewing applications, and the way in which rights would be enforced. In the absence of relevant information, it was

[34] Reference was made to the Appellate Body report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India" *(Wool Shirts)*, WT/DS33/AB/R, DSR 1997:I, 323 at 334. Additionally, the *Superfund* report made clear that "the impact of a measure inconsistent with [an applicable agreement] is not relevant for a determination of nullification or impairment by the CONTRACTING PARTIES" ("United States - Taxes on Petroleum and Certain Imported Substances" *(Superfund)* adopted on 17 June 1987, BISD S34/136, at 156).

[35] Reference was made to the arguments reflected in paragraph 4.3 above.

impossible for a national of a WTO Member to request such protection, even if it were available.

- Even though the level of actual damages suffered by United States' interests was irrelevant, since the United States had made a *prima facie* showing that India had failed to implement its obligations under Article 70.9 and it was, consequently, unnecessary for the United States to identify particular companies that would be eligible for exclusive marketing rights, the United States understood from its private sector that, had a mailbox system been in place since 1 January 1995, and had exclusive marketing rights been provided in accordance with Article 70.9, some companies would have begun seeking exclusive marketing rights under Indian law. Their ability to do so was dependent on the Indian health authorities processing their applications, but they had met all the requirements for such protection other than those dependent on the actions of the Indian health authorities. Evidence of this could be found in the letter to Ambassador Barshefsky from Dr. Harvey E. Bale, Jr.[36]
- The obligation in Article 70.9 to establish a system for the grant of exclusive marketing rights was not distinguishable from any other obligation in the TRIPS Agreement and did require changes in India's laws. Article 70.9, like Article 27, required the grant of certain rights upon the fulfilment of specified conditions. In the case of Article 27, a patent must be granted if an application was filed that was drawn to an invention that met the criteria of novelty, non-obviousness and industrial application. In the case of Article 70.9, exclusive marketing rights must be granted if a mailbox application was filed that met the criteria set out in Article 70.9. Both provisions demanded the establishment of a system for the grant of the specified rights.
- As with the obligation to establish a fully functional mailbox system under Article 70.8, the obligations in Article 70.9 established expectations on the part of WTO Members and potential applicants that exclusive marketing rights would be available. As long as India did not have in place a system for the grant of those rights, potential applicants would not be able to request the grant of such rights, let alone make informed business decisions with the understanding that such rights might be requested and granted. The expectations created by the inclusion of Article 70.9 in the TRIPS Agreement would be frustrated until India had established a clear and stable system for the grant of such rights. The *Superfund* case was thus relevant to this matter because it clarified that Members

[36] The letter referred to above in paragraph 4.11 and footnote 16 (see also Annex 3 of this report).

were obligated "to protect expectations" of other Members as to the "competitive relationship" between their respective products. Moreover, in applying the principle behind the *Superfund* decision to the present case, there was no need to wait for a violation to take place or speculate on whether it would take place, since the present case concerned a failure to take an affirmative action to implement a specific obligation in a WTO agreement.

- The grant of an additional five years in Article 65.4 to implement the provisions on product patent protection in Article 27 of the TRIPS Agreement had been balanced against the inclusion of obligations to establish fully functional mailbox and exclusive marketing rights systems in Articles 70.8 and 70.9. India could not now be permitted to pocket the benefit of an additional five years of transition and not implement the corresponding obligation. The Appellate Body recently had made this clear in the *Wool Shirts* case, in which India had argued that under the Agreement on Textiles and Clothing (ATC) the burden of proof should be shifted to the importing country taking temporary safeguard action. In rejecting the Indian argument, the Appellate Body had clarified that the ATC was a transitional arrangement containing "carefully negotiated language..... which reflects an equally carefully drawn balance of rights and obligations of Members.....".[37] This characterization was equally applicable to the balance between the transitional rules in Article 65.4 of the TRIPS Agreement and the obligations established in Article 70.8 and 70.9 of the TRIPS Agreement. As the Appellate Body succinctly had stated in the *Wool Shirts* report "[t]hat balance must be respected".[38] The *quid pro quo* for taking advantage of the transitional period was the grant of exclusive marketing rights. Far from turning Article 70.9 on its head, this represented the core balance in this area of the Agreement. If India did not want to grant patents, then it must grant exclusive marketing rights; conversely, if it did not want to grant exclusive marketing rights, then it must grant patents.
- There was nothing in the Agreement indicating that the obligation to provide exclusive marketing rights arose only after 2000. When the drafters of the Agreement intended a transitional period to apply to a particular obligation, they had specifically included the transition in the Agreement. There was no such transition with re-

[37] Appellate Body Report on "United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India" DSR 1997:I, 323 at 337, citing the Appellate Body Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", adopted 25 February 1997, WT/DS24/AB/R, DSR 1997:I, 11 at 23.
[38] *Id*.

spect to the obligations in Article 70.9. On the contrary, Article 70.9 specifically stated that the obligation to provide exclusive marketing rights applied "notwithstanding the provisions of Part VI" of the TRIPS Agreement, which established the transitional periods. As a result, just as with Article 70.8, the obligations of Article 70.9 must be fulfilled as of the date of entry into force of the WTO Agreement.

- India had provided no support for its argument that the obligation to comply with Article 70.9 had not yet arisen. None of the commentators India had quoted had stated that it was impossible for a pharmaceutical or agricultural chemical product to fulfil all the criteria for the grant of exclusive marketing rights. They all left open the possibility that those criteria might be fulfilled long before the end of the transitional period and none of them suggested that the obligation to implement Article 70.9 did not arise on 1 January 1995. Moreover, as Dr. Bale's letter[39] showed, there was at least one company that was seeking exclusive marketing rights in India in respect of two pharmaceutical products.

4.29 **India** rebutted by stating that the United States had not responded to its arguments, based on the methods of interpretation set out in the Vienna Convention on the Law of Treaties, demonstrating that the obligation to accord exclusive marketing rights was triggered by the events listed in Article 70.9. Neither the wording of the provision, nor its context, nor its object and purpose supported the United States' claim that the provision required developing countries to enable their executive authorities to grant such rights as from the entry into force of the WTO Agreement. India made the following comments on the United States' arguments:

- The United States had sidestepped the results of India's legal demonstration by asserting that, according to Article 3.8 of the DSU, trade damage was presumed and that it was therefore not necessary to speculate on whether products had become eligible for exclusive marketing rights. That response did not deal with the interpretative issue before the Panel, which was what triggered the application of the obligations under Article 70.9: the entry into force of the WTO Agreement in 1995 or the series of future events listed in that Article. The principle that a failure to observe an obligation was presumed to cause nullification or impairment was totally irrelevant in addressing the interpretative question of whether the obligation already existed.
- The principles recognized by the GATT CONTRACTING PARTIES, that the basic provisions of the GATT established conditions of competition and that mandatory legislation could con-

[39] The letter referred to above in paragraph 4.28, third indent.

stitute a measure within the meaning of those provisions even before the legislation was applied in a concrete case, were equally irrelevant, because they simply did not address the issue which was before this Panel, namely *as of when* certain conditions of competition had to be established and *as of when* mandatory legislation could be considered to be actionable (*emphasis by India*). It would be logically untenable to use these principles to turn transitional arrangements designed to postpone the applicability of obligations into current obligations forcing Members to immediately empower their executive authorities to take the measures necessary to meet the obligations applicable at the end of the transitional period.

- If the United States' argument that it would be easier to plan business if the transitional provisions of the TRIPS Agreement were interpreted to require legislative changes before the end of the transitional period were accepted, it would have to be applied to all the transitional arrangements contained in the WTO agreements. Thus, it would arguably be easier for Indian textiles' producers to plan business if all textiles-importing WTO Members had legislation presently in place providing for the elimination of textiles import restrictions on the date of the termination of the Agreement on Textiles and Clothing. Unfortunately, however, the obligation to bring the textiles restrictions into conformity with the GATT would arise only in the future just as the obligation to grant patents or exclusive marketing rights only arose in the future. Until the end of the transitional periods accorded under different WTO agreements, the source of predictability could therefore only be the relevant WTO agreement. The CONTRACTING PARTIES had never applied the principles invoked by the United States in the manner suggested by the United States. To do so would constitute an unanticipated change in obligations that could not legitimately be brought about by way of interpretation, and to do so only in the field of intellectual property rights but not in the many other areas covered by transitional arrangements would be fundamentally unfair.
- India's research had not revealed any case in which a product for which a patent application had been filed after 1 January 1995 had received marketing approval in India and had thus become eligible for exclusive marketing rights in India under Article 70.9. The letter from Dr. Bale produced by the United States merely stated that one company "has received a patent and marketing approval for a drug in the United States and Europe and is ready to request the grant of exclusive marketing rights from the Indian health authorities". The request that this company intended to submit to the Indian health authorities was obviously a request for marketing approval; only when that approval had been obtained would this

product become eligible for exclusive marketing rights. There was no evidence available in India of any such case. It should also be noted that before any applicant could make such a request, it must first request the Indian health authorities, i.e. the Drugs Controller General of India, to grant marketing approval.

- Although it was difficult to provide evidence or state with absolute certainty when products would start becoming eligible for exclusive marketing rights under Article 70.9, a delay of ten or more years between the date of filing of applications for patents and the grant of marketing approvals seemed likely. In India, registration and approval of new drugs required submission of technical data on safety and efficacy as well as analytical specifications in relation to steps of manufacture, in-process control and marketing status in other countries, clinical trial data generated within the country and examination labels and package inserts. The technical data were examined in consultation with the experts. The final bulk drug was required to be tested at the Central Drugs Laboratory, Calcutta, as per analytical specifications furnished. A new drug derived out of cell-line and recombinant DNA based products also needed approval from the Ministry of Science and Technology and the Ministry of Environment. If a new drug was already marketed in a number of countries and pre-clinical and clinical data generation was adequate, Phase III multi-centric clinical trial was required to be carried out on a protocol approved by the Drugs Controller General of India. If the data were complete, as per the requirements of Schedule Y of the Drugs and Cosmetics Rules, an average time of three years was taken for approval and registration of new molecules with a maximum period of eight to ten years. Discovery of drugs in India for the purpose of registration and approval took much longer as, at that point of time, there might not be access to scientific data available on the drug published in international journals and literature. In respect of agricultural chemicals, the time schedule for grant of marketing approvals would depend on the submission of satisfactory data by the applicant and the satisfaction of the Registration Committee constituted under the Insecticides Act. As in the case of pharmaceuticals, it could not be stated with absolute certainty as to when products would become eligible for exclusive marketing rights under Article 70.9.

4.30 The **United States** reiterated that it knew of two pharmaceutical products that were now becoming eligible for exclusive marketing rights under Article 70.9. The only step remaining was the establishment by India of a system for the grant of such rights so that an application for marketing approval/exclusive marketing rights could be filed and processed. The United States' pharmaceutical company Eli Lilly Corp. had two pharmaceutical products that were the subject of a patent application filed in the United States after 1 January 1995 and had been granted patent protec-

tion and marketing approval after that time. This company was in the process of determining how to apply for exclusive marketing rights in India and had asked the United States' Government for any information it had on the process for doing so. The United States could not say, for example, whether the company must indicate in its application for marketing approval that it was a candidate for exclusive marketing rights, and whether it must include a fee to preserve its ability to get those rights. Alternatively, the United States could not say whether any special procedure for the grant of exclusive marketing rights had been established (i.e. whether the application for marketing approval would result automatically in the grant of exclusive marketing rights). The United States indicated that companies would be wary about proceeding without knowing what the system for the grant of such rights was, for fear of losing their ability to receive those rights because of some procedural problem. The United States' Government had no information on the Government of India's intended system for the grant of these rights.

(b) The Scope of "Exclusive Marketing Rights"

4.31 As regards the exclusive marketing rights to be provided in accordance with the standard set forth in the Agreement, the **United States** argued that Article 70.9 required India to grant exclusive marketing rights that were not subject to compulsory licences or any other form of use without the permission of the right holder. Since Article 70.9 did not define the term "exclusive" when used with marketing rights, either explicitly or through reference to other provisions of the TRIPS Agreement, this unqualified term should be applied based on its ordinary meaning.[40] The term "exclusive" was defined in the Oxford English Dictionary as meaning "[h]aving the power or the function of excluding" or "[e]xcluding all other persons from the rights conferred".[41] The ordinary meaning of the terms used would therefore indicate that no competitors were permitted on the market without the consent of the holder of the "exclusive" marketing rights. There was no basis to believe that the drafters had intended to depart from this ordinary meaning of "exclusive marketing rights".

4.32 **India** responded that the scope of exclusive marketing rights was not an issue relating to an existing measure and could therefore not be the subject of a ruling by the Panel. It made the following arguments to support this statement:

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[40] Reference was made to the Vienna Convention on the Law of Treaties, Article 31.1. The Appellate Body has recognized that both Article 31 and Article 32 of the Vienna Convention apply to disputes under the WTO Agreement. Appellate Body Report on "Japan-Taxes on Alcoholic Beverages" (adopted 1 November 1996), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, DSR 1996:I, 97 at 104-106.

[41] Reference was made to the Oxford English Dictionary (Second Edition 1989), volume V, p. 510, definitions 1 and 6.b, respectively. Other relevant definitions include: "[e]xcluding (some other) from participation" (definition 2); "[e]xclusively confined to" (definition 6.b); "[s]trictly limited to the object or objects designated" (definition 7); "[e]mployed or followed to the exclusion of everything else; single, sole" (definition 8).

- The United States was seeking a ruling on a potential future measure. The United States was apparently asking for this finding because of concerns it had about the nature of some provisions in the lapsed Patents (Amendment) Ordinance 1994 and the Patents (Amendment) Bill of 1995, which would have accorded the Government discretionary powers to subject exclusive marketing rights to certain conditions. However, even the said Ordinance and Bill did not make it mandatory for the executive authorities to grant exclusive marketing rights subject to compulsory licensing or other use. However, since neither of these instruments was in force in India, the scope of exclusive marketing rights was a matter that had not yet arisen. The United States was thus essentially asking the Panel to make a declaratory judgement on a potential future action that the executive authorities of India might be authorized to take on the basis of a law Parliament might adopt.
- The WTO dispute settlement procedures did not permit rulings on potential future measures. Article 64 of the TRIPS Agreement stated that the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the DSU shall apply to consultations and the settlement of disputes under the TRIPS Agreement except as otherwise specifically provided in that Article. The texts of Article XXIII:1(a) of GATT 1994, Article 19.1 of the DSU and Article 22.8 of the DSU made clear that the provisions defining the cause of action, the remedy available and the scope for retaliation all presupposed the existence of a measure that was *currently* nullifying or impairing benefits and capable of being brought into conformity with the obligations under the WTO Agreement (*emphasis by India*). The only WTO procedure that permitted the resolution of interpretative issues in the abstract was that set out in Article IX:2 of the WTO Agreement, according to which the WTO Ministerial Conference and the General Council had the power to adopt authoritative interpretations.
- The customary practice of the CONTRACTING PARTIES to GATT 1947 had been to examine under Article XXIII only measures that were currently applied. The CONTRACTING PARTIES had never ruled on potential future measures or what type of law might be required to meet *future* obligations (*emphasis by India*). They had proceeded on the assumption that a contracting party would meet its obligations under the GATT as long as its legislature had not yet taken a decision to the contrary or had left the executive authority the option of acting in accordance with the

GATT.[42] According to Article XVI:1 of the WTO Agreement "the WTO shall be guided by the..... customary practices of the CONTRACTING PARTIES to GATT 1947.....". In *Japan - Taxes on Alcoholic Beverages*, the Appellate Body had noted that Article XVI:1 of the WTO Agreement brought the legal history and experience under GATT 1947 into the realm of the WTO in a way that ensured continuity and consistency. The customary practice of the CONTRACTING PARTIES, while not binding on panels, should be taken into account by panels where relevant to any dispute. The Panel could therefore not deviate from the customary practice of the CONTRACTING PARTIES without due cause and justification.

- Panel rulings on potential future measures would be regarded by the WTO Membership as an unacceptable interference in domestic decision-making processes. GATT contracting parties had generally refused to consult under the formal dispute settlement procedures on measures they had not yet taken. When asked to consult on provisions in the Treaty of Rome that accorded the European Communities the competence to impose quantitative restrictions inconsistently with the GATT, the European Communities had pointed out that "many contracting parties had permissive legislation of a general character which, if implemented in full, would enable them to impose restrictions in a manner contrary to Article XI. These countries were, however, not required to consult with the CONTRACTING PARTIES about their possible intentions as regards the implementation of such legislation".[43] The United States had shared this view in the past, as illustrated by its reaction to the report of the panel on *Wine and Grape Products*[44] which had examined a law which *mandatorily* imposed on the executive authority the requirement to apply a definition of industry for the purposes of anti-dumping and countervailing duty investigations of wine and grape products that was inconsistent with the Tokyo Round Subsidies Code (*emphasis by India*). When this report was adopted in 1992, the United States had declared that it "reserved its *position of opposition to the Panel's view that it was ripe for the Panel to consider a matter that did not involve an actual initiation of an action, but rather an abstract question* whether a proceeding,

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[42] Reference was made to the summary of this practice in *United States - Standards for Reformulated and Conventional Gasoline*: "The Panel observed that it had not been the usual practice of a panel established under the General Agreement to rule on measures that, at the time the Panel's terms of reference were fixed, were not and would not become effective."

[43] Reference was made to GATT document L/778.

[44] Reference was made to the Panel Report on "United States - Definition of Industry Concerning Wine and Grape Products", adopted on 28 April 1992, BISD 39S/436.

if initiated, would have been consistent with the Subsidies Code"[45] (*emphasis by India*). In a case involving countervailing duties, the United States had thus formally objected to a panel examination of a future action prescribed by its existing law; in the present case involving intellectual property rights, the United States was seeking the examination of a measure that was not even referred to in any existing law. The Members of the WTO had often expressed legitimate concerns regarding the future policies of their trading partners, for instance about possible action under Section 301 of the United States Trade Act of 1974 or about protectionist bills under consideration by the United States Congress.[46] However, the view had nevertheless prevailed that formal international inquiries into matters still under domestic consideration were an inappropriate and unwelcome interference into the domestic decision-making process, and the drafters of the DSU therefore rightly had not authorized panels to make declaratory judgements on potential future measures. Questions of striking an appropriate balance of interests at the national level between the holder of an exclusive marketing right, on the one hand, and society, on the other, as well as of the conformity of possible legislation with the basic provisions of the Constitution of India and the various decisions of the Apex Court which had elaborated these provisions were outside the jurisdiction of a dispute settlement panel.

4.33 The **United States** responded that it was not seeking specific or declaratory relief; it was seeking a finding by the Panel that identified those obligations India had failed to implement. The Agreement required, and India had not contested this, that exclusive marketing rights be granted so that competitors would not be permitted on the market without the consent of the right holder. India had entered into these obligations with a full understanding of what implementing these obligations would entail and could not now claim that it was permitted to rebalance, as the Appellate Body had stated in the *Wool Shirts* case, these obligations off against other interests. Only full implementation by India would ensure that the balance that had been struck in the TRIPS Agreement was respected.

4.34 **India** considered this revised request for a finding also a request for a specific remedy, only more artfully disguised. The United States was not claiming that India had accorded exclusive marketing rights under which "competitors of the owner of such right (are) permitted on the market absent the owner's consent"; it claimed that India had not provided any exclusive marketing rights. The specific finding sought by the United States did not relate to the legal consistency of a

[45] Reference was made to GATT document SCM/M/59, p.31.
[46] Reference was made to the GATT Council discussion on unilateral measures in February 1989 (GATT document C/163).

measure that India was claimed to have taken, but to the ways in which India was to implement its obligations.

4.35 The **United States** remained of the view that, instead of asking for specific or declaratory relief, the finding that it was seeking was a determination from the Panel that India's laws and regulations were not in compliance with its obligations under Article 70.9 to provide exclusive marketing rights meeting the standard set forth in the Agreement. It did so for the following reasons:

- Unlike many other provisions of the WTO agreements, the TRIPS Agreement contained obligations to act affirmatively to establish rights, procedures and remedies in respect of intellectual property. The United States was not alleging that India had taken an action that was inconsistent with its obligations under the TRIPS Agreement; on the contrary, it believed that India had failed to take affirmative actions that it was required to take under the TRIPS Agreement. In defining how India had violated the TRIPS Agreement, the Panel must indicate with some specificity which affirmative obligation India had not met. It was important to distinguish between the request that the Panel define how India was out of compliance with its TRIPS obligations and the request that the Panel suggest a way in which India could meet those obligations. The requested finding above represented an example of a request to define what obligations India had not met. The request that the Panel suggest that India implement these obligations in a manner similar to the way in which Pakistan was implementing these obligations was an example of the second category. India was attempting to blur the distinction between these two categories and between the affirmative obligations in the TRIPS Agreement and the prohibitions found in other WTO agreements.
- India had not contested, nor could it contest, that the TRIPS Agreement required that exclusive marketing rights be granted so that competitors were not permitted on the market without the consent of the right holder. There was no basis in the TRIPS Agreement to conclude that the drafters had intended to depart from the ordinary meaning of the terms used. Whenever they had intended a type of right to be subject to permissive or mandatory exceptions, they had provided specifically for such exceptions in the text defining the right.[47] Likewise, where the permissive or mandatory exceptions applying to one type of right were intended to apply to another type of right, this had specifically been provided in the text

[47] In this regard, the United States said that note should be taken of the exceptions explicitly permitted in the case of copyrights (Article 13), trademarks (Article 17), geographic indications of origin (Article 24), patents (Articles 30 and 31), lay-out designs of integrated circuits (Article 37.1), and industrial designs (Article 26.2).

of the Agreement.[48] Therefore, had the drafters of the Agreement intended the exclusive marketing rights to be subject to a permissive or mandatory exception, they would have either included such exception in the text of Article 70, or they would have incorporated by reference an exception in another part of the Agreement. India had failed to grant to the holder of marketing rights the exclusive right to control the entry of competitors onto the market during the period of those rights and, thereby, to implement Article 70.9.

Request for a Suggestion that India Implement its Obligations under Article 70.8 and 70.9 in a Manner Similar to the Way in Which Pakistan Had Implemented these Obligations

4.36 The **United States** requested the Panel to suggest that India meet its obligations under Article 70.8 and 70.9 in a manner similar to the way in which Pakistan had implemented these obligations.[49] It stressed that this request should be distinguished from the findings it was seeking from the Panel that would identify the obligations under these provisions which India had failed to implement.

4.37 **India** said that this United States' request had been introduced for the first time at the first substantive meeting of the Panel with the parties. To submit such an additional request after the first submission constituted an unacceptable procedural scheme, as had been recognized by the recent WTO Panel on *European Communities - Regime for the Importation, Sale and Distribution of Bananas*.[50]

4.38 **India** also advanced the following reasons why the United States' request should be rejected as legally inappropriate:

- It had serious doubts whether a panel constituted to resolve a dispute on the basis of rights and obligations enshrined in a multilateral agreement should formally endorse a settlement bilaterally negotiated between two sovereign States in the context of their particular overall relations.
- There were technical reasons that would make it inappropriate to transpose the system adopted by Pakistan to India. Pakistan had agreed with the United States that the relevant date of filing for the purposes of Article 70.8 would be the date on which a patent application had been filed not in Pakistan, as foreseen in Article 70.8, but *in another Member* (*emphasis by India*). In India, patent applications for pharmaceutical and agricultural chemical products had been filed and a filing date had been given to each of these appli-

[48] According to the United States, the example of this approach to exceptions could be found in the TRIPS Agreement's Section on lay-out designs of integrated circuits (Article 37.2).
[49] Reference was made to document IP/D/2/Add.1.
[50] For a further elaboration by India of this argument, see above in relation to Article 63.

cations. The United States' request for a panel suggestion would therefore imply that applications made in other Members would have to be inserted by India into the queue of applications already made. Consequently, the order of priority of the applications would have to be changed in a manner that was not foreseen in the TRIPS Agreement and that favoured some Members over others. The United States was therefore requesting that the Panel suggest a solution whose consistency with the TRIPS Agreement would be doubtful in the case of India.

V. ARGUMENTS PRESENTED BY THIRD PARTY

European Communities and their Member States

5.1 The European Communities and their Member States argued in their third party submission that, while India had made a *bona fide* attempt to implement the "mailbox" mechanism by the Patents (Amendment) Ordinance 1994, this Ordinance had meanwhile lapsed and was no longer in force, since it had not been confirmed within six weeks of the re-assembly of the Indian Parliament in early 1995 by the Indian legislative authorities as required by the Indian Constitution. This meant that filings made under the Ordinance did not presently enjoy the legal status they should be granted under Articles 70.8 and 70.9 of the TRIPS Agreement, and the status of filings made after the date when the Ordinance lapsed until such time as India were to take the necessary steps to implement Articles 70.8 and 70.9 of the TRIPS Agreement was presently also unclear. Under these circumstances, India did not presently provide for the mailbox mechanism and the mechanism for the granting of exclusive marketing rights as foreseen under Articles 70.8 and 70.9 of the TRIPS Agreement and was therefore not living up to its obligations under the WTO Agreement.

5.2 At the third party meeting, the European Communities and their Member States, expressed surprise about the arguments of India in its first submission that it had observed its obligations as contained in Articles 70.8 and 70.9, on three counts:

- India had adopted an Ordinance in late 1994 allowing the filing of patent applications concerning pharmaceutical and agricultural chemical products, since these products were not patentable under existing Indian law. This Ordinance had meanwhile lapsed and had been replaced, according to India, by administrative instructions to the Indian patent authorities to continue to accept filings. How could India now argue that simple administrative instructions to accept filings were sufficient, while it had felt the need to act by an Ordinance in the first place which had been meant to be replaced by a formal act of its legislature? An administrative instruction was only capable of binding the administration itself; it could not have an effect on the applicants. In other words, if there was a dispute between several applicants about the time of the filing, such a

dispute could not be resolved by simply adopting an instruction addressed to the administration. A legislative act capable of creating rights and obligations between applicants was therefore necessary.

- Questions arose as to what were the precise terms of the administrative instructions, where they had been published and what were the guarantees in case of a dispute before the Indian courts. In answering these questions, India would have to admit that simple administrative instructions did not fulfil the requirements laid down in Articles 70.8 and 70.9.
- As far as the exclusive marketing rights under Article 70.9 were concerned, India claimed that no applications had been filed so far. India seemed to believe that because of the absence of such applications the entry into force of the mechanism allowing such filings could be postponed. This position was untenable. Article 70.9 was intimately linked with Article 70.8 which in turn left no doubt that it applied as of the date of entry into force of the TRIPS Agreement for a Member, i.e. 1 January 1995. In promulgating the Ordinance already referred to, India had itself recognized the obligation to put the mechanism required by Article 70.8 into place by that date. India could not now argue that the rules governing the exclusive marketing rights envisaged under Article 70.9 should only be adopted once applications for such exclusive marketing rights had been received. Moreover, how would it be possible to file such applications in the absence of any rules governing such applications? Was it not the absence of such rules that had led to the absence of applications? Rules must be put in place before applications could be made and those rules should have existed as of 1 January 1995.

5.3 Turning to the question of how to handle applications made before the rules would be adopted that India was obliged to introduce, the European Communities and their Member States expressed concern regarding the fate of applications that had been made after the obligations under Articles 70.8 and 70.9 had become applicable but before India had taken the necessary domestic measures to implement these provisions. Another concern related to the fate of the filings made under the Ordinance adopted at the end of 1994. India owed other WTO Members assurances on the fate of such applications and filings. Since such assurances had not been given so far, the European Communities and their Member States urged the Panel to include in its report findings with regard to these applications and filings.

5.4 In conclusion, the European Communities and their Member States lent their full support to the requests made by the United States in the present dispute and asked the Panel to find that India, not having carried out its obligations under Articles 70.8 and 70.9 of the TRIPS Agreement, should bring its domestic legislation into conformity with these obligations, also with regard to applications that would

have been lodged under these provisions had the rules been adopted in good time and not lapsed subsequently.

VI. INTERIM REVIEW

6.1 On 8 July 1997, India requested the Panel to review, in accordance with Article 15.2 of the DSU, certain precise aspects of the interim report that had been issued to the parties on 27 June 1997. The United States did not request a review, but reserved, in a letter dated 9 July 1997, its rights to comment on any changes suggested by India. No further comments were subsequently submitted by the United States. Neither India nor the United States requested the Panel to hold an additional meeting. The Panel reviewed the entire range of arguments presented by India and finalized its findings as in Section VII below, taking into account the specific aspects of these arguments it considered to be relevant.

6.2 India requested the Panel to review its findings mainly for the following reasons:

- In respect of Article 70.8 of the TRIPS Agreement, India did not share the Panel's assessment of the legal situation in India;
- It was procedurally and legally incorrect for the Panel to rule on Article 63 of the TRIPS Agreement, mainly because the United States had requested a ruling on this provision only in case the Panel were to find that India had a valid mailbox system in place; and
- The Panel's discussion of Article 70.9 of the TRIPS Agreement did not define the issue presented to the Panel correctly and did not fully take into account India's arguments.

The Panel carefully examined these assertions, as elaborated below.

Article 70.8

6.3 In its review request, India essentially reiterated its argument in paragraph 4.9 above, arguing that the effect of the Panel's finding in what is now paragraph 7.28 was to force developing countries to adopt now legislation that the TRIPS Agreement clearly required them to adopt only on 1 January 2005. Furthermore, India submitted that the Panel's findings in what are now paragraphs 7.36 and 7.37 on the legal situation in India were erroneous and largely speculative and requested the Panel to reconsider its findings in those paragraphs.

6.4 The Panel was not persuaded by these arguments. As explained in paragraph 7.31 below, the obligation under Article 70.8 was a special obligation imposed on those Members benefitting from the transitional arrangements, clearly distinguishable from the obligation to provide full patent protection under Article 27. Regarding the assessment of the legal situation in India, as stated in paragraph 7.40 below, the Panel felt that the United States had successfully raised questions as to the legal security of the current "mailbox" system in India and that India had failed to rebut

these challenges. In the Panel's view, India's explanation on why the mailbox system that it had put in place administratively was not in contradiction with current law nor with the Constitution[51] did not remove concerns on the legal security of the system.

6.5 Accordingly, the Panel did not accept India's request on this point, except that it slightly modified what are now paragraphs 7.28 and 7.29 and that it expanded what is now paragraph 7.31.

Article 63

6.6 In its review request, India noted that the Panel had found that India did not have a valid mailbox system in place. Given that the United States had requested a ruling on Article 63 only if the Panel were to find that India had a valid mailbox system in place, the Panel, in India's view, should not have made any findings or recommendations on Article 63. India requested the Panel to strike from its findings and recommendations the references to Article 63 and to replace them by a sentence noting that its findings on the mailbox system made the request for a finding on Article 63 moot. India further noted that the discussion on procedural issues contained in what are now paragraphs 7.8 to 7.15 was only relevant to the findings on Article 63. India thus requested that these paragraphs also be struck from the final report.

6.7 According to India, it was perfectly logical for the United States to present its claim under Article 63 only in the alternative. India argued that Article 63 required Members to publish and notify measures "made effective" by them, in other words, measures with legal effect actually taken by them. Consequently, if a Member failed to take a measure prescribed by a provision of the TRIPS Agreement, it could not be found to violate that provision *and* Article 63, given that there was then no measure that had been made effective (*emphasis by India*).

6.8 The Panel was not persuaded by this argument. The Panel felt that India's reading of the term "made effective" was unduly narrow. The consistency of a measure with a Member's international obligations under the WTO Agreement and the putting of the measure into effect in the Member's domestic jurisdiction were two separate issues. In the Panel's view, a measure that was inconsistent with WTO rules could still be "made effective" within the meaning of Article 63 of the TRIPS Agreement. Indeed, the very purpose of notifications under Article 63.2 was to assist the Council for TRIPS in its review of the operation of the TRIPS Agreement and "in particular, Members' compliance with their obligations thereunder"[52]. If a measure that was inconsistent with the TRIPS Agreement were relieved from the notification obligation *a priori*, this function of the Council for TRIPS could not be achieved.

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[51] Paragraph 4.12 above.
[52] Article 68 of the TRIPS Agreement.

6.9 Finally, India argued that, if the Panel's recommendation on Article 63 related to the existing system, it would serve no purpose and that, if it related to a future modified system, it would relate to a matter that had not arisen in this dispute. India further argued that the purpose of the WTO dispute settlement procedure was not to generate interpretations that were not required to resolve the dispute. In support of its position, India quoted the panel in the *Semiconductor* case, which, facing the dual claim that a measure was inconsistent with GATT Article XI and not published in accordance with GATT Article X, had refused to rule on the transparency issue by pointing out:

> "The measures under examination had been found to be inconsistent with Article XI. At issue was thus their elimination or bringing them into conformity with GATT, not their publication."[53]

Thus, according to India, the United States' claim on Article 63 should not be addressed by the Panel, even if it could be interpreted as an additional claim. If the Panel were to take that step, it would be the first panel to do so.

6.10 The Panel disagreed. This Panel was not the first to address the issue of transparency in addition to the violation of substantive obligations. The panel on *Restrictions on Imports of Apples* (complaint by the United States) had stated as follows:

> "The Panel recognized that, given its finding that the EEC measures were a violation of Article XI:1 and not justified by Article XI:2(c)(i) or (ii), no further examination of the administration of the measure would normally be required. Nonetheless, and even though the Panel was concerned with measures which had already been eliminated, it considered it appropriate to examine the administration of the EEC measures in respect of the provisions mentioned above, in view of the questions of great practical interest which had been raised by both parties.
>
> "...The Panel therefore considered that the allocation of back-dated quotas did not conform to the requirements of Article XIII:3(b) and (c). It also interpreted the requirements of Article X:1 as likewise prohibiting back-dated quotas. It therefore found that the EEC had been in breach of these requirements since it had given public notice of the quota allocation only about two months after the quota period had begun."[54]

6.11 The following passage from the Appellate Body report on the *Shirts and Blouses* case had been cited by India:

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[53] Panel Report on "Japan - Trade in Semi-conductors", adopted on 4 May 1988, BISD 35S/116, para. 128.

[54] Panel Report on "European Economic Community - Restrictions on Imports of Apples, Complaint by the United States", adopted on 22 June 1989, BISD 36S/135, paras. 5.20 and 5.23.

> "Given the explicit aim of dispute settlement that permeates the DSU, we do not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to 'make law' by clarifying existing provisions of the WTO Agreement outside the context of resolving a particular dispute."[55]

The Panel fully agreed with the Appellate Body on this point. In the present case, the Panel had no intention of "making law" by clarifying existing provisions of the TRIPS Agreement outside the context of resolving the dispute before it. Rather, in view of the Appellate Body's observation on the limitation of its mandate under Articles 17.6 and 17.13 of the DSU in its recent report on the *Periodicals* case[56], the Panel felt all the more strongly the need to avoid a legal vacuum in the event that, upon appeal, the Appellate Body were to reverse the Panel's findings on Article 70.8.

6.12 Accordingly, the Panel decided to retain the paragraphs on Article 63 unchanged from the way they had appeared in the interim report, except for certain drafting modifications in paragraphs 7.11 and 7.44.

Article 70.9

6.13 India objected to the characterization of the issue in the interim report in what is now paragraph 7.52, where it stated: "Thus, the central question before this Panel is that of timing: as of when should there be a mechanism ready for the grant of exclusive marketing rights?". In India's view, the more appropriate question was whether Article 70.9 obliged Members to grant exclusive marketing rights to particular products that met the conditions specified in that provision or whether this provision obliged Members to authorize their executive authorities to grant such rights before the occasion to exercise such authority arose. India requested the Panel to reformulate the question accordingly.

6.14 The Panel was not persuaded that India's formulation of the question was the more accurate one. However, to clarify the issue further, it introduced paragraph 7.53 in the final report. It also slightly modified what is now paragraph 7.54.

6.15 In its review request, India reiterated its argument in paragraph 4.27 regarding the ordinary meaning of the term "shall be granted". The Panel modified what is now paragraph 7.56 to clarify its position.

6.16 India further objected to the summary of India's arguments which now appears in paragraphs 7.57 to 7.62. According to India, India did not argue that Article 70.9 applied only as from certain dates or only during certain periods, nor could India be reasonably expected to indicate such dates. India's essential argument was

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[55] Appellate Body Report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India", adopted on 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 340.

[56] Appellate Body Report on "Canada - Certain Measures Concerning Periodicals", adopted on 30 July 1997, WT/DS31/AB/R, DSR 1997:I, 449 at 468.

that, because operators would "normally" be interested in exclusive marketing rights only in the five-year period preceding patentability, the objective of Article 70.9 could not have been to oblige developing countries to change their laws as from the entry into force of the WTO Agreement. The gist of India's argument was that there was simply no economic or political reality behind the assumption that Article 70.9 had been drafted with the objective to make developing countries change their laws as from the entry into force of the WTO Agreement. For reasons expressed in paragraphs 7.58 and 7.59 below, the Panel did not agree with India's argument, and did not find it necessary to change its conclusions in this respect. However, at the suggestion of India, the Panel modified what is now paragraph 7.57.

6.17 India reiterated its argument in paragraph 4.27 to the effect that no other developing country had notified the creation of a system for the grant of exclusive marketing rights under its domestic law and that this indicated that Article 70.9 was not understood by the developing country Members concerned as a provision that entailed the obligation to make changes in their domestic law as from the entry into force of the TRIPS Agreement. India requested the Panel to address this argument, given the importance of subsequent practice in treaty interpretation. The Panel understood that this request was an implicit reference to Article 31(3) of the Vienna Convention on the Law of Treaties, which reads:

> "There shall be taken into account, together with the context: (a) ... ; (b) any *subsequent practice* in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (c) ..." (*emphasis added*)

In the Panel's view, however, India had failed to demonstrate that the "subsequent practice" by developing country Members in fact established the agreement of all WTO Members regarding the interpretation of Article 70.9. On the contrary, the record showed that there had been no agreement on this issue in the Council for TRIPS; at most meetings of the Council, concern had been expressed by some Members about the absence of notifications or the limited information content of notifications related to the implementation of Article 70.9.[57] Moreover, the matter had also been the subject of another recourse to the DSU in "Pakistan - Patent Protection for Pharmaceutical and Agricultural Chemical Products" (WT/DS36). In any event, to paraphrase an Appellate Body report[58], the Panel felt that it was much too early for practice to have arisen under the TRIPS regime which had commenced only on 1 January 1995.

6.18 The interim report contained a heading entitled "Practical Considerations" immediately preceding what is now paragraph 7.60. India stated that it did not un-

[57] The record of discussions on these matters in the Council for TRIPS can be found in documents IP/C/M/2, 6, 7, 8, 9, 11, 12 and 13.

[58] Appellate Body Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", adopted on 25 February 1997, WT/DS24/AB/R, DSR 1997:I, 11 at 25.

derstand why the Panel had created a separate section given that such considerations were only relevant to the extent that they elucidated the context, object and purpose of Article 70.9. India suggested the deletion of the heading, which the Panel accepted.

6.19 Finally, India considered it inappropriate and procedurally indefensible for the Panel to corroborate its findings on Article 70.9 by reference to unsubstantiated and contested evidence submitted by interested companies of one of the parties to the dispute. The Panel noted that in its use of the evidence in the findings, it had made what it considered to be an objective assessment of that evidence - as required under Article 11, second sentence, of the DSU - taking into account India's reaction thereto. The Panel further noted that it had not relied on this piece of evidence as a sole basis for its findings and that India had presented no counter-evidence other than the comment contained in the fourth indent of paragraph 4.29 above. Accordingly, the Panel did not introduce any changes to the report on this point.

Suggestions by the Panel

6.20 In the interim report, the section corresponding to what was now "Suggestions by the Panel" was entitled "Remedies" and contained one additional paragraph. India requested the change in the title and the deletion of this paragraph, which the Panel accepted and introduced in its final report.

VII. FINDINGS

A. Claims of the Parties

Introduction

7.1 This dispute arises essentially from the following facts. Section 5 of the Indian Patents Act 1970 does not permit product patents to be granted in respect of "substances intended for use, or capable of being used, as food or as medicine or drug".[59] Only "claims for the methods or processes of manufacture shall be patentable" in respect of those substances.[60] Thus, India currently does not make available patent protection for pharmaceutical and agricultural chemical products commensurate with the obligations of Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), which requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology ... " subject to certain exceptions not appli-

[59] According to Section 2(1)(*l*) of the Patents Act, the term "medicine or drug" includes "insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants" (see Annex 1 of this report).

[60] See paragraph 2.10 above and Annex 1 of this report.

cable in this case and to the transition provisions of Articles 65.4 and 70.8 of the TRIPS Agreement.

7.2 On 31 December 1994, while Parliament was in recess, the President of India promulgated the Patents (Amendment) Ordinance 1994, with a view to meeting India's obligations under Article 70.8 and 70.9 of the TRIPS Agreement. The Ordinance inserted a new Chapter IVA in the Patents Act to deal with "a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug". The Ordinance explicitly allowed the filing of patent applications in respect of those substances and subsequent processing by the Patent Offices notwithstanding the provisions of Sections 5 and 12 of the Patents Act.[61] It also established a system for the grant of "exclusive marketing rights" with respect to the products that are the subject of such patent applications, subject to certain conditions. The Ordinance was notified to the WTO Council for Trade-Related Aspects of Intellectual Property Rights ("Council for TRIPS").[62]

7.3 The Ordinance had been issued in exercise of the powers conferred upon the President by Article 123 of the Indian Constitution, which enables the President to legislate when Parliament (either House or both Houses) is not in session and the President "is satisfied that circumstances exist which render it necessary for him to take immediate action". However, such Presidential actions expire six weeks after the reassembly of Parliament. Thus, under the relevant provisions of the Indian Constitution, the Patents Ordinance 1994 lapsed on 26 March 1995.[63] In March 1995, the Indian administration introduced the Patents (Amendment) Bill 1995 into Parliament to implement the contents of the Ordinance on a permanent basis. However, the Bill lapsed because of the dissolution of Parliament on 10 May 1996. The expiry of the Ordinance was not publicized, nor was it notified to the Council for TRIPS.

7.4 Currently, India allows the filing and handling of patent applications for pharmaceutical or agricultural chemical products through unpublished "administrative practices", even though those products are not patentable under Section 5 of the Patents Act 1970. Between 1 January 1995 and 15 February 1997, a total of 1,339 applications for pharmaceutical and agricultural chemical products have been received.[64] All these applications are, according to India, stored separately for future action under subparagraphs (b) and (c) of Article 70.8 and under Article 70.9 of the TRIPS Agreement.[65]

7.5 Under the current Indian legislation, there is no legal basis - procedurally or substantively - for the grant of exclusive marketing rights when a product which is the subject of a patent application under Article 70.8 (commonly called a "mailbox"

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[61] Section 12 sets out the procedure for the reference of patent applications by the Controller to examiners (see Annex 1 of this report).
[62] See document IP/N/1/IND/1.
[63] See paragraph 2.3 above.
[64] See paragraph 2.11 above.
[65] See paragraph 2.8 above.

application) becomes eligible for protection under Article 70.9 of the TRIPS Agreement. So far, no request for the grant of exclusive marketing rights has been submitted to the Government of India.

Claims of the Complainant

7.6 The United States essentially claims before the Panel that (a) India has failed to implement its obligation under Article 70.8 of the TRIPS Agreement to establish a mechanism that preserves the novelty of applications for pharmaceutical and agricultural chemical product patents during the TRIPS transition period; (b) such a mechanism must ensure that persons, who filed or would have filed applications had the "mailbox" been in place on time and maintained, can file such applications and receive the filing date they would have received; or, in the alternative, (c) India has failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement in respect of a mechanism for filing patent applications pursuant to Article 70.8; (d) India has failed to implement its obligations under Article 70.9 of the TRIPS Agreement, which arose on 1 January 1995, to establish a system for the grant of exclusive marketing rights; and (e) under a system for the grant of exclusive marketing rights under Article 70.9, competitors of the owner of such rights should not be permitted on the market in the absence of the owner's consent. The United States requests the Panel to recommend that India bring its measures into conformity with its obligations under the TRIPS Agreement. The United States further requests that (f) the Panel suggest that India implement its obligations under Articles 70.8 and 70.9 in a manner similar to the way in which Pakistan has indicated it is implementing these obligations[66].

Claims of the Respondent

7.7 India essentially claims that (i) India has provided a means for filing patent applications for pharmaceutical and agricultural chemical products that is consistent with Article 70.8 of the TRIPS Agreement; (ii) India is not obligated to establish a system for the grant of exclusive marketing rights under Article 70.9 before all the conditions for the grant of the rights stipulated therein have been met in respect of a specific product; and (iii) the United States' requests for the findings described in (b) and (e) of the previous paragraph are requests for specific remedies or declaratory judgements inconsistent with Article 19 of the DSU in that they do not relate to the legal consistency of the existing measures but to the ways in which India is to implement its obligations. Regarding the United States' alternative claim on transparency (i.e., item (c) in the previous paragraph) and its request that the Panel suggest how India should implement its obligations under Article 70.8 and 70.9 (i.e., item (f) in the same paragraph), India requests the Panel to dismiss them because (iv) the Panel's terms of reference do not cover the United States' Article 63 claim

[66] In this regard, reference is made to document WT/DS36/4.

and the scope of factual and legal claims cannot be expanded after the first written submission; and, in the alternative, (v) Article 63 does not apply to India until 1 January 2000 under Article 65.2 of the TRIPS Agreement and, in any event, the means of filing that it has established is based on the Patents Act 1970, which has been published.

B. Procedural Issues

7.8 Before moving on to the examination of substantive claims, we take up the procedural objections raised by India. India requests the Panel to dismiss the claims on transparency (item (c) in paragraph 7.6 above) and implementation (item (f) in the same paragraph) because, according to India, they were submitted too late to be accepted as valid claims before the Panel. We note that Article 63 of the TRIPS Agreement was not mentioned in the request for the establishment of a panel[67] or in the first written submission by the United States. Similarly, the request for a suggestion for implementation was put forward by the United States for the first time in its oral statement at the first substantive meeting of the Panel. India argues that these two claims were not specified in the United States' request for the establishment of a panel as required by Article 6.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and that these claims, at the latest, should have been elaborated by the United States in its first written submission. In support of its argument, India quotes from the recent panel report on *European Communities - Regime for the Importation, Sale and Distribution of Bananas.*[68]

Article 6.2 of the DSU provides that:

> "The request for the establishment of a panel shall be made in writing. It shall indicate whether consultations were held, identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. In case the applicant requests the establishment of a panel with other than standard terms of reference, the written request shall include the proposed text of special terms of reference."

We note that, regarding Article 6.2 of the DSU, the *Bananas* panel found that:

> "While a reference to a specific provision of a specific agreement may not be essential if the problem or legal claim is otherwise clearly described, in the absence of some description of the problem, a mere reference to an entire agreement or simply to 'other' unspecified agreements or provisions is inadequate under the terms of Article 6.2. Accordingly, we find that references to a WTO agreement without mentioning any provisions or to unidentified

[67] WT/DS50/4.

[68] Panel Report on "European Communities - Regime for the Importation, Sale and Distribution of Bananas", issued on 22 May 1997, WT/DS27/R.

> 'other' provisions are too vague to meet the standards of Article 6.2 of the DSU."[69]

Furthermore, the panel stated that:

> "For purposes of determining whether a Complainant in this matter has made a claim, we have examined its first written submission, as we consider that document determines the claims made by a complaining party. To allow the assertion of additional claims after that point would be unfair to the respondent, as it would have little or no time to prepare a response to such claims."[70]

7.9 While we do not disagree with the general conclusions of the *Bananas* panel on this point, there is an important difference between the *Bananas* case and the present case: this Panel 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. However, we do not intend to cut off India's objection solely based on this ground. It would seem unfair to do so in view of the fact that India had not heard the new United States' arguments when the ruling was made.

7.10 We now look at the admissibility of each of these requests in turn, first that relating to the transparency obligations under Article 63 and then that relating to implementation.

Transparency

7.11 In respect of the transparency issue, there are two other significant differences between the *Bananas* case and this case. First, as noted above, Article 6.2 of the DSU requires the panel request, which effectively sets a panel's terms of reference in most cases, to "provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly". The United States argues that the "problem" in this case is India's failure to implement a mailbox system that allows and grants legal status to submissions of certain patent applications. In its view, if India has a valid system in place, its failure to make that system known to WTO Members is part of this "problem".[71] We agree. The *Bananas* panel noted in the passage quoted above that: "a reference to a specific provision of a specific agreement may not be essential if the problem or legal claim is otherwise clearly described". Here, there is a more detailed description of the "problem" that the United States alleges in respect of Indian non-compliance with the TRIPS Agreement. In our view, the panel request in this case does describe the problem sufficiently to raise the issue of

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[69] Panel Report on "European Communities - Regime for the Importation, Sale and Distribution of Bananas", issued on 22 May 1997, WT/DS27/R, para. 7.30.

[70] *Id*., para. 7.57.

[71] See paragraph 4.19 above.

whether, assuming India has a valid mechanism for receiving mailbox applications, it is in compliance with Article 63 of the TRIPS Agreement.[72]

7.12 Second, and more fundamentally, we note that the United States' claim concerning Article 63 was a direct response to the Indian argument in its first written submission to the effect that India had a valid mailbox system in place. The United States asserts that this argument by India was a surprise because it had not been told by India during the consultations that India had such a system in place. In support of this assertion, the United States submitted that written questions it posed to India in this regard during the consultations had not been answered until the proceedings before this Panel started. To counter this assertion, India submitted to the Panel its internal record of the consultations indicating that India had informed the United States about the fact that "product patent applications in the pharmaceutical and agrochemical sector were being received under the provisions of the Patents Act of 1970" and that "the Patents Act 1970 has provided the necessary legal scope for receipt of applications for product patents".[73] In our view, however, this is mere factual information regarding the filing of product patent applications and does not amount to a legal claim for the existence of a valid mailbox system. In this regard, we note that it is agreed that under the Patents Act it is possible to *file* a patent application for these products. The issue is how such applications are handled (*e.g.*, whether they are subject to examination and rejection) and the Indian statements do not address this issue. Accordingly, it would seem unreasonable to require that the United States should have anticipated the particular line of Indian defence in advance and should have included its alternative claim on transparency in its panel request or in its first written submission.

7.13 It is true that the interests of parties involved, including those of third parties, would be harmed if a panel would freely accept new claims and arguments which had not been reflected in the first written submissions. However, it should also be recognized that the panel process is a dynamic one where claims by the parties become refined and elaborated through arguments and counter-arguments.[74] Thus, in an exceptional case like this, we are of the view that a new argument which is a direct response to a party's first written submission is acceptable, provided that such an argument is presented, at the latest, by the close of the first substantive meeting. Moreover, in this particular case, we note that the parties had an opportu-

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[72] The panel request includes the following passage: "The legal regime in India currently does not make patent protection available for inventions as specified in Article 27 of the TRIPS Agreement, or provide systems that conform to obligations of the TRIPS Agreement regarding the acceptance of applications and the grant of exclusive marketing rights. As a result, 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" (*emphasis added*).

[73] Paragraph 4.20 above.

[74] The *Bananas* panel acknowledges this dynamic nature of the panel process when it discusses "cure" of omitted arguments at a later stage. Panel Report on "European Communities - Regime for the Importation, Sale and Distribution of Bananas", *op. cit.*, para. 7.44.

nity to elaborate their arguments on this issue through oral and written submissions to the Panel.[75]

7.14 One could argue that such an interpretation would not sufficiently protect the interests of third parties, which were not exposed to the new argument and thus were not able to present their views on that point in their submissions to the Panel. However, in our view, principal parties to the dispute have an overriding interest under the circumstances.[76] If a third party is not satisfied with the proceedings or the outcome of a case to which it has submitted its views, it "may have recourse to normal dispute settlement procedures" in its own right.[77] We also observe that the appellate process protects third party interests. If the new argument is such an important one that the case is appealed on that point, third parties can make their own submissions to the Appellate Body even though they may not have expressed their views on that particular point in the panel process.[78]

7.15 Put another way, our view is that the examination of the United States' claim on transparency is within the terms of reference of this Panel, cited in paragraph 1.2 above. Since this claim is a direct response to the Indian argument on the existence of a valid mailbox system in India, which in turn was a rebuttal to the United States' argument in its request for the establishment of a panel as elaborated in its first written submission, it constitutes part of "the matter referred to the DSB by the United States in ... document [WT/DS50/4]".

Request for Suggestion Concerning Implementation

7.16 The reasoning underlying our finding in respect of the United States' claim on Article 63 of the TRIPS Agreement does not apply to the United States' request for a panel suggestion on implementation (item (f) in paragraph 7.6 above). However, we note that this particular request by the United States is not *sensu stricto* a legal claim. It is simply a request for the Panel to exercise its discretionary authority under Article 19.1, second sentence, of the DSU. In view of the fact that a panel can, on its own initiative, suggest how its recommendations should be implemented and that, in this particular case, the respondent was given an ample opportunity to present its views on the complainant's request, there is no reason why this Panel should not examine the United States' request.

7.17 In conclusion, we reject the procedural objections submitted by India and proceed with the examination of substantive issues.

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[75] See paragraph 1.3 above.

[76] We note that the interests of the third party in this particular case were not harmed on the issue of transparency. Independently from the United States' arguments, the European Communities had already referred to this issue in reaction to the first written submission from India at the third party session (see paragraph 5.2 above).

[77] Article 10.4 of the DSU.

[78] Rule 24, Working Procedures for Appellate Review, WT/AB/WP/3.

C. Interpretation of the TRIPS Agreement

7.18 Before examining specific measures in dispute, we first deal with a general interpretative issue, namely standards applicable to interpretation of the TRIPS Agreement. In the first instance, Article 3.2 of the DSU directs panels to clarify the provisions of the covered agreements, including the TRIPS Agreement, "in accordance with customary rules of interpretation of public international law". As a number of recent panel reports and Appellate Body reports have pointed out, customary rules of interpretation of public international law are embodied in the text of the 1969 Vienna Convention on the Law of Treaties ("Vienna Convention"). Article 31(1) of the Vienna Convention provides:

> "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."

Accordingly, the TRIPS Agreement must be interpreted in good faith in light of (i) the ordinary meaning of its terms, (ii) the context and (iii) its object and purpose. In our view, good faith interpretation requires the protection of legitimate expectations derived from the protection of intellectual property rights provided for in the Agreement. A similar view has also been taken in the *Underwear* panel report:

> "[T]he relevant provisions [of the Agreement on Textiles and Clothing] have to be interpreted in good faith. Based upon the wording, the context and the overall purpose of the Agreement, exporting Members can ... legitimately expect that market access and investments made would not be frustrated by importing Members taking improper recourse to such action." [79]

7.19 Second, we must bear in mind that the TRIPS Agreement, the entire text of which was newly negotiated in the Uruguay Round and occupies a relatively self-contained, *sui generis* status in the WTO Agreement, nevertheless is an integral part of the WTO system, which itself builds upon the experience over nearly half a century under the General Agreement on Tariffs and Trade 1947 ("GATT 1947"). Indeed, Article XVI:1 of the WTO Agreement provides:

> "Except as otherwise provided under this Agreement or the Multilateral Trade Agreements, the WTO shall be guided by the decisions, procedures and customary practices followed by the CONTRACTING PARTIES to GATT 1947 and the bodies established in the framework of GATT 1947."

Since the TRIPS Agreement is one of the Multilateral Trade Agreements, we must be guided by the jurisprudence established under GATT 1947 in interpreting the provisions of the TRIPS Agreement unless there is a contrary provision. As the Appellate Body indicated in the *Japan -Alcoholic Beverages* case, adopted panel

[79] Panel Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", adopted on 25 February 1997, WT/DS24/R, para. 7.20.

reports "create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute".[80] Indeed, in light of the fact that the TRIPS Agreement was negotiated as a part of the overall balance of concessions in the Uruguay Round, it would be inappropriate not to apply the same principles in interpreting the TRIPS Agreement as those applicable to the interpretation of other parts of the WTO Agreement.

7.20 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).[81] Regarding Article III of GATT, the panel on *Italian Agricultural Machinery* stated that "the intent of the drafters was to provide equal conditions of competition once goods had been cleared through customs".[82] This principle was later elaborated by the *Superfund* panel, which stated that "[t]he general prohibition of quantitative restrictions under Article XI ... and the national treatment obligation of Article III ... have the same rationale, namely to protect expectations of the contracting parties as to the competitive relationship between their products and those of the other contracting parties".[83] The panel on *Section 337*, which dealt with issues involving protection of intellectual property at the border, also reached similar conclusions.[84]

7.21 The protection of legitimate expectations is central to creating security and predictability in the multilateral trading system. In this connection, we note that disciplines formed under GATT 1947 (so-called GATT *acquis*) were primarily directed at the treatment of the goods of other countries, while rules under the TRIPS Agreement mainly deal with the treatment of nationals of other WTO Members. While this calls for the concept of the protection of legitimate expectations to apply in the TRIPS areas 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), it does not in our view make inapplicable the underlying principle. The Preamble to the TRIPS Agreement, which recognizes the need for new rules and disciplines concerning "the applicability of the basic principles of GATT 1994 ...", provides a useful context in this regard.

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[80] Appellate Body Report on "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS13/AB/R, DSR 1996:I, 97 at 108.

[81] We note in this regard that Article 64 of the TRIPS Agreement (on dispute settlement) provides for the application of Article XXIII of GATT 1994, as elaborated by the DSU, to the settlement of disputes under the TRIPS Agreement.

[82] Panel Report on "Italian Discrimination against Imported Agricultural Machinery", adopted on 23 October 1958, BISD 7S/60, para. 12-13.

[83] Panel Report on "United States - Taxes on Petroleum and Certain Imported Substances", adopted on 17 June 1987, BISD 34S/136, para. 5.2.2.

[84] Panel Report on "United States - Section 337 of the Tariff Act of 1930", adopted on 7 November 1989, BISD 36S/345, para. 5.13.

7.22 In conclusion, we find 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.

D. Article 70.8

7.23 We now turn to the examination of the United States' claim on Article 70.8 of the TRIPS Agreement. Article 70.8 provides as follows:

> "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)."

The United States claims that India has failed to fulfil its obligations under this paragraph by not establishing a valid system for receiving "mailbox" applications. In this regard, we note that the only obligation India currently assumes under this paragraph is that of subparagraph (a), the effective date of which is "the date of entry into force of the WTO Agreement", i.e., 1 January 1995. Obligations under subparagraphs (b) and (c) will become binding on India only "as of the date of application of this Agreement", which in this particular instance means no later than 1 January 2005 by virtue of the provisions of paragraphs 2 and 4 of Article 65 of the TRIPS Agreement. Thus, the question before this Panel is whether India has taken the action necessary to implement its obligations under subparagraph (a) of Article 70.8.

Nature of the Obligations

7.24 Subparagraph (a) of Article 70.8, like all other provisions of the covered agreements, must be interpreted in good faith in light of (i) the ordinary meaning of its terms; (ii) the context; and (iii) its object and purpose, following the rules set out in Article 31(1) of the Vienna Convention.[85]

7.25 Subparagraph (a) starts with the phrase "notwithstanding the provisions of Part VI". This indicates that this provision is an exception to the transitional arrangements contained in Part VI of the TRIPS Agreement. Thus, if a Member does not make available as of 1 January 1995 patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member cannot avail itself of a transitional period under Article 65 regarding the operation of this subparagraph. This is clear from the textual analysis, and in any event is not in dispute between the parties. The substantive obligation to be assumed by such a Member as from 1 January 1995 is to provide "a means" by which applications for patents for inventions in respect of pharmaceutical and agricultural chemical products "can be filed". The 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.

7.26 We thus need to analyze the context of this subparagraph. The means for filing is necessary because, under subparagraphs (b) and (c), a Member which does not make patents available as of 1 January 1995 for pharmaceutical and agricultural chemical products must examine, after the expiry of the transitional period, the applications so filed and must accord patent protection for those products that meet certain criteria. In addition, the Member is obligated to grant exclusive marketing rights to those products that meet the conditions set out in Article 70.9 even during the transitional period. The terms of subparagraph (a) must be understood in this context.

7.27 Furthermore, the object and purpose of Article 70.8 must be taken into account in our analysis. There seems to be a common understanding between the parties to the dispute regarding the object and purpose of subparagraph (a). India concedes that the purpose of subparagraph (a) is to "*ensure* that each patent applicant obtains a date of filing on the basis of which patent protection [can] be granted as from the date on which Article 27 applies and that exclusive marketing rights [can] be granted to products at the point at which they are eligible for such rights" (*emphasis added*).[86] We affirm this view. The object and purpose of Article 70.8(a) can be derived from the structure of the TRIPS Agreement. Article 27 requires that patents be made available in all fields of technology, subject to certain narrow exceptions. Article 65 provides for transitional periods for developing countries: in general five years from the entry into force of the WTO Agreement, i.e. 1 January 2000, and an additional five years to provide for product patents in

[85] See paragraph 7.18 above.
[86] Paragraph 4.9 above.

areas of technology not so patentable as of 1 January 2000. Thus, in such areas of technology, developing countries are not required to provide product patent protection until 1 January 2005. However, these transitional provisions are not applicable to Article 70.8, which ensures that, if product patent protection is not already available for pharmaceutical and agricultural chemical product inventions, a means must be in place as of 1 January 1995 which allows for the entitlement to file patent applications for such inventions and the allocation of filing and priority dates to them so that the novelty of the inventions in question and the priority of the applications claiming their protection can be preserved for the purposes of determining their eligibility for protection by a patent at the time that product patent protection will be available for these inventions, i.e. at the latest after the expiry of the transitional period.

7.28 In order to achieve the object and purpose of Article 70.8, there must be a mechanism to preserve the novelty of pharmaceutical and agricultural chemical inventions which are currently outside the scope of product patent protection and the priority of applications claiming their protection, for the purposes of determining their eligibility for protection by patents. Once these inventions can be protected by product patents, Article 27 requires them to be available for, at least, those inventions that are (i) new, (ii) involve an inventive step and (iii) are capable of industrial application. In accordance with the normal meaning of these conditions, an invention is new and involves an inventive step if, at the filing date or, if applicable, the priority date of the application in which patent protection is claimed, the invention did not form part of the prior art and required an inventive step to be deduced from that prior art by a person skilled in the art. Thus, in order to prevent the loss of the novelty of an invention in this sense, 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. In our view, preservation of novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions so as to provide for effective future patent protection after examination of the applications as of, at the latest, 1 January 2005 is the central object and purpose of Article 70.8(a). This is a special obligation imposed on those Members benefitting from the transitional arrangements.

7.29 The findings above can be confirmed by the negotiating history of the TRIPS Agreement.[87] We note that in the negotiation of the TRIPS Agreement the question of patent protection for pharmaceutical and agricultural chemical products was a key issue, which was negotiated as part of a complex of related issues con-

[87] We note that Article 32 of the Vienna Convention gives the negotiating history a status of "supplementary means of interpretation" only. Here we use it only to confirm the meaning resulting from the application of the rules set out in Article 31 of the Vienna Convention.

cerning the scope of the protection to be accorded to patents and some related rights and the timing of the economic impact of such protection. A critical part of the deal struck was that developing countries that did not provide product patent protection for pharmaceuticals and agricultural chemicals were permitted to delay the introduction thereof for a period of ten years from the entry into force of the WTO Agreement. However, if they chose to do so, they were required to put in place a means by which patent applications for such inventions could be filed so as to allow the preservation of their novelty and priority for the purposes of determining their eligibility for protection by a patent after the expiry of the transitional period. In addition, they were required to provide also for exclusive marketing rights in respect of the products in question if those products obtained marketing approval during the transitional period, subject to a number of conditions. It is our view that this means that Article 70.8(a) requires the developing countries 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 takes away any reasonable doubts as to 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.

7.30 Finally, we recall that one of the precepts developed under GATT 1947 is that rules and disciplines governing the multilateral trading system serve to protect legitimate expectations of Members as to the competitive relationship between their products and those of the other Members.[88] As the *Superfund* panel pointed out, such rules and disciplines "are not only to protect current trade but also to create the predictability needed to plan future trade".[89] Predictability in the intellectual property regime is indeed essential for the nationals of WTO Members when they make trade and investment decisions in the course of their businesses.

7.31 To sum up, in determining whether India has taken the action necessary to implement its obligations under subparagraph (a) of Article 70.8, we need to examine whether the current Indian system for the receipt of mailbox applications can sufficiently protect the legitimate expectations of other WTO Members as to the competitive relationship between their nationals and those of other Members, by ensuring the preservation of novelty and priority in respect of products which were the subject of mailbox applications. Our findings are not based on the notion that, to implement Article 70.8(a) fully, a Member must already, as of 1 January 1995, have created the rights that will be granted after 2005: i.e., the Member must already have amended its patent law to provide that mailbox applications *will* lead to the grant of patents after 2005 if the conditions foreseen in paragraphs (b) and (c) of Article 70.8 are met. Rather, as indicated in paragraphs 7.28 and 7.29 above, our view is that Article 70.8(a) requires the Members in question to establish a means

[88] See paragraphs 7.20 and 7.21 above.

[89] Panel Report on "United States - Taxes on Petroleum and Certain Imported Substances", *op. cit.*, para. 5.2.2.

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. Since we are not concluding that immediate action should be taken to give effect to the conditions of competition that must prevail after 1 January 2005 through the mechanism of Article 70.8 (b) and (c), we do not consider our findings would have the implications for the transitional periods under other WTO agreements to which India has alluded.[90] We are, however, of the view that India does have an obligation to take legislative measures as from 1 January 1995 to the extent that such measures are necessary in India to implement Article 70.8(a) in the way indicated above. In other words, we do not agree with India that the transitional arrangements of the TRIPS Agreement necessarily relieve India of the obligation to make legislative changes in its patent regime during the first five years of operation of the Agreement. As indicated in paragraph 7.28 above, Article 70.8(a) is a special obligation linked with the possibility of some developing country Members to avail themselves of an extended transitional period until 1 January 2005. Not to require this provision to be implemented with a sound legal basis would upset the delicate balance of the transitional arrangements of Articles 65, 70.8 and 70.9 that was negotiated during the Uruguay Round.

Mechanism for Implementing the Obligations

7.32 The United States claims that Indian law must be modified to implement India's obligations under Article 70.8 and that the current administrative practice of receiving mailbox applications is not a valid "means" for implementation. The United States claims that the Indian administration itself had admitted the necessity of legislative changes when it promulgated the Patents (Amendment) Ordinance 1994, the issuance of which was permissible only if the President "is satisfied that the circumstances exist which render it necessary for him to take immediate action" under Article 123 of the Indian Constitution.[91] To this argument, India essentially points out that Article 70.8 does not prescribe the choice of a particular method of implementation. India further points out that the purpose of Article 123 of the Indian Constitution is to enable legislation even when Parliament is not in session, and the United States' reading of the term "necessary" is an incorrect one.[92]

7.33 In respect of this particular issue, we note that Article 1.1 of the TRIPS Agreement provides in part as follows:

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[90] See paragraph 4.9 above.
[91] See paragraphs 4.3 and 7.3 above.
[92] See paragraph 4.6 above.

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

Thus, it is up to India to decide how to implement its obligations under Article 70.8. We therefore find that the mere fact that India relies on an administrative practice to receive mailbox applications without legislative changes does not in itself constitute a violation of India's obligations under subparagraph (a) of Article 70.8. The lapse of the Patents (Amendment) Ordinance 1994, which was promulgated for the purpose of specifically addressing these obligations, does not automatically mean the lack of a "means" for filing patent applications for pharmaceutical and agricultural chemical products in India.

7.34 However, in order to make an objective assessment regarding the consistency of the current Indian mechanism with the TRIPS Agreement, as required under Article 11 of the DSU, we must ask ourselves the following question: can that mechanism achieve the object and purpose of Article 70.8 and thereby protect the legitimate expectations of other WTO Members, by ensuring the preservation of novelty and priority in respect of products which were the subject of mailbox applications? To answer this, we need to analyze the current Indian system from the viewpoint of whether it ensures the degree of legal security and predictability for patent applicants of other WTO Members that they are entitled to legitimately expect under the provisions of Article 70.8(a). There appear to be a few serious problems.

7.35 First, under Section 12(1) of the Patents Act 1970, when the complete specification has been filed in respect of a patent application, the Controller must refer the matter to an examiner. Section 12(2) clearly obliges the examiner ordinarily to complete examination within 18 months from the date of reference from the Controller.[93] Under Section 15(2) of the Patents Act, any application for the grant of a patent on a pharmaceutical or agricultural chemical product must be refused by the Controller for lack of patentability.[94] In light of these provisions, 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. We recall that the *Malt Beverages* panel dealt with a similar issue. There, the respondent offered as a defence that certain GATT-inconsistent legislation was not currently enforced. The panel rejected this defence by stating as follows:

> "Even if Massachusetts may not currently be using its police powers to enforce this mandatory legislation, the measure continues to be mandatory legislation which may influence the decisions of economic operators. Hence, a non-enforcement of a mandatory law

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93 See paragraph 2.10 above.

94 *Id*. Furthermore, under Section 9 of the Patents Act, a complete specification must be filed within 12 months of the filing of a provisional application, failing which the application is deemed abandoned (see Annex 1 of this report).

> in respect of imported products does not ensure that imported beer and wine are not treated less favourably than like domestic products to which the law does not apply."[95]

We find great force in this line of reasoning. There is no denying that economic operators -in this case potential patent applicants - are influenced by the legal insecurity created by the continued existence of mandatory legislation that requires the rejection of product patent applications in respect of pharmaceutical and agricultural chemical products. We note that the present situation is slightly different from the *Malt Beverages* case in that India is entitled to retain this mandatory legislation until 1 January 2005 by virtue of Article 65.4 of the TRIPS Agreement. The existence of the legislation *per se* is not a problem under the TRIPS Agreement. However, in the absence of clear assurance that applications for pharmaceutical and agricultural chemical product patents will not be rejected and that novelty and priority will be preserved despite the wording of the Patents Act, the legal insecurity remains.

7.36 This legal insecurity is further compounded by the lapse of the Patents (Amendment) Ordinance 1994, which formally and publicly established legal procedures for the receipt of mailbox applications. This is a particular problem according to the United States because a group of Indian patent law experts advised the Indian Government that a formal legal basis for mailbox applications was required to give them legitimacy under Indian law. Although India counters that the group issued no specific report on this issue and that the group contained patent law and not constitutional law experts, a press note issued at the time of the promulgation of the Ordinance indicates that the Ordinance was based in part on the group's recommendations.[96]

7.37 Second, even if Patent Office officials do not examine and reject mailbox applications, a competitor might seek a judicial order to force them to do so in order to obtain rejection of a patent claim.[97] If the competitor successfully establishes the illegality of the separate storage and non-examination of mailbox applications before a court, the filing of those applications could be rendered meaningless. The

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[95] Panel Report on "United States - Measures Affecting Alcoholic and Malt Beverages", adopted on 19 June 1992, BISD 39S/206, para. 5.60.

[96] See paragraph 2.4 above. We also note that the Preamble to the Patents Ordinance contained the following passage: "... whereas with a view to meeting India's obligations, it has become necessary to amend the Patents Act 1970 in conformity with the obligations under the [WTO] agreement ..." (see document IP/N/1/IND/1). While India is, as discussed above, free to choose the legal form of implementing its obligations under the WTO Agreement, we note that India has not officially and publicly changed or corrected the view expressed in this Preamble.

[97] Because, under the current Indian system, patent applications for pharmaceutical and agricultural chemical products are not examined and such applications are not published, competitors might not be in a position to raise objections. However, since data such as the title of the invention, the filing date of the application and the name of the applicant are publicized in the Official Gazette, competitors will often be able to find out with which patent applications filed in other countries the applications correspond.

evidence submitted by India - two Supreme Court rulings on administrative practices - does not sufficiently demonstrate that a court will uphold the validity of administrative actions which apparently contradict mandatory legislation. One case cited by India involved a situation where the administrative practice was not contrary to the statutory provisions. In the other case, the Supreme Court reached a conclusion that administrative guidelines had no statutory force and conferred no right on any citizen to complain that they were not being met.[98] These cases may confirm the Indian position that its reliance on an administrative practice regarding the handling of pharmaceutical and agricultural chemical product patent applications is not unconstitutional, but they do not specifically answer the question we are facing, i.e., whether a court will uphold the validity of administrative actions which apparently contradict mandatory legislation.

7.38 Third, despite India's commitment to seek legislative changes before the expiry of the transitional period available to it, without a sufficient legal basis now for preserving novelty and priority, there would remain doubt during the transitional period regarding the eligibility of these products for future patent protection. As a result, the legal status of patent applications in respect of these products would remain insecure and unpredictable for a possibly long period, which could last until 1 January 2005.

7.39 The fact that patent applications have been filed in respect of pharmaceutical and agricultural chemical products does not alter the situation. It is unknowable how many applications would have been filed if an appropriate system had been in place. As it appears that a number of United States' pharmaceutical companies do not believe that India has established a mailbox application system, and consequently have not filed applications for patent protection of pharmaceutical products[99], it is reasonable to assume that potential applicants both in India and outside the country have lost opportunities for patent protection for their products in a belief that there is no mechanism to secure their rights. In this regard, we note that the interests of those persons who would have filed patent applications had there been an appropriate mechanism in place after the expiry of the Patents (Amendment) Ordinance 1994 should be protected, since the lack of an adequate mailbox application system has effectively deprived them of benefits which they would have enjoyed in the future under the TRIPS Agreement.

7.40 The United States has raised these questions in a persuasive manner. 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".[100] 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

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[98] See paragraphs 4.10 and 4.12 above.

[99] See Annex 3 of this report.

[100] Appellate Body Report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India", adopted on 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 337.

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, again to paraphrase the Appellate Body, 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.

7.41 In consideration of the above, we find that the lack of legal security in the operation of the mailbox system in India is such that the system cannot adequately achieve the object and purpose of Article 70.8 and protect legitimate expectations contained therein for inventors of pharmaceutical and agricultural chemical products. It would be extremely difficult to make informed trade and investment decisions based upon the current legal situation in India. To quote again from the *Superfund* panel, "the predictability needed to plan future trade" cannot be created under the system.[101] Thus, security and predictability in the multilateral trading system, which is one of the central goals of the dispute settlement mechanism, cannot be achieved. Consequently, the answer to the question we posed ourselves in paragraph 7.34 above clearly cannot be answered in the affirmative.

7.42 Furthermore, independently of India's transparency obligations under Article 63, we believe that there is a serious issue in the current Indian system of mailbox applications in that it is not made public. Within the context of Article 70.8, it may be questioned whether unpublicized administrative practices can be regarded as "a means by which applications for patents for such inventions *can* be filed". If the means is not publicized, how can an inventor file a claim? India argues that "it [is] sufficient that individual companies that [wish] to submit an application [can] obtain the necessary information from the relevant authorities".[102] In our view, the mere existence of such possibility is hardly sufficient, even if we take into account the fact that economic operators in this area are usually well informed about systems for the protection of their rights. There must be a guarantee that the public - including interested nationals of other WTO Members - is adequately informed. For potential applicants from other WTO Members to be adequately informed, it is arguable that they must not only have information about the existence of a system for the filing of patent applications for pharmaceutical and agricultural chemical products, but also be informed of the purpose of such a system, i.e., to protect the novelty of the inventions in question and the priority of the applications claiming their protection so that the applications concerned are capable of leading to the grant of a patent under the conditions of subparagraphs (b) and (c) of Article 70.8, and to lead to the grant of exclusive marketing rights under the conditions set out in Article 70.9 even during the transitional period. Otherwise, the security and predictability necessary for the operation of the TRIPS Agreement would be lost, and legitimate expectations of interested nationals of other WTO Members would not be protected. However, we make no specific finding on the points discussed in this

[101] See paragraph 7.30 above.
[102] See paragraph 4.7 above.

paragraph, since we deal in more detail with the transparency claim in the following section.

7.43 In conclusion, we find that India has failed to take the action necessary to implement its obligations under subparagraph (a) of Article 70.8 because of the lack of legal security regarding the status of product patent applications in respect of pharmaceutical and agricultural chemical products under the system it presently operates.

E. Article 63

7.44 The United States claims that India has violated Article 63 of the TRIPS Agreement by its failure to make public any information on the existence of a new system for the filing of mailbox applications after the expiry of the Patents (Amendment) Ordinance 1994. Although the United States formulates it as an alternative claim in the event that the Panel were to find that India has a valid mailbox system in place, and we have, as stated above, found that the current mailbox system in India is at variance with Article 70.8(a) of the TRIPS Agreement, we believe it necessary to make our findings clear on the issue of transparency in order to avoid a legal vacuum in the event that, upon appeal, the Appellate Body were to reverse our findings on Article 70.8.[103]

7.45 In response to the United States' claim, India argues - apart from the procedural objections described earlier - that under Article 65.2 India, as a developing country, is entitled to delay the application of Article 63 until 1 January 2000. Paragraphs 1 and 2 of Article 63 read as follows:

> "1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.
>
> "2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify

[103] See paragraphs 6.6 to 6.12 above.

> such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967)."

Paragraphs 1 and 2 of Article 65 further read as follows:

> "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."

7.46 The issue before the Panel is whether this exemption should be understood to cover the transparency obligations under Article 63 or whether such a procedural obligation to publish and notify national laws and regulations should be understood as becoming applicable at the time that a Member is obliged to start applying a substantive provision of the TRIPS Agreement, i.e. that the timing of the transparency obligation is a function of the timing of the substantive obligation. In the former case, India would not be under an obligation to publish and notify, as from 1 January 1995, laws and regulations giving effect to the requirements of Article 70.8(a). In examining this matter, we note that the TRIPS Agreement contains a range of procedural and institutional provisions, relating not only to transparency but also to dispute settlement, the establishment of the Council for TRIPS and international cooperation, which have to be understood, and have been understood in the practice of the Council for TRIPS, as applying either from 1 January 1995 or from the time that the corresponding substantive provision has to be met consistently with the provisions of Part VI and Article 70. An example is Part V of the TRIPS Agreement on "Dispute Prevention and Settlement", which includes both transparency provisions (Article 63) and dispute settlement provisions (Article 64). If transparency provisions were not applicable to India by virtue of Article 65.2, then the logical conclusion would be that dispute settlement provisions are equally not applicable. This clearly cannot be the case and we reject the Indian argument on this point.

7.47 We also note that the WTO Members have confirmed this understanding in the actions taken by the Council for TRIPS. The Council has considered Article 63.2 as requiring that "as of the time that a Member is obliged to start applying a provision of the TRIPS Agreement, the corresponding laws and regulations shall be

notified without delay".[104] Moreover, the Preparatory Committee for the World Trade Organization, which met in 1994, noted that "one substantive obligation, Article 70.8, which comes into force as of the date of entry into force of the WTO Agreement was referred to and there was acceptance that, under Article 63.2, national laws and regulations should be notified as of the time that the corresponding substantive obligation applies".[105] The Preparatory Committee's report was adopted by the General Council in January 1995 as reflected in document WT/GC/M/1. In our view, such an interpretation is fully consistent with the terms of the TRIPS Agreement in their context and in the light of its object and purpose. The purpose of the notification obligation in Article 63.2 is "to assist [the Council for TRIPS] in its review of the operation of this Agreement". In order to undertake this task, clearly the Council needs the information as from the time that obligations become applicable.

7.48 It is clear that a mechanism for receiving mailbox applications is, whether made effective by law or through administrative practices, a measure "of general application" within the meaning of Article 63.1. As the *Underwear* panel observed in respect of Article X of GATT 1994, to the extent the measure "affects an unidentified number of economic operators, including domestic and foreign producers", it is a measure of general application.[106] Thus, India has an obligation to publish or, where this is not practicable, make publicly available the specific terms and provisions of its mailbox system in such a manner as to enable governments and right holders to become acquainted with them under Article 63.1 of the TRIPS Agreement. India claims that the existence of the mailbox system was recognized in a written answer from the Government to a question in Parliament.[107] However, such a way of conveying information cannot be regarded as a sufficient means of publicity under Article 63.1 of the TRIPS Agreement. India has not complied with this obligation. Equally, we find unpersuasive the Indian claim that only the Patents Act 1970, on which the administrative practices are based, is subject to the publication requirement. In view of the fact that the Patents Act contains mandatory provisions which are contrary to the administrative practice, the text of the Patents Act alone would at best mislead the public regarding the existence of the mailbox system, and would not satisfy the requirement under Article 63.1.

7.49 With respect to its notification obligations under Article 63.2, it is evident that India did not notify to the Council for TRIPS the legal basis of the current sys-

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[104] Procedures for Notification of, and Possible Establishment of a Common Register of, National Laws and Regulations under Article 63.2, Decision of the Council for TRIPS of 21 November 1995 (see document IP/C/2).

[105] PC/R, paragraph 45, approving the reports and recommendations contained in document PC/IPL/7, paragraph 9.

[106] Panel Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", *op. cit.*, para. 7.65. This conclusion was upheld by the Appellate Body in its report on the same case, WT/DS24/AB/R, DSR 1997:I, 11 at 29.

[107] See Annex 2 of this report.

tem for the handling of mailbox applications after the expiry of the Patents (Amendment) Ordinance 1994.

7.50 In view of the above, we find that India has failed to comply with its transparency obligations under paragraphs 1 and 2 of Article 63 of the TRIPS Agreement.

F. Article 70.9

7.51 Finally, we turn to our examination of the United States' claim regarding exclusive marketing rights under Article 70.9 of the TRIPS Agreement. Article 70.9 reads as follows:

> "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."

It is not contested that currently there is neither legislation nor administrative practice in place in India regarding the grant of exclusive marketing rights on those products that satisfy the conditions of Article 70.9. India also admits that legislation is needed to effect a system of granting exclusive marketing rights. As noted above, the Patents (Amendment) Ordinance 1994 had provisions to establish such a system as of 1 January 1995, but the system lapsed with the expiry of the Ordinance.

7.52 The United States claims that the obligation to establish an exclusive marketing rights system arose on 1 January 1995 and that, since India has failed to provide for an exclusive marketing rights system in its legislation, it is currently not in compliance with Article 70.9. India claims that, since there has not been any request for the grant of exclusive marketing rights in India so far, India has not failed to implement its obligations under Article 70.9 and that India is not obligated to make exclusive marketing rights generally available before all the events specified in Article 70.9 have occurred. Thus, the central question before this Panel is that of timing: as of when should there be a mechanism ready for the grant of exclusive marketing rights?

7.53 To be more specific, this question contains two subquestions:

(a) Is India in breach of the TRIPS Agreement if, at the appropriate time, its executive authorities do not have the legal authority to grant exclusive marketing rights, even if the grant of such rights has not yet been refused to an eligible product?

(b) If the answer is yes, what is the appropriate time by which such legal authority must be provided?

In our view, the answer to question (a) is yes for the following reasons. Most of the provisions in the WTO Agreement aim to prevent governments from taking measures that might be harmful to trade and, therefore, concern the existence of legislation requiring governments to act in a way that is inconsistent with the obligations under the WTO Agreement. Thus, if a Member has legislation mandating the executive to act in such a way, it is in breach of its obligations even if that particular legislation has not yet been applied.[108] The TRIPS Agreement is different from other covered agreements in that most of its provisions require Members to take positive action; in this particular case to grant exclusive marketing rights pursuant to Article 70.9. In situations where it is necessary for a Member to give effect to such positive action, a failure to provide the executive with the required authority constitutes a breach of the Agreement, because the lack of the authority mandates the executive not to comply with the Member's WTO obligations. The underlying reasoning is that, as we have already discussed, the absence of legislation frustrates legitimate expectations regarding the conditions of competition.[109] Thus, if the executive branch of the Indian Government does not have the authority to give effect to the obligations under Article 70.9, it would be in breach of its obligations under the TRIPS Agreement even in the absence of a specific act of non-compliance. Given this analysis, the issue before the Panel becomes one of timing: as of when does the TRIPS Agreement oblige the Indian executive to have the necessary authority to grant exclusive marketing rights and, thus, protect the legitimate expectations of other Members as to the competitive relationship between their nationals and Indian nationals.

Textual Analysis

7.54 The starting point of our analysis on the question of timing should be the wording of Article 70.9.[110] We note that, as is also the case with Article 70.8, Article 70.9 uses the term "notwithstanding the provisions of Part VI". The ordinary meaning of this term clearly indicates that Members to which this provision applies cannot avail themselves of the transitional arrangements under Part VI, including Article 65. Thus, the effective date of this provision must be the date of entry into force of the WTO Agreement, which means a Member which is subject to the provisions of Article 70.9 must be ready to grant exclusive marketing rights at any point in time subsequent to 1 January 1995.

7.55 India seems to have reached a different conclusion based on the wording of Article 70.9. First, India notes that Article 70.9, in contrast to Article 70.8(a), does not contain the phrase "provide as from the date of entry into force of the WTO

[108] See, for instance, panel reports on "United States - Taxes on Petroleum and Certain Imported Substances", *op. cit.*, para. 5.2.9., and on "United States - Measures Affecting Alcoholic and Malt Beverages", *op. cit*., para. 5.59.

[109] See discussions in paragraphs 7.18 to 7.22 above and, for a concrete example of such frustration, paragraph 7.62 below.

[110] See paragraphs 7.18 and 7.24 above.

Agreement". However, this difference is not significant in view of the fact that Article 70.9 is directly tied to Article 70.8(a). Article 70.9 applies "where a product is the subject of a patent application in a Member in accordance with paragraph 8(a)". Given that Article 70.8(a) must be implemented as of the date of entry into force of the WTO Agreement, one would expect the same implementation date would apply in the absence of a clear indication to the contrary.

7.56 Second, India argues that the obligations under Article 70.9 should be distinguished from those under other provisions of the TRIPS Agreement because it uses the term "exclusive marketing rights shall be granted ...". According to India, there is a material difference between this expression and such other expressions as "patents shall be available ..." in Article 27.[111] We are not persuaded by this argument. Both parties agree that the implementation of Article 70.9 requires a system under which applications for exclusive marketing rights can be made. Articles 27 and 70.9 have a common basis in that they require a Member to establish a system for the grant of specific rights. Seen in this context, the terms "shall be available" and "shall be granted" can almost be used interchangeably.[112]

Context, Object and Purpose

7.57 The analysis of the context and the object and purpose of Article 70.9 does not change the above conclusion. Article 70.9, like all other provisions of the TRIPS Agreement, must be interpreted in good faith, taking into account legitimate expectations of other WTO Members. Clearly, Article 70.9 shares the object and purpose of Article 70.8, to which there is an explicit reference: i.e., to provide a degree of protection of the interests of inventors of pharmaceutical and agricultural chemical products during the transition period. India, while generally agreeing with this observation, tries to narrow down its scope by claiming that the purpose of Article 70.9 is to give such inventors the economic privilege of an exclusive marketing right only for the five-year period preceding 1 January 2005 if their product inventions remain unpatentable beyond the five-year transitional period for developing countries stipulated in Article 65.2. We are not convinced by this argument. The object and purpose of the provision is to provide for specific marketing rights. In context, they partly compensate for the absence of effective patent protection in countries which avail themselves of the transitional periods under the TRIPS Agreement. Such rights have to be granted as soon as the conditions are met any time after the entry into force of the WTO Agreement. Neither from the object and

[111] See paragraph 4.27 above.

[112] India maintains that the ordinary meaning of the term "available" is "at disposal" or "obtainable", which is presumably different from "granted". This argument would have been more persuasive if what is to be "granted" were an exclusive privilege accorded on an *ad hoc* basis. However, here we are dealing with exclusive marketing "rights". The term "right" connotes an entitlement to which a person has a just claim. As such, it implies general, non-discretionary availability in the case of those eligible to exercise it. In our view, an exclusive marketing right cannot be "granted" in a specific case unless it is "available" in the first place.

purpose of Article 70.9, nor from its context, nor from its text, do they take effect only after the year 2000.

7.58 India also appears to claim that the granting of exclusive marketing rights is not needed before 1 January 2000 based on the argument that it makes no commercial sense to obtain an exclusive marketing right for a five-year period unless that period is immediately followed by the period of full patent protection.[113] This is a mere speculation on how economic operators might react to a specific legal situation. Such a speculation does not entitle India to delay the application of its obligations under Article 70.9 until 1 January 2000, especially because there is no guarantee that the decision on the grant of patents will be taken on 1 January 2005.[114] We are not persuaded by the economic logic of this speculation, either. Depending on the situation of a particular market, an exclusive marketing right for a period of five years followed by a gap of a few years until full patent protection is granted some time subsequent to 1 January 2005 might be essential for manufacturers of pharmaceutical and agricultural chemical products in order to set up their position in the market. Competitors, knowing that the grant of subsequent patent protection is imminent, are likely to be discouraged from entering into the market during this brief window of opportunity.

7.59 India further argues that the transitional provisions of the TRIPS Agreement accord developing country Members the right to choose between providing for the patentability of the product inventions in question and the grant of exclusive marketing rights and that it would be logically inconsistent with this right to opt out of the obligation to grant exclusive marketing rights if Article 70.9 were interpreted to oblige Members to provide in their legislation for the general availability of exclusive marketing rights as from the date of entry into force of the WTO Agreement.[115] We do not find this argument to be persuasive. As is the case with Article 70.8(a), the granting of exclusive marketing rights is a special obligation linked with the enjoyment by Members of the transitional arrangements under Articles 65 and 66 of the Agreement.[116] To accept India's interpretation on this point would be to exonerate those Members from this obligation, upsetting the carefully negotiated balance of rights and obligations during the transitional period.

7.60 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. India suggests that this result ignores the fact that in reality it will take many years before anyone will be in a position to apply for the grant of exclusive marketing rights under Article 70.9. However, even if we accept that

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[113] See paragraph 4.27 above.

[114] If India were to use the full transitional period available to it, it would be obliged to examine the patentability of these inventions from 1 January 2005. This process could take some time with the result that the decision on grant would be taken somewhat later.

[115] See paragraph 4.27 above.

[116] See paragraph 7.28 above.

some delay after 1 January 1995 may well occur, we do not accept that the delay would extend to the date of the establishment of this Panel or that the result of our prior analysis should be changed. Under Article 70.9, exclusive marketing rights must be granted by India after a product meets the following conditions:

(a) A mailbox application has been filed in India in respect of a pharmaceutical or agricultural chemical product;

(b) A patent application has been filed in respect of that product in another WTO Member after 1 January 1995;

(c) The other Member has granted the patent;

(d) The other Member has approved the marketing of the product; and

(e) India has approved the marketing of the product.

India argues that "common sense and practical experience indicate[s] that all these steps [take] a long time and *normally* the products in question [will] not get on the market in a developing country before the expiry of the ten-year transitional period" (*emphasis added*).[117] That may be so. However, an average period of time is not relevant in this analysis. What really matters is when it would be possible for one product to meet the terms of Article 70.9. While one could generally argue that these events take some time to materialize, one can never indicate exactly how long they will take. Indeed, according to the United States, there is at least one United States' pharmaceutical company that has completed steps (b) through (d) above with respect to two products.[118]

7.61 We also note that steps (a), (b), (c) and (d) in the previous paragraph are events that are beyond the control of the authorities in India. In other words, they do not provide any definite basis for the postponement of the obligations under Article 70.9. Step (e) is under the control of the Indian authorities. However, if marketing approvals are denied purely for the purpose of delaying the grant of exclusive marketing rights, it would give rise to questions regarding good faith application of the TRIPS Agreement. Moreover, the range of products affected, i.e. pharmaceuticals and agricultural chemicals, is large and differing marketing approval regimes will apply according to the products in question.[119] For these reasons, we are not convinced that India can establish any specific date later than 1 January 1995 as the date by which it should have in place the legal means necessary to give effect to the exclusive marketing rights provisions of Article 70.9.

7.62 Postponement of the effective date cannot follow merely from the fact that there has been no request for the grant of exclusive marketing rights so far. Where, as we discussed with respect to Article 70.8, lack of legal security is likely to dis-

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[117] See paragraph 4.27 above.

[118] See paragraph 4.30 above. See also the discussion in paragraph 7.62 below.

[119] For example, India has indicated with respect to agricultural chemicals that "marketing approvals would depend on the submission of satisfactory data by the applicant and the satisfaction of the Registration Committee constituted under the Insecticides Act" (see paragraph 4.29, above).

courage potential applicants to file an application,[120] this is certainly the case if a system is non-existent. The lack of a system may discourage applications, and the lack of applications may prolong the lack of a system. This appears to be a real issue. We recall that the evidence put forward by the United States indicates that there is a possibility that at least one United States' manufacturer, which has received marketing approval in the United States and Europe, might apply for the grant of exclusive marketing rights in India. According to the United States, "[t]he company was wary about proceeding without knowing what the system for the grant of such right was, for fear of losing its ability to receive [exclusive marketing] rights because of some procedural problem".[121]

Conclusion

7.63 In conclusion, we find that India has failed to implement its obligations under Article 70.9 and honour the legitimate expectations of its trading partners to that effect. It is the obligation of Members to establish a system for the grant of exclusive marketing rights to be available at any time after entry into force of the WTO Agreement.

7.64 In this connection, the United States requests this Panel to find that the obligations under Article 70.9 include the granting to the holder of marketing rights the exclusive right to control the entry of competitors onto the market during the period of those rights "so that competitors of the owner will not be permitted on the market absent the owner's consent". We consider a finding on the nature of the right to be granted under Article 70.9 unnecessary to settle this particular dispute, which concerns the current non-existence of an exclusive marketing rights system in India. Rather, it is sufficient for the Panel to recommend that India bring itself into conformity with its obligations under the TRIPS Agreement.

G. Suggestions by the Panel

7.65 Regarding the United States' request that this Panel suggest that India implement its obligations under paragraphs 8 and 9 of Article 70 in a manner similar to the way in which Pakistan has indicated it is implementing these obligations, as reflected in document WT/DS36/4, we do not deem such a suggestion appropriate, since it would impair India's right to choose how to implement the TRIPS Agreement pursuant to its Article 1.1.

7.66 We recall, however, that we have noted that the interests of those persons who would have filed patent applications had there been an appropriate mechanism in place after the expiry of the Patents (Amendment) Ordinance 1994 should be protected, since the lack of an adequate mailbox application system has effectively

[120] See paragraph 7.41 above.
[121] See paragraph 4.30 above and Annex 3 of this report.

deprived them of benefits which they would have enjoyed in the future.[122] The interests of those who have already filed such applications under the Patents (Amendment) Ordinance 1994 or the administrative practices currently in place should also be protected. We deem it appropriate to make a suggestion in this regard. This suggestion is not a declaratory judgement. Rather, it should be understood as an attempt to secure a positive solution to this dispute as required under Article 3.7 of the DSU.

VIII. CONCLUSIONS

8.1 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.

8.2 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. The Panel further suggests that, in establishing a mechanism that preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period, India should take into account the interests of those persons who would have filed patent applications had an appropriate mechanism been maintained since the expiry of the Patents Ordinance 1994, as well as those who have already filed such applications under that Ordinance or the administrative practices currently in place.

[122] See paragraph 7.39 above.

ANNEX 1

INDIA

The Patents Act, 1970[123]
(No. 39 of 1970)

Section 2

(1) In this Act, unless the context otherwise requires, -

.....

(j) "invention" means any new and useful -

(i) art, process, method or manner of manufacture;

(ii) machine, apparatus or other article;

(iii) substance produced by manufacture,

and includes any new and useful improvement of any of them, and an alleged invention;

.....

(l) "medicine or drug" includes -

(i) all medicines for internal or external use of human beings or animals,

(ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals,

(iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals,

(iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants;

(v) all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to;

.....

Chapter II - Inventions not patentable

Section 5

In the case of inventions -

[123] The short title.

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Chapter III - Applications for patents

Section 6

(1) Subject to the provisions contained in section 134, an application for a patent for an invention may be made by any of the following persons, that is to say, -

(a) by any person claiming to be the true and first inventor of the invention;

(b) by any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application;

(c) by the legal representative of any deceased person who immediately before his death was entitled to make such an application.

(2) An application under sub-section (1) may be made by any of the persons referred to therein either alone or jointly with any other person.

Section 7

(1) Every application for a patent shall be for one invention only and shall be made in the prescribed form and filed in the patent office.

(2) Where the application is made by virtue of an assignment of the right to apply for a patent for the invention, there shall be furnished with the application, or within such period as may be prescribed after the filing of the application, proof of the right to made the application.

(3) Every application under this section shall state that the applicant is in possession of the invention and shall name the owner claiming to be the true and first inventor; and where the person so claiming is not the applicant or one of the applicants, the application shall contain a declaration that the applicant believes the person so named to be the true and first inventor.

(4) Every such application (not being a convention application) shall be accompanied by a provisional or complete specification.

Section 8

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application -

(a) a statement setting out the name of the country where the application is being prosecuted, the serial number and date of filing of the application and such other particulars as may be prescribed; and

(b) an undertaking that, up to the date of the acceptance of his complete specification filed in India, he would keep the Controller informed in writing, from time to time, of details of the nature referred to in clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) The Controller may also require the applicant to furnish, as far as may be available to the applicant, details relating to the objections, if any, taken to any such application as is referred to in sub-section (1) on the ground that the invention is lacking in novelty or patentability, the amendments effected in the specifications, the claims allowed in respect thereof and such other particulars as he may require.

Section 9

(1) Where an application for a patent (not being a convention application) is accompanied by a provisional specification, a complete specification shall be filed within twelve months from the date of filing of the application, and if the complete specification is not so filed the application shall be deemed to be abandoned:

Provided that the complete specification may be filed at any time after twelve months but within fifteen months from the date aforesaid, if a request to that effect is made to the Controller and the prescribed fee is paid on or before the date on which the complete specification is filed.

(2) Where two or more applications in the name of the same applicant are accompanied by provisional specifications in respect of inventions which are cognate or of which one is a modification of another and the Controller is of opinion that the whole of such inventions are such as to constitute a single invention and may properly be included in one patent, he may allow one complete specification to be filed in respect of all such provisional specifications.

(3) Where an application for a patent (not being convention application) is accompanied by a specification purporting to be a complete specification, the Controller may, if the applicant so requests at any time before the acceptance of the specification, direct that such specification shall be treated for the purposes of this Act as a provisional specification and proceed with the application accordingly.

(4) Where a complete specification has been filed in pursuance of an application for a patent accompanied by a provisional specification or by a specification treated by virtue of a direction under sub-section (3) as a provisional specification, the Controller may, if the applicant so requests at any time before the acceptance of the complete specification, cancel the provisional specification and post-date the application to the date of filing of the complete specification.

Section 10

(1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject matter to which the invention relates.

(2) Subject to any rules that may be made in this behalf under this Act, drawings may, and shall, if the Controller so requires, be supplied for the purposes of any specification whether complete or provisional; and any drawings so supplied shall, unless the Controller otherwise directs, be deemed to form part of the specification, and references in this Act to a specification shall be construed accordingly.

(3) If, in any particular case, the Controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an invention, such model or sample as he may require shall be furnished before the acceptance of the application, but such model or sample shall not be deemed to form part of the specification.

(4) Every complete specification shall -

(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

(c) end with a claim or claims defining the scope of the invention for which protection is claimed.

(5) The claim or claims of a complete specification shall relate to a single invention, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification and shall, in the case of an invention such as is referred to in section 5, relate to a single method or process of manufacture.

(6) A declaration as to the inventorship of the invention shall, in such cases as may be prescribed, be furnished in the prescribed form with the complete specification or within such period as may be prescribed after the filing of that specification.

(7) Subject to the foregoing provisions of this section, a complete specification filed after a provisional specification may include claims in respect of developments of, or additions to, the invention which was described in the provisional specification, being developments or additions in respect of which the applicant would be entitled under the provisions of section 6 to make a separate application for a patent.

Section 11

(1) There shall be a priority date for each claim of a complete specification.

(2) Where a complete specification is filed in pursuance of a single application accompanied by -

(a) a provisional specification; or

(b) a specification which is treated by virtue of a direction under subsection (3) of section 9 as a provisional specification,

and the claim is fairly based on the matter disclosed in the specification referred to in clause (a) or clause (b), the priority date of that claim shall be the date of the filing of the relevant specification.

(3) Where the complete specification is filed or proceeded with in pursuance of two or more applications accompanied by such specifications as are mentioned in sub-section (2) and the claim is fairly based on the matter disclosed -

(a) in one of those specifications, the priority date of that claim shall be the date of the filing of the application accompanied by that specification;

(b) partly in one and partly in another, the priority date of that claim shall be the date of the filing of the application accompanied by the specification of the later date.

(4) Where the complete specification has been filed in pursuance of a further application made by virtue of sub-section (1) of section 16 and the claim is fairly based on the matter disclosed in any of the earlier specifications, provisional or complete, as the case may be, the priority date of that claim shall be the date of the filing of that specification in which the matter was first disclosed.

(5) Where, under the foregoing provisions of this section, any claim of a complete specification would, but for the provisions of this sub-section, have two or more priority dates, the priority date of that claim shall be the earlier or earliest of those dates.

(6) In any case to which sub-sections (2), (3), (4) and (5) do not apply, the priority date of a claim shall, subject to the provisions of section 137, be the date of filing of the complete specification.

(7) The reference to the date of the filing of the application or of the complete specification in this section shall, in cases where there has been a post-dating under section 9 or section 17 or, as the case may be, an ante-dating under section 16, be a reference to the date as so post-dated or ante-dated.

(8) A claim in a complete specification of a patent shall not be invalid by reason only of -

(a) the publication or use of the invention so far as claimed in that claim on or after the priority date of such claim; or

(b) the grant of another patent which claims the invention, so far as claimed in the first mentioned claim, in a claim of the same or a later priority date.

Chapter IV - Examination of applications

Section 12

(1) When the complete specification has been filed in respect of an application for a patent, the application and the specification relating thereto shall be referred by the Controller to an examiner for making a report to him in respect of the following matters, namely: -

(a) whether the application and the specification relating thereto are in accordance with the requirements of this Act and of any rules made thereunder;

(b) whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application;

(c) the result of investigations made under section 13; and

(d) any other matter which may be prescribed.

(2) The examiner to whom the application and the specification relating thereto are referred under sub-section (1) shall ordinarily make the report to the Controller within a period of eighteen months from the date of such reference.

Section 15

(1) Where the Controller is satisfied that the application or any specification filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may either -

(a) refuse to proceed with the application; or

(b) require the application, specification or drawings to be amended to his satisfaction before he proceeds with the application.

(2) If it appears to the Controller that the invention claimed in the specification is not an invention within the meaning of, or is not patentable under, this Act, he shall refuse the application.

ANNEX 2

LOK SABHA

UNSTARRED QUESTION NO. 2601

To be answered on 2 August 1996

Amendment in Indian Patents Act, 1970

2601. SHRI ANAND RATNA MAURYA

Will the Minister of INDUSTRY be pleased to state:

(a) whether applications have been received from multinational companies for product, patents in pharmaceuticals, food and agro-chemicals in anticipation of favourable changes in the Indian Patents Act, 1970 in accordance with World Trade Organization guidelines;

(b) if so, the number of applications pending and the dates of their pendency; and

(c) the action taken or proposed to be taken thereon?

ANSWER

THE MINISTER OF INDUSTRY (SHRI MURASOLI MARAN)

(a) to (c) The Patent Offices have received 893 patent applications in the field of drug or medicine from Indian as well as foreign companies/institutions up 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.

ANNEX 3

May 2, 1997

The Honorable Charlene Barshefsky
United States Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Ambassador Barshefsky:

I am writing to you regarding India's failure to implement "mailbox" provisions under the WTO TRIPS Agreement on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer and more productive lives. Investing nearly $19 billion a year in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

As Senior Vice President in charge of PhRMA's international matters, I am in contact with each of the PhRMA member companies with regard to their international operations. I have discussed with them in some detail whether they believe India has mailbox and exclusive marketing rights systems in place, and whether they would use such systems if they were in place. Based on these discussions, I can state the following.

PhRMA member companies do not believe that India has established a mailbox application system or a system for the grant of exclusive marketing rights. Few PhRMA companies have filed applications for pharmaceutical product patents in India, knowing that because a "mailbox" system was not in place, there is a considerable risk that those applications would not receive the legal status required by

the TRIPS Agreement. These companies were willing to expend the resources and time necessary to file such applications in the hope that India may ultimately implement its TRIPS Article 70.8 obligations in a way that minimizes the damages created by the delay.

Other companies did not file applications for patent protection of pharmaceutical products because India has failed to establish such a system. I know of at least half-a-dozen such PhRMA member companies. These companies are prepared to file mailbox applications when a system is established, with the filing dates they should have been able to specify had a system been in place since 1 January 1995. These filing dates would, presumably, be based on their United States or other foreign filing date.

With respect to requests for exclusive marketing rights, not all companies are in a position to request such rights at this time. However, at least one PhRMA company is in a position to do so. It has received a patent and marketing approval for a drug in the United States and Europe and is ready to request the grant of exclusive marketing rights from the Indian health authorities. This company will in the very near future have another drug that meets these characteristics.

As you know, PhRMA companies are experiencing great losses in India because of its failure to provide patent protection for pharmaceutical products. Unless India establishes a mechanism to ensure that mailbox applications can be filed and given the legal status required by the TRIPS Agreement (i.e., all applications that would have been filed after 1 January 1995, had a system been in place), they will continue to face enormous losses for decades to come. Furthermore, without a system for the grant of exclusive marketing rights in place, at least one company and perhaps many others will incur significant additional losses.

Thank you for your attention to this matter.

Sincerely,

Harvey E.Bale, Jr., Ph.D.
Senior Vice President
International
PhRMA, Pharmaceutical Research
and Manufacturers of America

EUROPEAN COMMUNITIES - MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES)

Report of the Appellate Body
WT/DS26/AB/R, WT/DS48/AB/R

Adopted by the Dispute Settlement Body
on 13 February 1998

European Communities, *Appellant/Appellee*
United States, *Appellant/Appellee*
Canada, *Appellant/Appellee*
Australia, New Zealand and Norway, *Third Participants*

Present:
Feliciano, Presiding Member
Ehlermann, Member
Matsushita, Member

TABLE OF CONTENTS

Page

Page

Page

I. INTRODUCTION: STATEMENT OF THE APPEAL

1. The European Communities, the United States and Canada appeal from certain issues of law and legal interpretations in the Panel Reports, *EC Measures Concerning Meat and Meat Products (Hormones)*.[1] These two Panel Reports, circulated to Members of the World Trade Organization ("WTO") on 18 August 1997, were rendered by two Panels composed of the same three persons.[2] These Panel Reports are similar, but they are not identical in every respect. The Panel in the complaint brought by the United States was established by the Dispute Settlement Body (the "DSB") on 20 May 1996. On 16 October 1996, the DSB established the Panel in the complaint brought by Canada. The European Communities and Canada agreed, on 4 November 1996, that the composition of the latter

[1] Complaint by the United States, WT/DS26/R/USA, (the "US Panel Report") and Complaint by Canada, WT/DS48/R/CAN, (the "Canada Panel Report").
[2] As the composition of both Panels was identical, we will refer to the Panels as "the Panel".

Panel would be identical to the composition of the Panel established at the request of the United States.

2. The Panel dealt with a complaint against the European Communities relating to an EC prohibition of imports of meat and meat products derived from cattle to which either the natural hormones: oestradiol-17β, progesterone or testosterone, or the synthetic hormones: trenbolone acetate, zeranol or melengestrol acetate ("MGA"), had been administered for growth promotion purposes. This import prohibition was set forth in a series of Directives of the Council of Ministers that were enacted before 1 January 1995. Those Directives were:

1. Council Directive 81/602/EEC of 31 July 1981 ("Directive 81/602")[3];
2. Council Directive 88/146/EEC of 7 March 1988 ("Directive 88/146")[4]; and
3. Council Directive 88/299/EEC of 17 May 1988 ("Directive 88/299").[5]

3. Directive 81/602 prohibited the administration to farm animals of substances having a hormonal action and of substances having a thyrostatic action. It also prohibited the placing on the European market of both domestically produced and imported meat and meat products derived from farm animals to which such substances had been administered. Two exceptions to this prohibition were provided for. One exception covered substances with an oestrogenic, androgenic or gestagenic action when used for therapeutic or zootechnical purposes and administered by a veterinarian or under a veterinarian's responsibility. The other exception related to three natural hormones (oestradiol - 17β, progesterone and testosterone) and two synthetic hormones (trenbolone acetate and zeranol) used for growth promotion purposes if allowed under the regulations of the Member States of the European Economic Community ("EEC"), until a detailed examination of the effects of these substances could be carried out and until the EEC could take a decision on the use of these substances for growth promotion. The sixth hormone involved in this appeal, MGA, was not included in the second exception; it was covered by the general prohibition concerning substances having a hormonal or thyrostatic action.

4. Seven years later[6], Directive 88/146 was promulgated prohibiting the administration to farm animals of the synthetic hormones: trenbolone acetate and

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3 Official Journal, No. L 222, 7 August 1981, p. 32.
4 Official Journal, No. L 70, 16 March 1988, p. 16.
5 Official Journal, No. L 128, 21 May 1988, p. 36.
6 It should be noted that on 31 December 1985 the Council of Ministers adopted Directive 85/649/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, Official Journal, No. L 382, 31 December 1985, p. 228. This Directive prohibited the use of all the hormones (except MGA, the use of which had been previously prohibited) for growth promotion purposes and established more detailed provisions concerning authorized therapeutic uses. This Directive was challenged in the Court of Justice of the European Communities, which annulled it on

zeranol, for any purposes, as well as the administration of the natural hormones: oestradiol - 17β, progesterone and testosterone, for growth promotion or fattening purposes. This Directive permitted Member States of the EEC to authorize, under specified conditions, the use of the three natural hormones for therapeutic and zootechnical purposes. Directive 88/146 explicitly prohibited both the intra-EEC trade and the importation from third countries of meat and meat products obtained from animals to which substances having oestrogenic, androgenic, gestagenic or thyrostatic action had been administered. Trade in meat and meat products derived from animals treated with such substances for therapeutic or zootechnical purposes was allowed only under certain conditions. Those conditions were set out in Directive 88/299.

5. Effective as of 1 July 1997, Directives 81/602, 88/146 and 88/299 were repealed and replaced with Council Directive 96/22/EC of 29 April 1996 ("Directive 96/22").[7] This Directive maintains the prohibition of the administration to farm animals of substances having a hormonal or thyrostatic action. As under the previously applicable Directives, it is prohibited to place on the market, or to import from third countries, meat and meat products from animals to which such substances, including the six hormones at issue in this dispute, were administered. This Directive also continues to allow Member States to authorize the administration, for therapeutic and zootechnical purposes, of certain substances having a hormonal or thyrostatic action. Under certain conditions, Directive 96/22 allows the placing on the market, and the importation from third countries, of meat and meat products from animals to which these substances have been administered for therapeutic and zootechnical purposes.

6. The Panel circulated its Reports to the Members of the WTO on 18 August 1997. The US Panel Report and the Canada Panel Report reached the same conclusions in paragraph 9.1:

> (i) The European Communities, by maintaining sanitary measures which are not based on a risk assessment, has acted inconsistently with the requirements contained in Article 5.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures.
>
> (ii) The European Communities, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations which result in discrimination or a disguised restriction on international trade, has acted inconsistently with the requirement

procedural grounds in its Judgment of 23 February 1988, [1988] E.C.R. 855. Shortly afterwards, the European Commission submitted to the Council a proposal for a substantively identical Directive, which the Council adopted on 7 March 1988 as Directive 88/146/EEC.

[7] Official Journal, No. L 125, 23 May 1996, p. 3.

contained in Article 5.5 of the Agreement on the Application of Sanitary and Phytosanitary Measures.

(iii) The European Communities, by maintaining sanitary measures which are not based on existing international standards without justification under Article 3.3 of the Agreement on the Application of Sanitary and Phytosanitary Measures, has acted inconsistently with the requirements of Article 3.1 of that Agreement.

In both Reports, the Panel recommended in paragraph 9.2:

> ... that the Dispute Settlement Body requests the European Communities to bring its measures in dispute into conformity with its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures.

7. On 24 September 1997, the European Communities notified the DSB of its decision to appeal certain issues of law covered in the Panel Reports and certain 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 two notices of appeal[8] with the Appellate Body pursuant to Rule 20 of the *Working Procedures for Appellate Review* (the "*Working Procedures*"). Pursuant to Rule 21 of the *Working Procedures*, the European Communities filed an appellant's submission on 6 October 1997. On 9 October 1997, the United States and Canada filed appellants' submissions pursuant to Rule 23(1) of the *Working Procedures*. On 20 October 1997, the United States and Canada each filed an appellee's submission pursuant to Rule 22 of the *Working Procedures* and the European Communities filed its own appellee's submission pursuant to Rule 23(3) of the *Working Procedures*. On the same day, Australia, New Zealand and Norway filed separate third participants' submissions in accordance with Rule 24 of the *Working Procedures*.

8. The oral hearing was held on 4 and 5 November 1997. The participants and third participants presented oral arguments and responded to questions put to them by the Members of the Division hearing this appeal. The participants and third participants also gave oral concluding statements.

[8] WT/DS26/9, 25 September 1997, and WT/DS48/7, 25 September 1997.

II. ARGUMENTS OF THE PARTICIPANTS AND THIRD PARTICIPANTS

A. Claims of Error by the European Communities - Appellant

1. Burden of Proof

9. The European Communities argues that the Panel erred in its allocation of the burden of proof in this dispute in three respects. In the view of the European Communities, the Panel erred on the issue of burden of proof under the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the "*SPS Agreement*") in general; in allocating the burden of proof under Article 3.3 of the *SPS Agreement*; and in allocating the burden of proof under Article 5.1 of the *SPS Agreement.*

10. In respect of the issue of burden of proof under the *SPS Agreement* in general, the European Communities argues that the Panel erred in finding that the burden of proof under the *SPS Agreement* rests on the Member imposing a measure.[9] According to the European Communities, none of the general considerations invoked by the Panel supports the view that special rules on the burden of proof should be applied in proceedings concerning the *SPS Agreement*.

11. As to the allocation of the burden of proof under Article 3.3 of the *SPS Agreement*, the European Communities disagrees with the Panel's finding that Article 3.3 constitutes an exception to the general obligation, contained in Article 3.1, to base measures on international standards, and that the burden of proof under Article 3.3 is therefore on the responding party.[10] The European Communities argues that the *SPS Agreement* expressly recognizes that a Member has the right to choose an appropriate level of sanitary and phytosanitary protection, and that Article 3.3 lays down specific conditions governing the exercise of that right in those cases where an international standard exists. According to the European Communities, Article 3.1 does not provide a "general obligation" to be read in isolation, but presents one of three options available to a Member when an international standard exists.

12. With regard to the burden of proof under Article 5.1 of the *SPS Agreement*, the European Communities opposes the Panel's finding that Canada and the United States had met their burden of presenting a *prima facie* case of inconsistency with Article 5.1, in respect of importation of meat treated with the MGA hormone.[11] The European Communities notes that Canada and the United States stated that they had conducted risk assessments and had authorized MGA for growth promotion, but refused to provide scientific evidence and information, claiming their studies were proprietary and confidential in nature. The European

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[9] US Panel Report, paras. 8.52-8.54; Canada Panel Report, paras. 8.55-8.57.
[10] US Panel Report, para. 8.86; Canada Panel Report, para. 8.89.
[11] US Panel Report, para. 8.253; Canada Panel Report, para. 8.256.

Communities believes that the Panel has fundamentally erred in law by condoning the refusals by Canada and the United States to submit all studies available.

2. Standard of Review

13. The European Communities claims that the Panel erred in law[12] by not according deference to the following aspects of the EC measures: first, the decision of the European Communities to set and apply a level of sanitary protection higher than that recommended by the Codex Alimentarius (the "Codex") for the risks arising from the use for growth promotion of the hormones in dispute; second, the EC's scientific assessment and management of the risk from the hormones at issue, and third, the EC's adherence to the precautionary principle and its aversion to accepting any increased carcinogenic risk.

14. It is submitted by the European Communities that WTO panels should adopt a deferential "reasonableness" standard when reviewing a Member's decision to adopt a particular science policy or a Member's determination that a particular inference from the available data is scientifically plausible. To the European Communities, the Panel in this case imposed its own assessment of the scientific evidence.

15. The European Communities asserts that GATT 1947 panel reports rejected a *de novo* standard of review in relation to fact-finding[13], and that this approach has been maintained by panels established under the DSU.[14] It is contended that the "reasonable deference standard of review" has been given expression in the *Marrakesh Agreement Establishing the World Trade Organization*[15] (the "*WTO Agreement*") in Article 17.6 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994* (the "*Anti-*

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[12] US Panel Report, paras. 8.124, 8.127, 8.133, 8.134, 8.145, 8.146, 8.194, 8.199, 8.213 and 8.255; Canada Panel Report, paras. 8.127, 8.130, 8.136, 8.137, 8.148, 8.149, 8.197, 8.202, 8.216 and 8.258.

[13] The European Communities refers to: Panel Report, *United States - Imposition of Anti-Dumping Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway*, adopted 27 April 1994, ADP/87; Panel Report, *United States - Imposition of Countervailing Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway*, adopted 28 April 1994, SCM/153; Panel Report, *Korea - Anti-Dumping Duties on Imports of Polyacetal Resins from the United States*, adopted 27 April 1993, BISD 40S/205; Panel Report, *United States - Measures Affecting Imports of Softwood Lumber from Canada*, adopted 27-28 October 1993, BISD 40S/358, Panel Report, *United States - Anti-Dumping Duties on Imports of Stainless Steel Plate from Sweden*, ADP/117, 24 February 1994, unadopted; Panel Report, *EC - Anti-Dumping Duties on Audio Tapes in Cassettes originating in Japan*, ADP/136, 28 April 1995, unadopted; and Panel Report, *United States - Imposition of Countervailing Duties on Certain Hot-rolled Lead and Bismuth Carbon Steel Products originating in France, Germany and the United Kingdom*, SCM/185, 15 November 1994, unadopted.

[14] The European Communities refers to: Panel Report, *United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear ("United States - Underwear")*, adopted 25 February 1997, WT/DS24/R; Panel Report, *United States - Measure Affecting Imports of Woven Wool Shirts and Blouses ("United States - Shirts and Blouses")*, adopted 23 May 1997, WT/DS33/R.

[15] Done at Marrakesh, Morocco, 15 April 1994.

Dumping Agreement"). The European Communities considers that the principle of reasonable deference is applicable in all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants, and that therefore, the Panel applied an inappropriate standard of review in the present case.

3. The Precautionary Principle

16. The European Communities submits that the Panel erred in law in considering that the precautionary principle was only relevant for "provisional measures" under Article 5.7 of the *SPS Agreement*.[16] The precautionary principle is already, in the view of the European Communities, a general customary rule of international law or at least a general principle of law, the essence of which is that it applies not only in the management of a risk, but also in the assessment thereof. It is claimed that the Panel therefore erred in stating that the application of the precautionary principle "would not override the explicit wording in Articles 5.1 and 5.2 [of the *SPS Agreement*]", and in suggesting that that principle might be in conflict with those Articles. The European Communities asserts that Articles 5.1 and 5.2 and Annex A.4 of the *SPS Agreement* do not prescribe a particular type of risk assessment, but rather simply identify factors that need to be taken into account. Thus, these provisions do not prevent Members from being cautious when setting health standards in the face of conflicting scientific information and uncertainty.

4. Objective Assessment of the Facts

17. The European Communities argues that the Panel failed to make an objective assessment of the facts and therefore did not comply with its obligations under Article 11 of the DSU. The Panel, it is alleged, disregarded or distorted the evidence with regard to both the MGA and the other five hormones at issue supplied by the Panel's experts, as well as the scientific evidence presented by the European Communities. In support of this contention, the European Communities submits that the Panel has manifestly distorted the views of both Dr. Lucier[17] and Dr. André.[18] According to the European Communities, contrary to what the Panel found, the evidence provided to the Panel by the majority of its own scientific experts indicated that there was a real risk of adverse effects arising from the use of the hormones at issue. It is also claimed that the Panel manifestly distorted the scientific evidence by considering that the 1995 European Communities Scientific Conference on Growth Promotion in Meat Production (the "1995 EC Conference") amounted to a risk assessment in the sense of Articles 5.1 and 5.2. The

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[16] US Panel Report, paras. 8.157 and 8.158; Canada Panel Report, paras. 8.160 and 8.161.
[17] See, in particular, US Panel Report, footnote 331; Canada Panel Report, footnote 437.
[18] See, in particular, US Panel Report, footnote 348; Canada Panel Report, footnote 455.

distinction made by the Panel between general studies on the health risks associated with hormones and specific studies addressing the health risks of residues in food of hormones used for growth promotion purposes was, in the view of the European Communities, devised by the Panel for the sole purpose of enabling it to conclude that the Monographs of the International Agency for Research on Cancer ("IARC")[19] are not relevant as a risk assessment in this case. This, the European Communities asserts, amounts to a distortion of relevant scientific evidence. The European Communities also alleges that the Panel violated Article 11 of the DSU by discarding several articles and opinions of individual scientists invoked by the European Communities.

18. With regard to the problems relating to the control of the correct use of the hormones, the European Communities contends that it submitted convincing specific evidence to the Panel, but that the Panel either failed to take this evidence into account or failed to summarize it properly in the Panel Report. Finally, the Panel allegedly ignored the arguments made by the European Communities as to why the situations compared by the Panel under Article 5.5 were not comparable. In rejecting the six reasons advanced by the European Communities as to why the distinction in the levels of sanitary protection between carbadox and olaquindox, on the one hand, and the hormones at issue in this dispute, on the other, is not arbitrary or unjustifiable, the European Communities argues that the Panel failed to take into account the evidence before it.

5. Temporal Application of the SPS Agreement

19. The European Communities states that the Panel's conclusion that the *SPS Agreement* applies to measures that were enacted before the entry into force of the *SPS Agreement* but that did not cease to exist after that date, is too sweeping.[20] According to the European Communities, the *SPS Agreement* shows a different intention in some of its provisions, at least if these provisions are interpreted in the way proposed by the Panel. Articles 5.1 to 5.5 require that certain preparatory actions and procedures be followed before a measure is adopted and obligations of this kind are exhausted once the measures under consideration are adopted. The European Communities, therefore, concludes that the *SPS Agreement* does not apply to the procedure for the elaboration of the EC measures at issue in this dispute.

6. Article 3.1

20. The European Communities submits that the Panel erred in interpreting the term "based on" in stating that Article 3.2 "equates" measures "based on"

[19] The 1987 Monographs of the IARC on the Evaluation of Carcinogenic Risks to Humans, Supplement 7 (the "1987 IARC Monographs").
[20] US Panel Report, paras. 8.25 and 8.26; Canada Panel Report, paras. 8.28 and 8.29.

international standards with measures which "conform to" such standards.[21] The European Communities asserts that these terms differ in their meaning.

21. It is pointed out by the European Communities that Article 3 employs the term "based on" in paragraphs 1 and 3, whereas it uses the term "conform to" in paragraph 2. Also, Article 2 distinguishes between "based on" (paragraph 2) and "conform to" (paragraph 4). This differing language in consecutive paragraphs of different articles cannot be accidental.

22. To the European Communities, a measure may deviate - but not substantially - from the content of a recommendation of the Codex and still be considered as "based on" that recommendation for the purposes of Article 3.1. However, what constitutes a "substantial" deviation is not defined in the *SPS Agreement*. The submission of the European Communities is that Article 3 of the *SPS Agreement* accomplishes its object of furthering international harmonization by allowing Members to choose one of three alternative options. First, a Member may opt to conform its sanitary measures to the Codex recommendations, in accordance with Article 3.2. Second, a Member may wish merely to "base [its] sanitary ... measures on international ... recommendations", in accordance with Article 3.1, instead of conforming to such recommendations. Third, a Member may decide, in accordance with Article 3.3, to establish sanitary measures which provide a "higher level of sanitary protection" than would measures "based on" the Codex recommendations. As noted above[22], it is firm view of the European Communities that these three options are of equal standing and that Article 3.3 cannot be qualified as an exception to Article 3.1. The European Communities therefore objects to the Panel's interpretation of and conclusions concerning Article 3.1.

7. Article 3.3

23. The European Communities contends that the Panel's finding that whatever the difference might be between the two exceptions in Article 3.3, a sanitary measure can only be justified under this provision if it is consistent with the requirements contained in Article 5[23], in effect reduces the two alternative conditions in the first sentence of Article 3.3 to "mere surplusage". According to the European Communities, Article 3.3 defines the concept of the first condition ("scientific justification") in the footnote thereto without making a direct reference to Article 5, paragraphs 1 to 8, as it does with respect to the second condition ("as a consequence of choosing a higher level of protection"). The absence in the footnote to Article 3.3 of language referring to Articles 5.1-5.8 is in itself sufficient indication of the intention of the drafters to qualify the application of Article 5 in the case of the first condition. Thus, the European Communities as-

[21] US Panel Report, para. 8.72; Canada Panel Report, para. 8.75.
[22] Para. 11 of this Report.
[23] US Panel Report, para. 8.83; Canada Panel Report, para. 8.86.

serts, the plain meaning and structure of Article 3.3 imply that the risk assessment requirements of Article 5 apply only if the second of these two alternative conditions is met.

8. Article 5.1

24. The European Communities contests the Panel's finding that Article 5.1 requires a Member imposing an SPS measure to submit evidence that it "took into account" a risk assessment when it enacted or maintained a measure[24], since neither the ordinary meaning of the words "based on", in context, nor the object and purpose of Article 5, suggest a "minimum procedural requirement" under Article 5.1.

25. The European Communities contends that to require concrete evidence in the preamble of the EC Directives or some other evidence that the European Communities actually considered the scientific studies in enacting or maintaining the measures at issue is unreasonable and arbitrary, and runs counter to the object and purpose of Article 5 and the *SPS Agreement*. There is no legal authority for the Panel's interpretation that risk assessment cannot be on-going and therefore no reason for restricting risk assessment to "old evidence". The European Communities asserts that there is a legitimate SPS goal of providing an opportunity for potentially affected Members to produce scientific evidence relevant to particular measures, and of ensuring consideration of that evidence by the Member adopting the SPS measure. Therefore, the European Communities submits that all parties and third parties should have the right to present "new" relevant evidence to the Panel.

26. With regard to the Panel's findings on the consistency of the import prohibition with the substantive requirements of Article 5.1, the European Communities claims that the Panel erred in its interpretation of Article 5.1 in six separate respects. First, the Panel was incorrect in distinguishing between studies that specifically address the hormones for growth promotion purposes, such as the 1982 Report of the EC Scientific Veterinary Committee[25] (the "Lamming Report") and the JECFA Reports[26], and studies which relate to hormones in general, such as the 1987 IARC Monographs and articles and opinions of individual scientists referred to by the European Communities.[27] The Panel's assumption that such a

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[24] US Panel Report, para. 8.113; Canada Panel Report, para. 8.116.

[25] 1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production.

[26] Evaluation of certain veterinary drug residues in food: Thirty-second Report of the Joint FAO/WHO Expert Committee on Food Additives, Technical Report Series 763 (World Health Organization, 1988); and the evaluation of certain veterinary drug residues in food: Thirty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives, Technical Report Series 788 (World Health Organization, 1989).

[27] US Panel Report, paras. 8.127 and 8.130; Canada Panel Report, paras. 8.130 and 8.133.

distinction makes a qualitative difference in terms of risk assessment is wrong, and the distinction is arbitrary. The European Communities argues that Articles 5.1 and 5.2 neither prescribe risk assessment techniques nor specify the requirements of a risk assessment.

27. Second, the Panel's view of Article 5.1 as imposing a substantive obligation on Members to conform their SPS measures to the conclusions reflected in the JECFA Reports or the reports of other scientific committees is manifestly incorrect. The "scientific basis" of SPS measures cannot be confined to the formalized conclusions of committees called upon to review or analyze the risks a substance may pose. Those conclusions are just one of the elements to be taken into account. The "available scientific evidence", referred to in Article 5.2, includes both generally held or majority scientific views as well as minority, or dissenting, scientific opinion (often first expressed by individual scientists). The European Communities also controverts the Panel's finding that the reports of the European Parliament are "non-scientific"[28], and contends that this finding is manifestly wrong, certainly as regards the so-called Pimenta Report.[29]

28. Third, the Panel's interpretation that "based on" within the meaning of Article 5.1 means "in conformity with" is mistaken.[30] The European Communities states that reports of scientific committees frequently say practically nothing or very little on some of the factors indicated in Articles 5.1 and 5.2. To the European Communities, Article 5.1 is designed to compel Members to have some plausible scientific rationale as the "basis" for their sanitary measures, but not to conform their measures absolutely to the technical and scientific conclusions of the reports.

29. Fourth, the European Communities contends that the "most fundamental error of interpretation" of the Panel relates to the concept of risk and risk assessment.[31] "Risk" does not mean "harm" or "adverse effect". "Risk", for the purposes of the *SPS Agreement*, is the "potential" for the harm or adverse effects arising and, therefore, the mere possibility of risk arising suffices for the purposes of Articles 5.1 and 5.2. A risk evaluated to be one in a million is sufficient justification. If there is a potential for adverse effects (no matter how small), then there is, according to the European Communities, a risk. The concept of risk in the *SPS Agreement* is a qualitative, not a quantitative concept. Any identified increase in cancer (whether quantitative or qualitative) must be sufficient to constitute a risk against which WTO Members are entitled to protect their population.

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[28] US Panel Report, para. 8.109; Canada Panel Report, para. 8.112.

[29] European Parliament, Session Documents, Report drawn up on behalf of the Committee of Inquiry into the Problem of Quality in the Meat Sector, Rapporteur: Mr. Carlos Pimenta, Document A2-11/891/PARTS A-B, March 1989 ("Pimenta Report").

[30] US Panel Report, para. 8.117; Canada Panel Report, para. 8.120.

[31] As reflected in para. 8.124 of the US Panel Report and para. 8.127 of the Canada Panel Report.

30. Fifth, the European Communities disputes the Panel's finding that the problem of control is irrelevant to risk assessment[32], as contrary to common sense and to the express language of Article 5.2 and Annex C of the *SPS Agreement* clarifies. The European Communities also points out that the condition "in accordance with good veterinary practice" is part of the content of the Codex recommendation, and that effective control is necessary to ensure that the hormones at issue are administered in accordance with good practice. Evaluation of any potential risk arising from lack of observance of good practice is an inherent part of the risk assessment exercise. Moreover, it was for the European Communities, and not for the Panel, to determine whether the control measures of an exporting Member are adequate to achieve the EC's appropriate level of sanitary protection. The Panel has disregarded the EC's arguments relating to the practical and technical difficulties that are specific to control of the hormones at issue. The European Communities also protests as an error in law the Panel's conclusion that banning the use of a substance does not necessarily offer better protection of human health than other means of merely regulating its use.

31. Finally, the European Communities submits that the Panel was manifestly wrong in finding that a risk assessment must be carried out for each individual substance.[33] Nowhere in the *SPS Agreement*, and in particular in Articles 5.1 and 5.2, is there language requiring a risk assessment "for each individual substance". In the view of the European Communities, there is nothing to prevent classes or categories of substances from being assessed together if this is scientifically justified.

9. Article 5.5

32. The European Communities argues that the Panel erred in its interpretation of Article 5.5. With respect to the first element, namely, the existence of different levels of protection in different situations, the Panel erroneously interpreted Article 5.5 in holding that situations involving the same health risk or substance are comparable situations for the purposes of Article 5.5.[34] The European Communities submits that it is inappropriate to compare the level of protection relating to hormones used for growth promotion purposes with the level of protection relating to naturally-occurring hormones. Science and the regulatory practices of Members do not treat man-made risks, such as the risks created by hormones used for growth promotion, and naturally-occurring risks, such as those arising from the presence of hormones in meat, milk, cabbage or broccoli, in the same way. The *SPS Agreement* applies only to man-made risks because the naturally-occurring hormones in meat and other foodstuffs are not "contaminants and toxins" within the meaning of the *SPS Agreement*. Furthermore, the European

[32] US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.
[33] US Panel Report, para. 8.257; Canada Panel Report, para. 8.260.
[34] US Panel Report, para. 8.176; Canada Panel Report, para. 8.179.

Communities submits that, contrary to what the Panel found[35], there is no difference, let alone a significant difference, in the EC level of protection against naturally-occurring hormones and its level of protection against added hormones. The EC measures provide for the same level of protection against naturally-occurring hormones and added hormones, namely, the risk determined by nature.

33. In respect of the second element of Article 5.5, namely, the arbitrary or unjustifiable nature of distinctions in levels of protection, the European Communities contends that the Panel has erroneously assumed that the only factors relevant to determining what is an arbitrary or unjustifiable distinction are "scientific" factors. Other factors, such as public perception of what is dangerous and of what level of risk is acceptable, and the benefit, if any, to be gained from shouldering a risk, must also be relevant. Moreover, the European Communities argues that, contrary to what the Panel found[36], the distinction between the level of protection adopted in respect of the hormones at issue when used for growth promotion and the level of protection adopted with respect to carbadox and olaquindox is not arbitrary or unjustifiable.

34. As to the third element of Article 5.5, namely discrimination or a disguised restriction on international trade resulting from the distinction in the levels of protection, the European Communities objects to the Panel's finding that it was sufficient to demonstrate "the significance of the difference in levels of protection combined with the arbitrariness thereof".[37] Article 5.5 makes a resultant "discrimination or a disguised restriction on international trade" an additional element beyond arbitrary and unjustifiable distinctions in the levels of protection a Member considers appropriate. The European Communities does not consider the approach developed by the Appellate Body in *Japan - Taxes on Alcoholic Beverages*[38] ("*Japan - Alcoholic Beverages*") and invoked by the Panel in this case as appropriate for the very different problem in determining discrimination (between countries) and a disguised restriction of trade in a regulatory regime designed to protect human health.

35. Furthermore, it is argued by the European Communities that Article 5.5 must be interpreted together with Article 2.3 of the *SPS Agreement*. Accordingly, "discrimination" in Article 5.5 means "discrimination between States where identical or similar conditions prevail". The Panel ignored Article 2.3 and assumed that discrimination can be between substances, risks and levels of protection. This assumption cannot be correct since otherwise the term "discrimination" would add nothing to "arbitrary and unjustifiable distinctions", in the view of the European Communities.

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35 US Panel Report, paras. 8.191 and 8.212; Canada Panel Report, paras. 8.194 and 8.215.
36 US Panel Report, para. 8.238; Canada Panel Report, para. 8.241.
37 US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.
38 Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

36. The European Communities stresses that there is no import ban for beef as such and that the restriction applies only to non-conforming products. This is the inevitable consequence of any SPS measure, and cannot be enough to establish a "disguised restriction on international trade". The European Communities continued to import the same amount of meat after the ban as before, and the prohibition of hormones for growth promotion has no effect on the surpluses of beef. The suggestion of the Panel that the reduction of beef surpluses in the European Communities might have been a secondary motive, is, in any event, not sufficient to establish the discrimination or disguised restriction on international trade contemplated in Article 5.5. Finally, the European Communities submits that the fact that 70% of the bovine meat produced in the United States and Canada is from cattle to which hormones have been administered for growth promotion is no indication of a disguised restriction on trade.

10. Procedural Issues

37. The European Communities asserts that a number of procedural decisions taken by the Panel were unfair and require review by the Appellate Body. The European Communities objects to the Panel's view that it need consider the EC's procedural objections only where the European Communities could make a "precise claim" of prejudice.[39] The Panel should have asked itself whether its procedural decisions were consistent with the DSU, not whether the European Communities could make a precise claim of prejudice. It is asserted by the European Communities that the Panel committed a legal procedural error in refusing to accept the scientific assessments of the European Communities, declining to set up an expert review group, and proceeding to decide itself a scientific matter on which the Panel had no expertise. The Panel's decision to receive a range of opinions from individual experts[40] deprived the European Communities of the procedural guarantees provided for expert review groups in the DSU. By following this procedure, the Panel put itself in a position to choose freely between different scientific opinions. The European Communities contends that the selection of scientific experts by the Panel violated Articles 11, 13.2 and Appendix 4 of the DSU as well as Article 13.2 of the *SPS Agreement*. The European Communities objects to the selection of two experts on the grounds that one of them was a national of a party or third party and had links with the pharmaceutical industry, while the other was a member of the Codex/JECFA group that had produced the report on the use of hormones in animal growth promotion and was the "rapporteur" of this study. Further, according to the European Communities, these two experts lacked expertise in the field.

38. The European Communities also alleges that the Panel erred in refusing to request that Canada and the United States provide the studies on which their

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[39] US Panel Report, paras. 8.14-8.15; Canada Panel Report, paras. 8.18-8.19.
[40] US Panel Report, para. 8.7; Canada Panel Report, para. 8.7.

authorities had based their decisions to authorize the use of MGA for growth promotion. In the view of the European Communities, the Panel had a duty to carry out an objective assessment of the facts, and declining to request the complainants to produce the evidence on which they based their own domestic decisions is not compatible with this duty. Moreover, Article 18.2 of the DSU provides safeguards for the protection of confidential information. Thus, the allegedly confidential nature of the information on MGA should have been no obstacle to its production and use in the proceeding. The European Communities also asserts that the Panel based the main part of its reasoning concerning Article 5.5 of the *SPS Agreement* on a claim that the complainants had *not* made, i.e. that there was a difference of treatment between artificially-added, or exogenous, natural and synthetic hormones when used for growth promotion purposes and the naturally-present endogenous hormones in untreated meat and other foods (such as milk, cabbage, broccoli or eggs). In the view of the European Communities, not only is this "claim" wrong in law and in fact, but the Panel also violated the DSU in relying on it especially since the United States expressly protested against the Panel's use of such a "claim". The European Communities asserts that panels are not entitled to make findings going beyond what has been requested by the parties.

39. The European Communities submits further that the Panel took a number of decisions granting "extended third party rights" to Canada and the United States - and not to other third parties - that are not justified by Article 9.3, and are contrary to Articles 7.1, 7.2, 18.2 and 10.3 of the DSU as well as the terms of reference of the Panel. These decisions were: first, to give access to all of the information submitted in the United States' proceeding to Canada; second, to give access to all the information submitted in the Canadian proceeding to the United States; third, to hold a joint meeting with the scientific experts; and fourth, to invite the United States to observe and make a statement at the second substantive meeting in the proceeding initiated by Canada.

B. Arguments by the United States - Appellee

1. Burden of Proof

40. With regard to the allocation of the burden of proof under Article 3.3 of the *SPS Agreement*, the United States refers to the Appellate Body Report in *United States - Shirts and Blouses*[41] and argues that, like Articles XX and XI:2(c)(i) of the GATT 1994, Article 3.3 of the *SPS Agreement* is not a positive rule establishing an obligation in itself. It is in the nature of an affirmative defence, and the Panel was therefore correct in finding that the burden of proof under Article 3.3 rests on the defending party. As to the burden of proof under Article 5.1 of the *SPS Agreement*, the United States contends that the European

[41] Adopted 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 335-338.

Communities, in complaining that Canada and the United States did not provide their confidential information concerning MGA, misses the point that the Panel had to determine whether the European Communities had based its import ban on a risk assessment.

2. Standard of Review

41. The United States submits that the deferential "reasonableness" standard of review advocated by the European Communities is without support in the text of either the DSU or the *SPS Agreement*. The United States observes that, under Article 5.1, the Panel was called upon to determine if the EC ban was "based on" an assessment, as appropriate to the circumstances, of the risks to human health. Such a determination does not require a panel to conduct its own risk assessment or substitute its own judgement regarding risks, but only to determine if the measure is "based on" a risk assessment. Under Article 2.2, the question for a panel is not whether it would have come to a different conclusion "based on" the evidence, but rather whether the scientific evidence submitted by the Member maintaining the measure is "sufficient" as a basis for that measure. The United States believes that in this sense, the European Communities is correct in asserting that a panel is not to conduct a *de novo* review of the scientific basis of the measure.

42. The United States argues, however, that nothing in the *SPS Agreement* or the *WTO Agreement* requires a Panel to defer to the Member maintaining the SPS measure. In examining measures under the *Agreement on Textiles and Clothing* (the "ATC"), which, like the *SPS Agreement*, does not provide for a particular standard of review, two previous panels found that it would not be appropriate either to apply a *de novo* standard of review or to grant undue deference to the administrative findings of national authorities.[42] The United States cautions that the GATT panel reports cited by the European Communities, involving anti-dumping and countervailing duty disputes, do not support the existence of a deferential standard of review in the *SPS Agreement*. Those GATT panel reports involved situations where national authorities had taken anti-dumping or countervailing duty measures pursuant to detailed national legislation and procedures mandated by the *Tokyo Round Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade* (the "*Tokyo Round Anti-Dumping Code*"). According to the United States, the *Decision on Review of Article 17.6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994* shows that Members have yet to decide if the standard of review set out in Article 17.6 of the *Anti-Dumping Agreement* is capable of gen-

[42] The United States refers to: Panel Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/R; and Panel Report, *United States - Shirts and Blouses*, adopted 23 May 1997, WT/DS33/R.

eral application. The United States asserts that the European Communities is mistaken in arguing that this standard of review applies to the *SPS Agreement*.

3. The Precautionary Principle

43. In the view of the United States, the claim of the European Communities that there is a generally-accepted principle of international law which may be referred to as the "precautionary principle" is erroneous as a matter of international law. The United States does not consider that the "precautionary principle" represents a principle of customary international law; rather, it may be characterized as an "approach" - the content of which may vary from context to context. The *SPS Agreement* does recognize a precautionary approach; indeed, Article 5.7 permits the provisional adoption of SPS measures even where the relevant scientific evidence is insufficient. Thus, the United States believes that there is no need to invoke a "precautionary principle" in order to be risk-averse since the *SPS Agreement*, by its terms, recognizes the discretion of Members to determine their own level of sanitary protection. The European Communities does not explain how "the precautionary principle" affects the requirements in the *SPS Agreement* that a measure be "based on" scientific principles and a risk assessment, and not maintained without sufficient scientific evidence. The EC's invocation of a "precautionary principle" cannot create a risk assessment where there is none, nor can a "principle" create "sufficient scientific evidence" where there is none.

4. Objective Assessment of the Facts

44. According to the United States, the European Communities improperly requests the Appellate Body to review the Panel's factual findings to determine whether they were either "inadequate" or "not objective", and thus inconsistent with Article 11 of the DSU. The United States submits that, according to Article 17.6 of the DSU, factual findings are clearly beyond review by the Appellate Body. Furthermore, the United States contends that the European Communities has not shown either improper influence or conflict of interest that might warrant consideration of the objectivity of the Panel.

5. Temporal Application of the SPS Agreement

45. The United States argues that the European Communities, in claiming that Articles 5.1 to 5.5 do not apply to SPS measures adopted before the *SPS Agreement* entered into force, has misread the *SPS Agreement*. There is no support for this claim in the text, context or negotiating history of the *SPS Agreement*. If the position of the European Communities were accepted, this would, in the view of the United States, leave a gaping exception to the disciplines of the *SPS Agreement*.

6. Article 3.1

46. According to the United States, since the EC measures are not "based on" the Codex standards, even under the broad test of "based on" proposed by the European Communities, there is no need for the Appellate Body to address the alleged difference between measures "based on" international standards and measures that "conform to" international standards. The United States recognizes that Article 3 of the *SPS Agreement* uses the two different terms in Articles 3.1 and 3.2, but suggests that whether any theoretical difference between those two terms would have any meaning in practice is a question for another case.

7. Article 3.3

47. The United States believes that the European Communities is incorrect in claiming that its ban need not be "based on" a risk assessment under Article 5.1 in order to qualify under Article 3.3 as a measure for which there is a "scientific justification" for departing from an international standard. A risk assessment provides the necessary "examination and evaluation of available scientific information" required in the footnote to Article 3.3. The European Communities provides no explanation why the "relevant provisions" of the *SPS Agreement*, referred to in that footnote, do not include Article 5.1. The context of the footnote to Article 3.3 includes the definition of "risk assessment" in Annex A of the *SPS Agreement*. According to the United States, the fact that Articles 5.1 and 5.2 relate to conducting a risk assessment make it clear that these Articles are "relevant provisions" of the *SPS Agreement* for purposes of the footnote, and that any doubt regarding the applicability of Article 5.1 is removed by the last sentence of Article 3.3.

8. Article 5.1

48. The United States maintains that the Panel's finding that there is a "procedural requirement" inherent in Article 5.1 is simply a common sense reading of Article 5.1. It would be difficult to see how a measure is "based on" a risk assessment if the Member did not even know of the existence of the risk assessment or never considered the risk assessment in enacting or maintaining the measure. Furthermore, the Panel Report should not be read as imposing a rigid requirement to be satisfied only by referring to the risk assessment in the preamble to the measure. Such a reference, the United States contends, is simply one means of demonstrating that a risk assessment was taken into account.

49. The Panel was correct, according to the United States, in finding that in order that a measure may be "based on" a risk assessment, the scientific principles underlying the measure must reflect the scientific conclusions reached by the scientists conducting the risk assessment. The United States submits that the European Communities did not, at any time during the panel proceedings, produce a risk assessment identifying any risk. In the case of the hormone MGA, it is even more obvious that the EC ban is not "based on" a risk assessment.

50. With regard to the problems of control of correct use of the hormones, the United States submits that the Panel correctly characterized the argument of the European Communities as being a general statement that there is no guarantee of 100 percent compliance with any system of laws. Such a generalized concern is not an adequate basis for the EC ban. Furthermore, there is no evidence that the control of the hormones at issue is more difficult than the control of other veterinary drugs (the use of which is allowed), or that control is more difficult under a regime where hormones are allowed for growth promotion under specific conditions than under a current regime where they are banned. During the oral hearing, the United States observed that the scientific studies indicated that the hormones are safe when used in accordance with good practice. According to the United States, these studies do not address the question of whether the hormones at issue are unsafe when not used in accordance with good practice.

51. As to whether a separate risk assessment is necessary for each particular substance, the United States submits that under Article 5.1, the European Communities must base its ban with respect to MGA on an "evaluation, as appropriate to the circumstances, of the potential for adverse effects on human health arising from the presence of residues of MGA in meat ...". The European Communities provided no such evaluation of MGA. The scientific studies that the European Communities referred to deal with a general class of compounds, and do not deal specifically with MGA.

9. Article 5.5

52. The United States supports the finding that the situation involving carbadox and the situation involving the six hormones at issue are different situations which can nonetheless be compared for the purposes of Article 5.5. To the United States, the Panel was correct in finding that the EC distinction in the levels of protection involving carbadox and the level of protection involving the hormones at issue was arbitrary and resulted in a disguised restriction on international trade. In coming to that conclusion, the Panel found that the hormones at issue, banned in the European Communities, were used for growth promotion purpose in the bovine meat sector where the European Communities wanted to limit supplies and was arguably less concerned with international competitiveness while carbadox, allowed in the European Communities, is used for growth promotion purposes in the pork meat sector where the European Communities has no domestic surpluses and where international competitiveness is a high priority. The United States claims that this issue relates to factual findings that are not reviewable by the Appellate Body.

10. Procedural Issues

53. The United States asks the Appellate Body to dismiss each of the procedural claims raised by the European Communities. The appeal by the European Communities on these issues, the United States claims, raises a threshold ques-

tion as to whether, and if so, under what circumstances, the procedures employed by the Panel during the proceeding could be considered to be issues of law covered in the Panel Report or legal interpretations developed by the Panel within the meaning of Article 17.6 of the DSU. The United States asserts that the European Communities has not pointed to any textual basis for its arguments, nor to any past practice under the GATT 1947 or the *WTO Agreement*. The United States submits that, to sustain a claim that a panel's handling of procedural issues was inconsistent with the DSU, a party to a dispute must have raised objections in a timely manner during the panel proceeding, if feasible. In the view of the United States, any other response to procedural objections will weaken the authority of panels and destabilize the dispute settlement system. It would also be fundamentally unfair to permit a party to wait and see what the outcome of a panel proceeding is and make its procedural objections only when it is too late for the panel to address them. The United States urges that the objections raised by the European Communities should be rejected to the extent that they were not first made to the Panel.

54. With respect to the EC's objection concerning the Panel's selection of experts, the United States observes that during the panel proceeding, the European Communities did not object to the participation of two experts who are not only nationals of the Member States of the European Union, but are also employed by institutions of such Member States. As to the EC's objection to the alleged links of one of the experts to the pharmaceutical industry, the United States asserts that the European Communities did not question these links at the time this expert's name was raised by the Panel, even though the European Communities expressed similar concerns at that time with regard to two other scientists proposed by the Panel.

55. Turning to the issue of whether a procedural objection should be based on a "precise claim" of prejudice, the United States believes that while a Panel clearly has the duty of following the relevant rules of the DSU and the covered agreements, a party seeking the reversal or a modification of a procedural ruling should assume the responsibility of providing concrete reasons and legal arguments justifying its objection. Otherwise, every procedural ruling of a Panel could be subject to objections posed for unspecified reasons.

56. The United States asserts that the Panel's decision to consult individual experts, instead of convening an expert review group, was consistent with the DSU and the *SPS Agreement*. The European Communities itself concedes that Article 13 of the DSU and Article 11.2 of the *SPS Agreement* are permissive, and not mandatory, provisions. The United States contends that the Panel was not required to convene an expert review group, either under the terms of Article 13 of the DSU or Article 11.2 of the *SPS Agreement*. If the Panel had convened an expert review group, the rules and procedures of Appendix 4 of the DSU would have been applicable. Since the Panel did not convene such a group, the Panel's decision not to follow the rules and procedures of Appendix 4 was completely consistent with the DSU and was within the discretion accorded to panels in their procedural decisions.

57. The United States contends that the Panel's harmonization of the two panel proceedings did not impair the rights of defence of the European Communities. The use of the same panelists for both proceedings accorded a procedural advantage to the European Communities. According to the United States, rather than having two meetings with each of the two separate Panels, the European Communities was able to have four sessions with the same Panel. The European Communities willingly agreed to have the same panelists in both proceedings.

58. With respect to the issue of extended third party rights, the United States submits that the European Communities failed to make to the Panel the detailed objections it made for the first time in its appellant's submission. There is no reason why, if one panel may grant such rights in one dispute, another panel may not also grant such rights in another dispute.[43] The United States believes that there were strong reasons to provide it with extended third party rights in the Canadian panel proceeding. The United States asserts that the European Communities is mistaken in asserting that the Panel's grant of extended third party rights gave the complainants access to documents. Both the United States and the European Communities made public their submissions and statements to the Panel in the United States' panel proceeding, and therefore Canada already had access to all these documents.

C. Arguments by Canada - Appellee

1. Burden of Proof

59. On the matter of allocation of the burden of proof under the *SPS Agreement* in general, Canada contends that the Panel adopted the reasoning provided by the Appellate Body in *United States - Shirts and Blouses*.[44] As to the allocation of the burden of proof under Article 3.3 of the *SPS Agreement*, Canada insists that the Panel's findings are correct, although it would be more accurate to hold that "... the burden of proof under Article 3.1 shifts to the defending party to show either that the measure in dispute is consistent with the obligation in Article 3.1, or to invoke the exception under 3.1 and show that it meets the conditions of that exception".[45] Should the Appellate Body reverse or modify the Panel's findings on the burden of proof, Canada submits that in any event, Canada has established a *prima facie* case of violation. With regard to the burden of proof under Article 5.1 of the *SPS Agreement*, Canada believes that it had provided sufficient evidence concerning the import ban on meat treated with MGA to establish a *prima facie* case.

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[43] The United States refers to Panel Report, *European Communities - Regime for the Importation, Sale and Distribution of Bananas*, adopted 25 September 1997, WT/DS27/R/USA (*"European Communities - Bananas"*).

[44] Adopted 23 May 1997, WT/DS33/AB/R.

[45] Canada's appellee's submission, para. 59.

2. The Precautionary Principle

60. The Panel did not take a position on whether the "precautionary principle" constituted part of the body of international law. Rather, in Canada's view, the Panel acknowledged that the "precautionary principle" was reflected in Article 5.7 of the *SPS Agreement*, and correctly held that the "precautionary principle" could not override Articles 5.1 and 5.2, or any other provision of the *SPS Agreement*. Canada also regards the issue of whether the "precautionary principle" is "built into" other provisions of the *SPS Agreement* as irrelevant in this appeal. Moreover, the European Communities has not explained what is meant by the "precautionary principle" having been "built into" other provisions of the *SPS Agreement*, and how this could in any way affect the conclusions of the Panel. The "precautionary principle" should be characterized as the "precautionary approach" because it has not yet become part of public international law. Canada considers the precautionary approach or concept as an *emerging* principle of international law, which may in the future crystallize into one of the "general principles of law recognized by civilized nations", within the meaning of Article 38(1)(c) of the *Statute of the International Court of Justice*.

3. Objective Assessment of the Facts

61. Canada submits that many of the claims made by the European Communities in its appellant's submission purport to be claims relating to errors of law but are in reality claims alleging errors of fact. The Appellate Body made it clear in its Report in *European Communities - Bananas*[46], that factual findings are, pursuant to Article 17.6 of the DSU, beyond review by the Appellate Body.

4. Temporal Application of the SPS Agreement

62. Canada argues that the distinction drawn by the European Communities between provisions of the *SPS Agreement* that include the terms "maintain" or "apply", and others that do not, is not sustainable. This dichotomy presented by the European Communities would mean that measures in existence on 1 January 1995 are indefinitely exempt from the disciplines of Articles 5.1 and 5.5, but it is hardly credible that the Members intended to exempt them. Other covered agreements contain specific provisions dealing with temporal issues, therefore, non-application of provisions of the *SPS Agreement*, such as Articles 5.1 and 5.5, would have been dealt with expressly in the text of the *SPS Agreement*. In any event, the EC measures at issue in this dispute include EC Directives 96/22/EC and 96/23/EC, which were adopted after the *WTO Agreement* entered into force.

[46] Adopted 25 September 1997, WT/DS27/AB/R.

5. Article 3.1

63. Canada maintains that the EC's argument that Article 3.1 does not constitute a "general obligation", but is one of three options available to Members when Codex recommendations exist, is incorrect. Article 3.1 sets out a positive obligation for Members to base their SPS measures on international standards, guidelines or recommendations. The words of Article 3.1 do not describe three "options". If the drafters of the agreement had intended such a meaning, they would have said so. Canada supports the Panel's conclusion that the terms "conform to" and "based on" are "co-extensive". Even if the Appellate Body accepts the view that "conforms to" is narrower in scope than "based on", Article 3.1 does not present a second "option", as argued by the European Communities. A measure that "conforms to" an international standard would also be "based on" that standard.

6. Article 3.3

64. The key element of the footnote to Article 3.3 is that it requires an examination and evaluation of available scientific information. Since the *SPS Agreement* defines a risk assessment as: "the *evaluation* of the potential for adverse effects on human ... health ...", the "examination and evaluation of scientific information" in the footnote to Article 3.3 refers to a risk assessment. A Member cannot, in Canada's view, determine that the relevant international standards are not sufficient to achieve its appropriate level of sanitary protection unless the Member does an evaluation of that risk (i.e. a risk assessment), taking into account available scientific evidence.

7. Article 5.1

65. Canada considers that the Panel's interpretation of Article 5.1 accords with the ordinary meaning of the words in their context. If a measure is "founded on" a risk assessment then there must be some evidence that the measure was built upon that foundation. Such a requirement would not amount to "freezing the scientific record", since the Panel made clear that it was looking for evidence that a risk assessment was taken into account when the EC measures were established *or at any later point in time*. In Canada's view, the Panel's reading of Article 5.1 is sound, and accords with the basic obligations set out in Article 2.2 that a measure must not be maintained without sufficient scientific evidence. If the scientific conclusions reflected in the EC measures do not conform with any of those reached in the risk assessments, then the scientific foundation for the measure clearly does not come from those risk assessments.

66. Canada submits that in defining what is a risk assessment, the European Communities focuses on the word "potential" to the exclusion of "evaluation". In doing so, the European Communities has stopped the process at identifying an adverse effect without carrying out the evaluation of the risk, i.e. performing a risk assessment.

67. At the oral hearing, when asked about the need for a separate risk assessment of each individual substance, Canada opined that one can use characteristics of chemical families as a starting point for exploring whether something might pose a hazard, but it is then necessary to go on and do a full evaluation of that chemical in order to determine whether it in fact poses a hazard.

8. Article 5.5

68. According to Canada, the scope of "different situations" referred to in Article 5.5 is at least as broad as the Panel found. The limited scope suggested by the European Communities conflicts with the ordinary meaning of "different situations". Canada also submits that in the light of the object and purpose of the *SPS Agreement* and the context of Article 5.5, there is no reason to limit the scope of comparison between levels of protection for human health. In Canada's view, the Panel correctly found that the European Communities had not justified the distinctions in its purported levels of protection. The Panel did not "confine" the range of factors to be taken into consideration; the Panel considered all the arguments the European Communities had provided, but found them wanting. Canada contests the argument of the European Communities that the significance of the difference in levels of protection is no guide to the significance of trade effects. No measure could be more trade restrictive than an import ban.

9. Procedural Issues

69. Canada submits that all of the procedural rulings made by the Panel were fair to all the parties, did not result in any prejudice or injustice, and were within the Panel's jurisdiction and discretion. In particular, Canada believes that the Panel acted within its jurisdiction in making comparisons and findings with respect to the levels of protection for endogenous natural hormones, even if those precise arguments on Article 5.5 of the *SPS Agreement* were not made by Canada or the United States. Article 11 of the DSU does not limit the mandate of the Panel by compelling it to use only the arguments made by the parties. A panel is not prevented from making an objective finding that does not correspond to either party's argument.

70. Concerning the Panel's decision to consult experts in their individual capacities, rather than as an expert review group, Canada submits that the process chosen by the Panel ensured that all the views of the experts advising the Panel were brought to the Panel's attention. Far from prejudicing the European Communities, this process gave the European Communities an opportunity to elicit evidence to support its arguments from any of the Panel's experts. While Article 11.2 of the *SPS Agreement* provides that in disputes involving scientific or technical issues, a Panel should seek advice from experts chosen by the Panel in consultation with the parties to the dispute, this provision does not require the Panel to accept all expert advice without scrutiny. Canada submits that, to the contrary,

the Panel had no authority to delegate its fact-finding duty to the experts in such a manner.

71. It is also submitted by Canada that the objection of the European Communities to the nationality of the experts selected to assist the Panel is without merit. Canada is unaware that the European Communities raised any such objection during the Panel's selection of experts. In Canada's view, by suggesting an expert who was a national of one of its Member States, the European Communities waived its right to object to the other scientists on the basis of their nationality. The Panel's decisions on "extended third party rights" were proper exercises of the Panel's discretion, and are not inconsistent with the DSU. The European Communities made references to materials that it had placed before the US Panel, but did not provide those materials in the Canada Panel proceeding. Thus, according to Canada, rather than prejudice the EC case, the Panel allowed all the submissions by the European Communities before the US Panel to be considered by the Canada Panel. Canada maintains that the decision of the Panel to convene a joint meeting of the experts was also within the discretion of the Panel. The European Communities has failed to demonstrate that it suffered any substantive prejudice as a result of this decision. In Canada's view, pursuant to Article 11 of the *SPS Agreement*, the Panel was entitled to seek advice from experts chosen by the Panel in consultation with the parties, but was under no obligation to convene a meeting with the experts, either severally or jointly.

D. Claims of Error by the United States - Appellant

1. Article 2.2

72. In its capacity as appellant, the United States submits that the Panel erred because, having made all of the findings necessary to find that the EC measure was inconsistent with Article 2.2, it did not take the final step and declare the import ban to be inconsistent with Article 2.2.[47] Article 2.2 requires the European Communities to have sufficient scientific evidence to support its measure. Since the Panel methodically listed and reviewed all of the scientific evidence presented by the European Communities, and in respect of each piece of evidence made a factual finding that the evidence did not support the EC measure, the United States submits that the Panel should have come to the legal conclusion that the EC import prohibition is maintained without sufficient scientific evidence. In the view of the United States, there was no need for the Panel to determine exactly how much scientific evidence is "sufficient" for purposes of Article 2.2. The Panel found that the European Communities had presented no evidence to support its ban; "no evidence" cannot be considered to meet the threshold of "sufficient evidence".

[47] US Panel Report, para. 8.271.

73. In justifying why it made no finding under Article 2.2, the Panel stated that Articles 3 and 5 provide for more specific obligations than the "basic rights and obligations" set out in Article 2. According to the United States, Articles 3 and 5 of the *SPS Agreement* do not necessarily provide for more specific rights and obligations than all of the "basic rights and obligations" set out in Article 2. Neither Article 3 nor Article 5 says how much evidence is necessary to support an SPS measure. Article 2.2 establishes that quantum of evidence in requiring that measures not be maintained "without sufficient scientific evidence". The United States submits, therefore, that nothing in the text of Articles 2, 3 or 5 indicate that all of the obligations in Article 2 are subsumed under the provisions of Articles 3 and 5.

2. Article 5.6

74. It is urged by the United States that the Panel erred[48] in failing to make a finding under Article 5.6 of the *SPS Agreement*, and that the Panel's findings on Article 5.5 are sufficient to establish that the EC ban is inconsistent with Article 5.6 of the *SPS Agreement*. The United States notes that the European Communities prohibits the use of the natural hormones to promote growth, while having no limits on the residues of these exact same substances either naturally-present or used for therapeutic or zootechnical purposes. Since the European Communities accepts the residues of these naturally-occurring hormones in meat as safe, then the EC ban is, in the view of the United States, more trade restrictive than required.

75. The United States also notes that the European Communities prohibits the use of the three synthetic hormones at issue, while permitting the use of similar hormones (the three natural hormones) for therapeutic and zootechnical purposes as well as the use of carbadox, another synthetic compound, for growth promotion purposes. In the view of the United States, the European Communities has, in each instance, chosen the most trade restrictive approach (a ban on trade) with respect to the six hormones for growth promotion purposes. The United States argues that the European Communities could permit residues of these hormones used for growth promotion purposes at the same levels that it permits for other purposes and still achieve its level of protection. The fact that the European Communities permits these levels for these other purposes demonstrates that similarly treating residues from growth promotion would be reasonably available to the European Communities and would be technically and economically feasible. Permitting these levels for growth promotion purposes would also be significantly less trade restrictive than the current EC ban.

76. The Panel found that "no scientific evidence is available which concludes that an identifiable risk arises from the use of any of the hormones at issue for

[48] US Panel Report, para. 8.247.

growth promotion purposes in accordance with good practice."[49] In the view of the United States, this finding is sufficient in itself to establish that the EC ban is inconsistent with Article 5.6. If there is no identifiable risk from the use of these hormones for growth promotion in accordance with good practice, then the EC ban cannot be necessary to achieve a level of protection from an identified risk. The ban is then, by definition, more trade restrictive than required to achieve the appropriate level of sanitary protection by the European Communities.

E. Claims of Error by Canada - Appellant

1. Article 5.6

77. Canada states that its appeal is designed to safeguard its right to rely on its arguments presented to the Panel with respect to Article 5.6, in the event that the Appellate Body decides to modify or reverse the Panel's findings with respect to Articles 3.1, 5.1 or 5.5 of the *SPS Agreement*. Canada asserts that the EC measures are inconsistent with Article 5.6 of the *SPS Agreement*. Canada submits that according to the wording of paragraph 5 of Annex A, Article 5.5 and the object and purpose of the *SPS Agreement*, if there is no scientific evidence of an identifiable risk, there is no basis on which to adopt a measure to achieve a level of sanitary protection under the *SPS Agreement*, except as provided in Article 5.7.

78. In Canada's view, if a Member could adopt a level of protection and implement a sanitary measure even if it did not provide scientific evidence of an identifiable risk, no effect could be given to the obligation contained in Article 5 to base measures on an assessment of risks. This approach would undermine the wording and object and purpose of the *SPS Agreement*. Canada notes that the Panel found that the European Communities had not provided any scientific evidence of an identifiable risk related to the hormones at issue when used for growth promotion purposes in accordance with good practice.[50] If there is no scientific evidence of an identifiable risk, and therefore no basis on which to adopt a measure to achieve a level of sanitary protection under the *SPS Agreement*, except for Article 5.7, then by definition, no SPS measure could be adopted that would not be more trade restrictive than required. In Canada's conclusion, applying the Panel's findings with respect to the six hormones at issue to the requirements of Article 5.6, the EC measures are more trade restrictive than required, and inconsistent with Article 5.6.

[49] US Panel Report, para. 8.134.
[50] Canada Panel Report, paras. 8.165 and 8.264.

F. Arguments by the European Communities - Appellee

1. Article 2.2

79. The European Communities questions whether the statement of the Panel regarding Article 2.2 amounts to an issue of law covered in the Panel Report or a legal interpretation developed by the Panel in the sense of Article 17.6 of the DSU. Although the Panel declined to rule on Article 2.2 because of a legal interpretation reached by the Panel regarding the relationship between Articles 2 and 5 of the *SPS Agreement*, the refusal by the Panel to rule on Article 2.2 places this statement outside the scope of appellate review. The Panel did not address the substantive requirements of Article 2.2, and has not made the necessary findings on whether the scientific evidence submitted by the European Communities is sufficient. The European Communities agrees with the United States that nothing in the text of Articles 2, 3 and 5 of the *SPS Agreement* indicates that all of the obligations set out in Article 2 are subsumed under the provisions of Articles 3 and 5. From the factual, procedural and substantive points of view, the questions that need to be considered under Article 2.2 are different from those examined by the Panel under Articles 3.1, 5.1, 5.2 and 5.5 of the *SPS Agreement*. It appears to the European Communities that there is no "sufficient basis" in the Panel Report for the Appellate Body to rule on the claims of the United States in respect of Article 2.2. Moreover, the United States bases its claims on certain paragraphs of the Panel Report that are founded on a manifest misunderstanding or clear distortion of the facts, or inadequate reasoning by the Panel, as explained by the European Communities in its own appeal.

80. The European Communities submits that, should the Appellate Body examine the applicability of Article 2.2 of the *SPS Agreement*, it should also examine the applicability of Article 5.7, which is expressly referred to in Article 2.2. The European Communities believes that its measures are consistent with Article 2.2 of the *SPS Agreement.*

81. The European Communities observes that in its appeal, the United States does not discuss what constitutes "sufficient" scientific evidence. Since the concepts of "risk" and "risk assessment" in the *SPS Agreement* are not quantitative, but qualitative concepts, the word "sufficient" also cannot be taken to refer to the quantitative, but rather to the qualitative, aspects of the scientific evidence used by the regulatory authorities of a Member. The use of the words "scientific principles" in the same Article reinforces the view that Article 2.2 and the *SPS Agreement* in general do not require sanitary measures to be "based on" the "best" scientific evidence or the "weight" of available scientific evidence. The European Communities submits, therefore, that the real question is not whether the sanitary measure is "based on" the "best" science or the "preponderance" of science or whether there is conflicting science. Rather, the question is only whether the government maintaining a measure has a scientific basis for that measure.

2. Article 5.6

82. The European Communities also questions whether the statements of the Panel regarding Article 5.6 amount to an issue of law covered in the Panel Report or a legal interpretation developed by the Panel, for purposes of Article 17.6 of the DSU. Although the Panel's refusal to rule on Article 5.6 rests on a certain view of the Panel regarding the relationship between Articles 2 and 5 of the *SPS Agreement*, such a refusal places the matter outside the scope of appellate review. The European Communities submits that the Panel did not apply the substantive requirements of Article 5.6, and did not make the necessary factual findings that: first, the EC measures are more trade restrictive than required to achieve the EC's level of protection; secondly, there is another measure reasonably available taking into account technical and economic feasibility; and thirdly, this other measure both achieves the EC's level of sanitary protection and is significantly less trade restrictive. Finally, the European Communities argues that Canada and the United States base their claims on certain paragraphs of the Panel Report that are founded on a manifest misunderstanding or clear distortion of the facts or inadequate reasoning by the Panel, as the European Communities has explained in its appeal.

83. The European Communities is convinced that the EC measures are consistent with Article 5.6 of the *SPS Agreement*. According to the European Communities, the objective is to ensure that consumers are not exposed to any residues of hormones used for growth promotion purposes. The European Communities acknowledges that some hormones are present naturally and cannot be avoided. It also acknowledges that some hormones are administered to cattle for therapeutic and zootechnical purposes, purposes which are unavoidable and beneficial. However, the European Communities has decided that the exposure of its population to hormones above this level should be avoided, and that in particular, there should be a zero level of tolerance for hormones used for growth promotion purposes.

84. The European Communities has considered some possible alternatives to the prohibition of imports of bovine meat containing residues of hormones administered for growth promotion: first, the application of Maximum Residue Limits ("MRLs") to such meat; second, the application of some kind of control to all imports of meat to determine whether hormones had been administered for growth promotion purposes; and third, reliance on the exporters labelling their meat to indicate whether hormones had been administered for growth promotion purposes. According to the European Communities, however, none of the above alternative measures would achieve the specified level of protection.

G. Arguments by the Third Participants

1. Australia

85. Australia considers that the Panel erred in law in its general interpretations concerning the burden of proof under the *SPS Agreement*[51], and supports the arguments put forward by the European Communities. However, it is also contended by Australia that paragraphs 8.54 and 8.58 of the Canada Panel Report and paragraphs 8.51 and 8.55 of the US Panel Report present correct interpretations of the burden of proof and that the Panel has, in general, followed these correct interpretations in its legal reasoning and findings.

86. The conclusion reached by the Panel with regard to the temporal application of the *SPS Agreement* is also supported by Australia. However, Australia also recognizes the concerns raised by the European Communities and agrees that there is nothing in the *SPS Agreement* that could be interpreted to mean that measures already in place at the time the *SPS Agreement* came into force are necessarily inconsistent simply because the "preparatory and procedural obligations" provided in Article 5 may not have been met. On the other hand, Australia admits that nothing in the *SPS Agreement* suggests that such measures can escape application of key provisions, such as Articles 5.1 and 5.2.

87. The Panel's interpretation that the *SPS Agreement* "equates" the terms "conform to" and "based on" ignores, in Australia's view, the ordinary meaning of these terms in their context and fails to give effect to all the terms of the *SPS Agreement*. The Panel has ignored the significant fact that the *SPS Agreement* uses the expression "conform to" in both Article 3.2 and Article 2.4, i.e. in the two situations where rebuttable presumptions are established that certain measures are consistent with the *SPS Agreement* and/or the GATT 1994. Australia believes that the issue of whether a particular measure is "based on" an international standard, or "conforms to" such a standard, is something which can only be determined on a case-by-case basis.

88. The Panel failed to give effect to all the terms of the *SPS Agreement* by its treatment of the two options provided in Article 3.3. According to Australia, the Panel has ignored the differences in the wording of the two options, and their explicit identification as alternatives by the use of the word "or" in Article 3.3. This interpretation has resulted in the Panel concluding that both alternatives mean that a measure can only be justified under Article 3.3 if it meets the requirements of Article 5. In Australia's view, while a Member's determination under the first of these options must be "based on" an examination and evaluation of available scientific information "in conformity with" the relevant provisions of the *SPS Agreement*, there remains an important distinction between the two options which the Panel failed to recognize.

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[51] US Panel Report, paras. 8.52-8.54; Canada Panel Report, paras. 8.55-8.57.

89. Australia also considers as erroneous the Panel's interpretation of "risk", specifically its use of the term "identifiable risk", which has no basis in the text of the *SPS Agreement*. What the Panel is required to examine under Articles 5.1 and 5.2 is whether the EC measure is "based on" a risk assessment, and not whether there was an "identifiable risk".

90. In discussing whether there is a need for a separate risk assessment for each individual substance, Australia draws particular attention to the wording of Article 5.1 providing for a risk assessment "as appropriate to the circumstances". This wording expressly recognizes that what constitutes an appropriate risk assessment may differ from case to case. In the view of Australia, the determination of whether a risk assessment is required for a particular individual substance should therefore be made on a case-by-case basis. The Panel recognized that in order to find an SPS measure inconsistent with Article 5.5 all elements of this provision need to be present[52] but the Panel, nevertheless, gave undue weight, in the view of Australia, to the significance of the distinction in the levels of protection. The Panel's reference to the Appellate Body Report in *Japan - Alcoholic Beverages*[53] concerning the requirements of Article III:2 of the GATT 1994 was misleading and inappropriate.

91. Although Australia supports the view of the United States that the EC measures are inconsistent with Article 2.2 of the *SPS Agreement*, Australia does not believe there was any need for the Panel to make such a finding.

2. New Zealand

92. New Zealand refers to its third party submission to the Panel relating to Articles 2.2 and 5.6. New Zealand submits that since the Panel found that there was no scientific evidence that indicated that an identifiable risk arises from the use of any of the hormones at issue when used for growth promotion purposes in accordance with good practice, the Appellate Body should consider the applicability of Articles 2.2 and 5.6 of the *SPS Agreement* to the import ban.

3. Norway

93. Norway stresses that the *SPS Agreement* does not contain obligations to harmonize different levels of protection. The right of every Member to set its own level of protection is, according to Norway, an inherent right that has always been accepted by the GATT and now by the *WTO Agreement*. In the view of Norway, Members have a variety of options when deciding on their appropriate level of protection. They may decide to adopt a more lenient approach or a more stringent approach. Member A may decide to have a (close to) zero tolerance for deaths related to the usage of certain substances, while Member B accepts one

[52] US Panel Report, para. 8.174; Canada Panel Report, para. 8.177.
[53] Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

death per million per year. This is entirely for Member A and Member B to decide. When, thereafter, each Member chooses the measure necessary to achieve its level of protection, that measure must comply with the basic obligations of Articles 2, 3 and 5 of the *SPS Agreement*. As long as the existence of a risk is established, the WTO is only concerned with the justification of the measure the Member chooses to apply to achieve the level of protection it has deemed appropriate. According to Norway, there is no requirement on that Member to come to the same conclusions concerning the evaluation of the available scientific evidence that other Members or international organizations may have reached.

94. On the issue of burden of proof, Norway argues that the Panel erred when it described Article 3.1 as the general rule, thus imposing an obligation on Members to harmonize their SPS measures. Article 3.1 clearly states that harmonization is merely an objective or option, by using the words "... on as wide a basis as possible". The "exceptions" to this objective are not limited to situations covered by Article 3.3. There are others, as can be seen from the words "... except as otherwise provided for in this Agreement, and in particular in paragraph 3". Norway submits that instead of designating one paragraph of Article 3 as a general rule and others as exceptions, the Panel should have read Article 3 within the context of Articles 2.2 and 2.3. In the view of Norway, where the SPS measure is identical for domestic and imported products, the general rule - as with all obligations - is that the complainant must present a *prima facie* case of violation. The requirement in Article 2.2 that measures be "necessary" does not alter the above. SPS measures are not exceptional measures, and the burden of proving that a measure is not necessary rests in the first instance with the complainant.

95. In respect of Article 5.5, Norway submits that it is the level of protection that is at issue, rather than the measure, which must "conform to" other parts of the *SPS Agreement*. It is for the complainant to prove that a decision on different levels of protection violates Article 5.5.

III. ISSUES RAISED IN THIS APPEAL

96. This appeal raises the following legal issues:

(a) Whether the Panel correctly allocated the burden of proof in this case;

(b) Whether the Panel applied the appropriate standard of review under the *SPS Agreement*;

(c) Whether, or to what extent, the precautionary principle is relevant in the interpretation of the *SPS Agreement*;

(d) Whether the provisions of the *SPS Agreement* apply to measures enacted before the date of entry into force of the *WTO Agreement*;

(e) Whether the Panel made an objective assessment of the facts pursuant to Article 11 of the DSU;

(f) Whether the Panel acted within the scope of its authority in its selection and use of experts, in granting additional third party rights to the United States and Canada and in making findings based on arguments not made by the parties;

(g) Whether the Panel correctly interpreted Articles 3.1 and 3.3 of the *SPS Agreement*;

(h) Whether the EC measures are "based on" a risk assessment within the meaning of Article 5.1 of the *SPS Agreement*;

(i) Whether the Panel correctly interpreted and applied Article 5.5 of the *SPS Agreement*; and

(j) Whether the Panel appropriately exercised "judicial economy" in not making findings on the consistency of the EC measures with Article 2.2 and Article 5.6 of the *SPS Agreement*.

IV. ALLOCATING THE BURDEN OF PROOF IN PROCEEDINGS UNDER THE *SPS AGREEMENT*

97. The first general issue that we must address relates to the allocation of the burden of proof in proceedings under the *SPS Agreement*. The Panel appropriately describes this issue as one "of particular importance"[54], in view of the nature of disputes under that Agreement. Such disputes may raise multiple and complex issues of fact.

98. The Panel begins its analysis by setting out the general allocation of the burden of proof between the contending parties in any proceedings under the *SPS Agreement*. The initial burden lies on the complaining party, which must establish a *prima facie* case of inconsistency with a particular provision of the *SPS Agreement* on the part of the defending party, or more precisely, of its SPS measure or measures complained about. When that *prima facie* case is made, the burden of proof moves to the defending party, which must in turn counter or refute the claimed inconsistency. This seems straightforward enough and is in conformity with our ruling in *United States - Shirts and Blouses*[55], which the Panel invokes and which embodies a rule applicable in any adversarial proceedings.

99. The Panel, however, proceeds to make a general, unqualified, interpretative ruling that the *SPS Agreement* allocates the "evidentiary burden" to the Member imposing an SPS measure. To support this general statement, which renders the Panel's reference to our own ruling in *United States - Shirts and Blouses* little more than lip-service, the Panel first points to:

> ... the wording of many of the provisions contained in [the SPS] Agreement and in particular the first three words thereof: "*Mem-*

[54] US Panel Report, para. 8.48; Canada Panel Report, para. 8.51.
[55] Adopted 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 335.

> *bers shall ensure* that ..." (e.g. Articles 2.2, 2.3, 5.1 and 5.6 of the SPS Agreement).[56]

100. The Panel next quotes Article 5.8 of the *SPS Agreement*, while parenthetically noting that this Article "relates more to transparency than to any requirement of legal justification".[57] Article 5.8 provides:

> When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

101. Lastly, the Panel seeks support for its general interpretative ruling in Article 3.2 of the *SPS Agreement*, which establishes a presumption of consistency with relevant provisions of that Agreement and of the GATT 1994 for measures that conform to international standards, guidelines and recommendations. From this presumption, the Panel extracts a reverse inference that if a measure does *not* conform to international standards, the Member imposing such a measure must bear the burden of proof in any complaint of inconsistency with a provision of the *SPS Agreement*.[58]

102. We find the general interpretative ruling of the Panel to be bereft of basis in the *SPS Agreement* and must, accordingly, reverse that ruling. It does not appear to us that there is any necessary (i.e. logical) or other connection between the undertaking of Members to ensure, for example, that SPS measures are "applied only to the extent necessary to protect human, animal or plant life or health ..."[59], and the allocation of burden of proof in a dispute settlement proceeding. Article 5.8 of the *SPS Agreement* does not purport to address burden of proof problems; it does not deal with a dispute settlement situation. To the contrary, a Member seeking to exercise its right to receive information under Article 5.8 would, most likely, be in a pre-dispute situation, and the information or explanation it receives may well make it possible for that Member to proceed to dispute settlement proceedings and to carry the burden of proving on a *prima facie* basis that the measure involved is not consistent with the *SPS Agreement*. The Panel's last reason involves, quite simply, a *non-sequitur*. The converse or *a contrario* presumption created by the Panel does not arise. The presumption of consistency with relevant provisions of the *SPS Agreement* that arises under Article 3.2 in respect of measures that conform to international standards may well be an *in-*

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[56] US Panel Report, para. 8.52; Canada Panel Report, para. 8.55.
[57] US Panel Report, para. 8.53; Canada Panel Report, para. 8.56.
[58] US Panel Report, para. 8.54; Canada Panel Report, para. 8.57.
[59] *SPS Agreement*, Article 2.2.

centive for Members so to conform their SPS measures with such standards. It is clear, however, that a decision of a Member not to conform a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a *penalty*.

103. In initiating its discussion on the requirements of Articles 3.1 and 3.3 of the *SPS Agreement*, the Panel turns once more to allocating the burden of proof between the complaining parties and the defending party. The Panel states:

> One purpose of the SPS Agreement, as explicitly recognized in the preamble, is to promote the use of international standards, guidelines and recommendations. To that end, Article 3.1 imposes an obligation on all Members to base their sanitary measures on international standards except as otherwise provided for in the SPS Agreement, and in particular in Article 3.3 thereof. In this sense, Article 3.3 provides an exception to the general obligation contained in Article 3.1. Article 3.2, in turn, specifies that the complaining party has the burden of overcoming a presumption of consistency with the SPS Agreement in the case of a measure based on international standards. It thereby suggests by implication that when a measure is not so based, the burden is on the respondent to show that the measure is justified under the exceptions provided for in Article 3.3.
>
> We find, therefore, that once the complaining party provides a *prima facie* case (i) that there is an international standard with respect to the measure in dispute, and (ii) that the measure in dispute is *not* based on this standard, the burden of proof under Article 3.3 shifts to the defending party.[60] (underlining added)

104. The Panel relies on two interpretative points in reaching its above finding. First, the Panel posits the existence of a "general rule - exception" relationship between Article 3.1 (the general obligation) and Article 3.3 (an exception)[61] and applies to the *SPS Agreement* what it calls "established practice under GATT 1947 and GATT 1994" to the effect that the burden of justifying a measure under Article XX of the GATT 1994 rests on the defending party.[62] It appears to us that the Panel has misconceived the relationship between Articles 3.1, 3.2 and 3.3, a relationship discussed below[63], which is qualitatively different from the relationship between, for instance, Articles I or III and Article XX of the GATT 1994. Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a

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60 US Panel Report, paras. 8.86 and 8.87; Canada Panel Report, paras. 8.89 and 8.90.
61 US Panel Report, para. 8.86; Canada Panel Report, para. 8.89.
62 US Panel Report, footnote 288; Canada Panel Report, footnote 393.
63 Paras. 169-172 of this Report.

Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on an international standard. Article 3.3 recognizes the autonomous right of a Member to establish such higher level of protection, provided that that Member complies with certain requirements in promulgating SPS measures to achieve that level. The general rule in a dispute settlement proceeding requiring a complaining party to establish a *prima facie* case of inconsistency with a provision of the *SPS Agreement* before the burden of showing consistency with that provision is taken on by the defending party, is *not* avoided by simply describing that same provision as an "exception". In much the same way, merely characterizing a treaty provision as an "exception" does not by itself justify a "stricter" or "narrower" interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose, or, in other words, by applying the normal rules of treaty interpretation. It is also well to remember that a *prima facie* case is one which, in the absence of effective refutation by the defending party, requires a panel, as a matter of law, to rule in favour of the complaining party presenting the *prima facie* case.[64]

105. Secondly, the Panel relies upon the reverse presumption or implication it discovered in Article 3.2 of the *SPS Agreement*. As already noted, we have been unable to find any basis for that implication or presumption.[65]

106. We believe, therefore, and so hold that the Panel erred in law both in its two interpretative points and its finding set out in paragraphs 8.86 and 8.87 of the US Panel Report and paragraphs 8.89 and 8.90 of the Canada Panel Report (quoted above).[66]

107. The legal interpretations developed and the findings set out above by the Panel appear to have been applied, *inter alia*, in the following paragraphs that have also been appealed by the European Communities:

> We recall the conclusions we reached above on burden of proof, in particular that the European Communities has, with respect to its measures which deviate from international standards, the burden of proving the existence of a risk assessment (and, derived therefrom, an identifiable risk) on which the EC measures in dispute are based. It is not, in this dispute, for the United States to prove that there is *no* risk.[67]
>
> ...
>
> We finally recall our findings reached above on the specific burden of proof under Article 3.3. In particular, we found that the burden

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64 Appellate Body Report, *United States - Shirts and Blouses*, adopted 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 335.

65 Para. 102 of this Report.

66 See para. 103 of this Report.

67 US Panel Report, para. 8.151; Canada Panel Report, para. 8.154.

> of proving that the requirements imposed by Article 3.3 (*inter alia*, consistency with Article 5) are met, in order to justify a sanitary measure which deviates from an international standard, rests with the Member imposing that measure. Since the EC measures examined in this section (relating to all hormones in dispute other than MGA) are not based on existing international standards and need to be justified under the exceptions provided for in Article 3.3, the European Communities bears the burden of proving that the determination and application of its level of protection is consistent with Articles 5.4 to 5.6.[68]

108. To the extent that the Panel[69] purports to absolve the United States and Canada from the necessity of establishing a *prima facie* case showing the absence of the risk assessment required by Article 5.1, and the failure of the European Communities to comply with the requirements of Article 3.3, and to impose upon the European Communities the burden of proving the existence of such risk assessment and the consistency of its measures with Articles 5.4, 5.5 and 5.6 *without regard to whether or not the complaining parties had already established their prima facie case*, we consider and so hold that the Panel once more erred in law.

109. In accordance with our ruling in *United States - Shirts and Blouses*[70], the Panel should have begun the analysis of each legal provision by examining whether the United States and Canada had presented evidence and legal arguments sufficient to demonstrate that the EC measures were inconsistent with the obligations assumed by the European Communities under each Article of the *SPS Agreement* addressed by the Panel, i.e., Articles 3.1, 3.3, 5.1 and 5.5. Only after such a *prima facie* determination had been made by the Panel may the onus be shifted to the European Communities to bring forward evidence and arguments to disprove the complaining party's claim.[71]

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[68] US Panel Report, para. 8.165; Canada Panel Report, para. 8.168.

[69] US Panel Report, paras. 8.151 and 8.165; Canada Panel Report, paras. 8.154 and 8.168.

[70] Adopted 23 May 1997, WT/DS33/AB/R, DSR 1997:I, 323 at 335-338.

[71] Our finding that the Panel erred in allocating the burden of proof generally to the Member imposing the measure, however, does not deal with the quite separate issue of whether the United States and Canada actually made a *prima facie* case of violation of each of the following Articles of the *SPS Agreement:* 3.1, 3.3, 5.1 and 5.5. See in this respect, footnote 180 of this Report.

V. THE STANDARD OF REVIEW APPLICABLE IN PROCEEDINGS UNDER THE *SPS AGREEMENT*

110. The European Communities appeals from certain findings of the Panel[72] upon the ground that the Panel failed to apply an appropriate standard of review in assessing certain acts of, and scientific evidentiary material submitted by, the European Communities.[73] The European Communities claimed, more specifically, that:

> ... the panel erred in law in not according deference to the following elements of the EC measures:
>
> - the EC's decision to set and apply a level of sanitary protection higher than that recommended by Codex Alimentarius for the risks arising from the use of these hormones for growth promotion;
> - the EC's scientific assessment and management of the risk from the hormones at issue; and
> - the EC's adherence to the precautionary principle and its aversion to accepting any increased carcinogenic risk.
>
> The panel also erred in law because it:
>
> - assigned a high probative value to the scientific views presented by some of the five scientific experts chosen by it (and to the views of the technical expert appointed by Codex Alimentarius);
> - disregarded in effect or distorted the scientific evidence presented by the EC and its scientific advisors, and systematically considered the scientific views of the panel-appointed experts or even a minority of those experts, of higher probative value than the scientific evidence presented by the EC scientists;
> - based its legal interpretations and findings on a number of critical issues on the majority of scientific views presented by its own appointed experts, instead of limiting itself to examining whether the scientific evidence presented by the EC was based on "*scientific principles*" (as required by Article 2:2 [of the *SPS Agreement*]).[74]

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[72] US Panel Report, paras. 8.124, 8.127, 8.133, 8.134, 8.145, 8.146, 8.194, 8.199, 8.213 and 8.255; Canada Panel Report, paras. 8.127, 8.130, 8.136, 8.137, 8.148, 8.149, 8.197, 8.202, 8.216 and 8.258.

[73] EC's appellant's submission, para. 140.

[74] EC's appellant's submission, para. 139.

111. In the view of the European Communities, the principal alternative approaches to the problem of formulating the "proper standard of review" so far as panels are concerned are two-fold. The first is designated as "*de novo* review". This standard of review would allow a panel complete freedom to come to a different view than the competent authority of the Member whose act or determination is being reviewed. A panel would have to "verify whether the determination by the national authority was 'correct' both factually and procedurally".[75] The second is described as "deference". Under a "deference" standard, a panel, in the submission of the European Communities, should not seek to redo the investigation conducted by the national authority but instead examine whether the "procedure" required by the relevant WTO rules had been followed.[76]

112. Clearly referring only to an appropriate standard of review of *factual* determinations by the domestic authorities of a Member, the European Communities submits that the principle of deference has been embodied in Article 17.6(i) of the *Anti-Dumping Agreement*, which reads as follows:

> 17.6 In examining the matter referred to in paragraph 5:
>
> (i) in its assessment of the facts of the matter, the panel shall determine whether the authorities' establishment of the facts was proper and whether their evaluation of those facts was unbiased and objective. If the establishment of the facts was proper and the evaluation was unbiased and objective, even though the panel might have reached a different conclusion, the evaluation shall not be overturned;

113. The European Communities further urges that the above-quoted standard, which it describes as a "deferential 'reasonableness' standard"[77] is applicable in "all highly complex factual situations, including the assessment of the risks to human health arising from toxins and contaminants"[78], and should have been applied by the Panel in the present case.

114. The first point that must be made in this connection, is that the *SPS Agreement* itself is silent on the matter of an appropriate standard of review for panels deciding upon SPS measures of a Member. Nor are there provisions in the DSU or any of the covered agreements (other than the *Anti-Dumping Agreement*) prescribing a particular standard of review. Only Article 17.6(i) of the *Anti-Dumping Agreement* has language on the standard of review to be employed by panels engaged in the "assessment of the facts of the matter". We find no indication in the *SPS Agreement* of an intent on the part of the Members to adopt or incorporate into that Agreement the standard set out in Article 17.6(i) of the *Anti-*

[75] EC's appellant's submission, para. 122.
[76] EC's appellant's submission, para. 123.
[77] EC's appellant's submission, para. 128.
[78] EC's appellant's submission, para. 127.

Dumping Agreement. Textually, Article 17.6(i) is specific to the *Anti-Dumping Agreement*.[79]

115. The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves.[80] To adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself, may well amount to changing that finely drawn balance; and neither a panel nor the Appellate Body is authorized to do that.

116. We do not mean, however, to suggest that there is at present no standard of review applicable to the determination and assessment of the facts in proceedings under the *SPS Agreement* or under other covered agreements. In our view, Article 11 of the DSU bears directly on this matter and, in effect, articulates with great succinctness but with sufficient clarity the appropriate standard of review for panels in respect of both the ascertainment of facts and the legal characterization of such facts under the relevant agreements. Article 11 reads thus:

> The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided in the covered agreements. Panels should consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution". (underlining added)

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[79] On the other hand, as suggested by the United States, we must note the *Decision on the Review of Article 17.6 of the Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*, which states:

> *Ministers*,
>
> *Decide* as follows:
>
> The standard of review in paragraph 6 of Article 17 of the Agreement on Implementation of Article VI of GATT 1994 shall be reviewed after a period of three years with a view to considering the question of whether it is capable of general application. (underlining added).

This Ministerial Decision evidences that the Ministers were aware that Article 17.6 of the *Anti-Dumping Agreement* was applicable only in respect of that Agreement.

[80] See, for example, S.P. Croley and J.H. Jackson, "WTO Dispute Panel Deference to National Government Decisions, The Misplaced Analogy to the U.S.Chevron Standard-of-Review Doctrine", in E.-U. Petersmann (ed.), *International Trade Law and the GATT/WTO Dispute Settlement System* (Kluwer, 1997) 185, p. 189; P.A. Akakwam, "The Standard of Review in the 1994 Antidumping Code: Circumscribing the Role of GATT Panels in Reviewing National Antidumping Determinations" (1996), 5:2 *Minnesota Journal of Global Trade* 277, pp. 295-296.

117. So far as fact-finding by panels is concerned, their activities are always constrained by the mandate of Article 11 of the DSU: the applicable standard is neither *de novo* review as such, nor "total deference", but rather the "objective assessment of the facts". Many panels have in the past refused to undertake *de novo* review[81], wisely, since under current practice and systems, they are in any case poorly suited to engage in such a review. On the other hand, "total deference to the findings of the national authorities", it has been well said, "could not ensure an 'objective assessment' as foreseen by Article 11 of the DSU".[82]

118. In so far as legal questions are concerned - that is, consistency or inconsistency of a Member's measure with the provisions of the applicable agreement - a standard not found in the text of the *SPS Agreement* itself cannot absolve a panel (or the Appellate Body) from the duty to apply the customary rules of interpretation of public international law.[83] It may be noted that the European Communities refrained from suggesting that Article 17.6 of the *Anti-Dumping Agreement* in its entirety was applicable to the present case. Nevertheless, it is appropriate to stress that here again Article 11 of the DSU is directly on point, requiring a panel to "make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements ...".

119. We consider, therefore, that the issue of failure to apply an appropriate standard of review, raised by the European Communities, resolves itself into the issue of whether or not the Panel, in making the above and other findings referred to and appealed by the European Communities, had made an "objective assessment of the matter before it, including *an objective assessment of the facts* ...". This particular issue is addressed (in substantial detail) below.[84] Here, however, we uphold the findings of the Panel appealed by the European Communities upon the ground of failure to apply either a "deferential reasonableness standard" or the standard of review set out in Article 17.6(i) of the *Anti-Dumping Agreement*.

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81 Panel Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/R; Panel Report, *Korea - Anti-Dumping Duties on Imports of Polyacetal Resins from the United States*, adopted 27 April 1993, BISD 40S/205; Panel Report, *United States - Imposition of Anti-Dumping Duties on Imports of Fresh and Chilled Atlantic Salmon from Norway*, adopted 27 April 1994, ADP/87; and Panel Report, *United States - Initiation of a Countervailing Duty Investigation into Softwood Lumber Products from Canada*, adopted 3 June 1987, BISD 34S/194.

82 Panel Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/R, para. 7.10.

83 DSU, Article 3.2.

84 Paras. 131-144 of this Report.

VI. THE RELEVANCE OF THE PRECAUTIONARY PRINCIPLE IN THE INTERPRETATION OF THE *SPS AGREEMENT*

120. We are asked by the European Communities to reverse the finding of the Panel relating to the precautionary principle. The Panel's finding and its supporting statements are set out in the Panel Reports in the following terms:

> The European Communities also invokes the precautionary principle in support of its claim that its measures in dispute are based on a risk assessment. To the extent that this principle could be considered as part of customary international law *and* be used to interpret Articles 5.1 and 5.2 on the assessment of risks as a customary rule of interpretation of public international law (as that phrase is used in Article 3.2 of the DSU), we consider that this principle would not override the explicit wording of Articles 5.1 and 5.2 outlined above, in particular since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement. We note, however, that the European Communities has explicitly stated in this case that it is not invoking Article 5.7.
>
> We thus find that the precautionary principle cannot override our findings made above, namely that the EC import ban of meat and meat products from animals treated with any of the five hormones at issue for growth promotion purposes, in so far as it also applies to meat and meat products from animals treated with any of these hormones *in accordance with good practice*, is, from a substantive point of view, not *based on* a risk assessment.[85] (underlining added)

121. The basic submission of the European Communities is that the precautionary principle is, or has become, "a general customary rule of international law" or at least "a general principle of law".[86] Referring more specifically to Articles 5.1 and 5.2 of the *SPS Agreement*, applying the precautionary principle means, in the view of the European Communities, that it is not necessary for *all* scientists around the world to agree on the "possibility and magnitude" of the risk, nor for *all* or most of the WTO Members to perceive and evaluate the risk in the same way.[87] It is also stressed that Articles 5.1 and 5.2 do not prescribe a particular type of risk assessment and do not prevent Members from being cautious in their risk assessment exercise.[88] The European Communities goes on to state that its measures here at stake were precautionary in nature and satisfied the

[85] US Panel Report, paras. 8.157 and 8.158; Canada Panel Report, paras. 8.160 and 8.161.
[86] EC's appellant's submission, para. 91.
[87] EC's appellant's submission, para. 88.
[88] EC's appellant's submission, para. 94.

requirements of Articles 2.2 and 2.3, as well as of Articles 5.1, 5.2, 5.4, 5.5 and 5.6 of the *SPS Agreement*.[89]

122. The United States does not consider that the "precautionary principle" represents customary international law and suggests it is more an "approach" than a "principle".[90] Canada, too, takes the view that the precautionary principle has not yet been incorporated into the corpus of public international law; however, it concedes that the "precautionary approach" or "concept" is "an *emerging* principle of law" which may in the future crystallize into one of the "general principles of law recognized by civilized nations" within the meaning of Article 38(1)(c) of the *Statute of the International Court of Justice*.[91]

123. The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international *environmental* law. Whether it has been widely accepted by Members as a principle of *general* or *customary international law* appears less than clear.[92] We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.[93]

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89 EC's appellant's submission, para. 98.

90 United States' appellee's submission, para. 92.

91 Canada's appellee's submission, para. 34.

92 Authors like P. Sands, J. Cameron and J. Abouchar, while recognizing that the principle is still evolving, submit nevertheless that there is currently sufficient state practice to support the view that the precautionary principle is a principle of customary international law. See, for example, P. Sands, *Principles of International Environmental Law*, Vol. I (Manchester University Press 1995) p. 212; J. Cameron, "The Status of the Precautionary Principle in International Law", in J. Cameron and T. O'Riordan (eds.), *Interpreting the Precautionary Principle* (Cameron May, 1994) 262, p. 283; J.Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law", in D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law* (Kluwer, 1996) 29, p. 52. Other authors argue that the precautionary principle has not yet reached the status of a principle of international law, or at least, consider such status doubtful, among other reasons, due to the fact that the principle is still subject to a great variety of interpretations. See, for example, P. Birnie and A. Boyle, *International Law and the Environment* (Clarendon Press, 1992), p. 98; L. Gündling, "The Status in International Law of the Precautionary Principle" (1990), 5:1,2,3 *International Journal of Estuarine and Coastal Law* 25, p. 30; A. deMestral (et. al), *International Law Chiefly as Interpreted and Applied in Canada*, 5th ed. (Emond Montgomery, 1993), p. 765; D. Bodansky, in *Proceedings of the 85th Annual Meeting of the American Society of International Law* (ASIL, 1991), p. 415.

93 In *Case Concerning the Gabcíkovo-Nagymaros Project (Hungary/Slovakia)*, the International Court of Justice recognized that in the field of environmental protection "... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight ...". However, we note that the Court did not identify the precautionary principle as one of those

124. It appears to us important, nevertheless, to note some aspects of the relationship of the precautionary principle to the *SPS Agreement*. First, the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.

125. We accordingly agree with the finding of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the *SPS Agreement*.

VII. APPLICATION OF THE *SPS AGREEMENT* TO MEASURES ENACTED BEFORE 1 JANUARY 1995

126. Although Directives 81/602, 88/148 and 88/299 were enacted before the entry into force of the *WTO Agreement* on 1 January 1995, the Panel held[94] that, in line with Article 28 of the *Vienna Convention on the Law of Treaties* (the "*Vienna Convention*")[95], the *SPS Agreement* should apply to the EC measures at issue because they continued to exist after 1 January 1995 and the *SPS Agreement* does not show any intention to limit its application to measures enacted after the entry into force of the *WTO Agreement*. The Panel stated that, to the

recently developed norms. It also declined to declare that such principle could override the obligations of the Treaty between Czechoslovakia and Hungary of 16 September 1977 concerning the construction and operation of the Gabcíkovo/Nagymaros System of Locks. See, *Case Concerning the Gabcíkovo-Nagymaros Project (Hungary/Slovakia)*, I.C.J. Judgement, 25 September 1997, paras. 140, 111-114. Not yet reported in the I.C.J. Reports but available on internet at http://www.icj-cij.org/idecis.htm.

[94] US Panel Report, para. 8.25; Canada Panel Report, para. 8.28.

[95] Done at Vienna, 23 May 1969, 1155 UNTS 331; (1969), 8 International Legal Materials, 679.

contrary, several provisions of the *SPS Agreement*, and in particular Articles 2.2, 3.3, 5.6, 5.8 and 14 thereof, confirm the *SPS Agreement* does indeed apply to SPS measures which were enacted before 1 January 1995 but were maintained thereafter.[96]

127. The European Communities submits that this conclusion of the Panel is "too sweeping"[97] and that the *SPS Agreement* shows an intention to limit the temporal application of the Agreement, and in particular Articles 5.1 to 5.5 thereof, to measures enacted after the entry into force of the Agreement.

128. We addressed the issue of temporal application in our Report in *Brazil - Measures Affecting Desiccated Coconut* and concluded on the basis of Article 28 of the *Vienna Convention* that:

> Absent a contrary intention, a treaty cannot apply to acts or facts which took place, or situations which ceased to exist, before the date of its entry into force.[98]

We agree with the Panel that the *SPS Agreement* would apply to situations or measures that did not cease to exist, such as the 1981 and 1988 Directives, unless the *SPS Agreement* reveals a contrary intention. We also agree with the Panel that the *SPS Agreement* does not reveal such an intention. The *SPS Agreement* does not contain any provision limiting the temporal application of the *SPS Agreement*, or of any provision thereof, to SPS measures adopted after 1 January 1995.[99] In the absence of such a provision, it cannot be assumed that central provisions of the *SPS Agreement*, such as Articles 5.1 and 5.5, do not apply to measures which were enacted before 1995 but which continue to be in force thereafter. If the negotiators had wanted to exempt the very large group of SPS measures in existence on 1 January 1995 from the disciplines of provisions as important as Articles 5.1 and 5.5, it appears reasonable to us to expect that they would have said so explicitly. Articles 5.1 and 5.5 do not distinguish between SPS measures adopted before 1 January 1995 and measures adopted since; the relevant implication is that they are intended to be applicable to both. Furthermore, other provisions of the *SPS Agreement*, such as Articles 2.2, 2.3, 3.3 and 5.6, expressly contemplate applicability to SPS measures that already existed on 1 January 1995. Finally, we observe, more generally, that Article XVI.4 of the *WTO Agreement* stipulates that:

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96 US Panel Report, para. 8.26; Canada Panel Report, para. 8.29.

97 EC's appellant's submission, para. 264.

98 Adopted 20 March 1997, WT/DS22/AB/R, p. 15.

99 Note that Article 14 of the *SPS Agreement* allows the *least-developed country Members* and other *developing country Members* to delay implementation of the provisions of that Agreement for a period of *five and two years*, respectively, following the date of entry into force of the *WTO Agreement*. Developing country Members may only delay application of the provisions of that Agreement where such application is prevented by lack of technical expertise, technical infrastructure or resources. This right to *defer* application of the provisions of the *SPS Agreement* concerns, however, both SPS measures existing before the entry into force of the *WTO Agreement* and SPS measures enacted since.

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

Unlike the GATT 1947, the *WTO Agreement* was accepted definitively by Members, and therefore, there are no longer "existing legislation" exceptions (so-called "grandfather rights").[100]

129. We are aware that the applicability, as from 1 January 1995, of the requirement that an SPS measure be based on a risk assessment to the many SPS measures already in existence on that date, may impose burdens on Members. It is pertinent here to note that Article 5.1 stipulates that SPS measures must be based on a risk assessment, *as appropriate to the circumstances*, and this makes clear that the Members have a certain degree of flexibility in meeting the requirements of Article 5.1.

130. We therefore affirm the finding of the Panel with regard to the temporal application of the *SPS Agreement*. We also note that the measure at issue in this appeal is, since 1 July 1997, no longer embodied in the pre-1995 Directives referred to above, but rather in Directive 96/22, which was elaborated and enacted *after* the entry into force of the *WTO Agreement*. None of the parties contests that the currently applicable measure is subject to the disciplines of Articles 5.1 and 5.5 of the *SPS Agreement*.

VIII. THE REQUIREMENT OF OBJECTIVE ASSESSMENT OF THE FACTS BY A PANEL UNDER ARTICLE 11 OF THE DSU

131. The European Communities claims that the Panel has disregarded or distorted the evidence submitted by the European Communities to the Panel, as well as the opinions and statements made by the scientific experts advising the Panel. It is claimed, in other words, that the Panel has failed to make an objective assessment of the facts as required by Article 11 of the DSU, and the European Communities asks us to reverse the findings so arrived at by the Panel.

132. Under Article 17.6 of the DSU, appellate review is limited to appeals on questions of law covered in a panel report and legal interpretations developed by the panel. Findings of fact, as distinguished from legal interpretations or legal conclusions, by a panel are, in principle, not subject to review by the Appellate Body. The determination of whether or not a certain event did occur in time and space is typically a question of fact; for example, the question of whether or not Codex has adopted an international standard, guideline or recommendation on MGA is a factual question. Determination of the credibility and weight properly to be ascribed to (that is, the appreciation of) a given piece of evidence is part

[100] With the exception of the measures taken by a Member under specific mandatory legislation referred to in paragraph 3(a) of the language incorporating the GATT 1994 into the *WTO Agreement*.

and parcel of the fact finding process and is, in principle, left to the discretion of a panel as the trier of facts. The consistency or inconsistency of a given fact or set of facts with the requirements of a given treaty provision is, however, a legal characterization issue. It is a legal question. Whether or not a panel has made an objective assessment of the facts before it, as required by Article 11 of the DSU, is also a legal question which, if properly raised on appeal, would fall within the scope of appellate review.

133. The question which then arises is this: when may a panel be regarded as having failed to discharge its duty under Article 11 of the DSU to make an objective assessment of the facts before it? Clearly, not every error in the appreciation of the evidence (although it may give rise to a question of law) may be characterized as a failure to make an objective assessment of the facts. In the present appeal, the European Communities repeatedly claims that the Panel disregarded or distorted or misrepresented the evidence submitted by the European Communities and even the opinions expressed by the Panel's own expert advisors. The duty to make an objective assessment of the facts is, among other things, an obligation to consider the evidence presented to a panel and to make factual findings on the basis of that evidence. The deliberate disregard of, or refusal to consider, the evidence submitted to a panel is incompatible with a panel's duty to make an objective assessment of the facts. The wilful distortion or misrepresentation of the evidence put before a panel is similarly inconsistent with an objective assessment of the facts. "Disregard" and "distortion" and "misrepresentation" of the evidence, in their ordinary signification in judicial and quasi-judicial processes, imply not simply an error of judgment in the appreciation of evidence but rather an egregious error that calls into question the good faith of a panel.[101] A claim that a panel disregarded or distorted the evidence submitted to it is, in effect, a claim that the panel, to a greater or lesser degree, denied the party submitting the evidence fundamental fairness, or what in many jurisdictions is known as due process of law or natural justice.

134. It is, accordingly, incumbent upon us to examine the claims of the European Communities that the Panel here disregarded or distorted at least some of the evidence submitted to it.

A. Evidence with Regard to MGA

135. According to the European Communities, the Panel's finding that the experts advising the Panel have stated on several occasions that they are not aware of any publicly available scientific studies that evaluate the safety of MGA[102] is

[101] It might be asked whether the European Communities did not merely intend to use "disregard" and "distortion" as unusually forceful synonyms for "misapprehend" or "misappreciation". It is not, however, clear that the European Communities did so intend, considering among other things the marked frequency with which "disregard" and "distortion" were used.

[102] US Panel Report, para. 8.255; Canada Panel Report, para. 8.258.

manifestly not true.[103] The Panel cited only two of its experts (Dr. Ritter and Dr. McLean) and the statements of these two scientists do not entirely support the Panel's conclusion. Furthermore, the Panel did not mention that Dr. André and Dr. Lucier, two other experts advising the Panel, had respectively said that MGA is a "real risk" and that MGA is an "extraordinarily potent progestant", that is "about 30 times more potent than progesterone and orally active".[104] We note that Dr. Ritter clearly stated with regard to MGA that he had "no information other than of a proprietary nature which [he] did not use"[105] and that Dr. McLean stated he had made no comment in his submission about MGA "because there hasn't been a large amount of data package available".[106] These two statements tend to support the Panel's conclusion. It is true that the Panel does not refer to the statements by Dr. Lucier and Dr. André. However, these statements do not contradict the Panel's conclusion that there is no publicly available study on the safety of MGA. Furthermore, while the Panel could have made a reference to and an evaluation of the statements by Dr. André and Dr. Lucier concerning MGA, it is generally within the discretion of the Panel to decide which evidence it chooses to utilize in making findings. We do not think that the Panel's silence on the statements of Dr. André and Dr. Lucier constitutes a distortion or disregard of evidence.

136. The European Communities argues that the Panel failed to request the submission of data on MGA and contends that this failure constituted a violation of Article 11 of the DSU. However, we see nothing in Article 11 to suggest that there is an obligation on the Panel to gather data relating to MGA and that it was therefore required to request the submission of this data.

137. Furthermore, the European Communities states that the Panel arbitrarily disregarded all the information concerning MGA that the European Communities had supplied to the Panel. The information here referred to are studies and reports of the IARC on hormones, including progestins, a category of substances to which MGA is said to belong. However, we note that the Panel did not simply ignore the IARC studies and reports but rather had indicated it did not consider them to be relevant because it found that a risk assessment needs to be carried out for each individual substance.[107]

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[103] EC's appellant's submission, para. 168.

[104] EC's appellant's submission, para. 170, quoting Annex to the US and Canada Panel Reports, para. 852.

[105] Annex to the US and Canada Panel Reports, para. 352.

[106] Annex to the US and Canada Panel Reports, para. 354.

[107] US Panel Report, para. 8.257; Canada Panel Report, para. 8.260. The Panel pointed out that with respect to the five other hormones in dispute, JECFA, Codex and the European Communities itself have conducted or invoked risk assessments for each individual substance. Furthermore, the Panel referred to the paper presented at the 1995 EC Scientific Conference by J. Bridges and O. Bridges on "Hazards of Growth Promoting Agents and Strategies of Risk Assessment" (Conference Proceedings, p. 250). US Panel Report, para. 8.260; Canada Panel Report, para. 8.263.

B. Evidence with Regard to the Five Other Hormones

138. With regard to the five other hormones in dispute, the European Communities contends that the Panel manifestly distorted the scientific evidence presented by the European Communities and eliminated dissenting scientific views of its own experts in an attempt to make the desired result fit the scientific record.[108] First, the European Communities submits[109] that the Panel incorrectly quotes some of the statements of Dr. Lucier and totally ignores other more relevant statements he made.[110] We note that the Panel did indeed quote Dr. Lucier incorrectly. The Panel wrongly interpreted Dr. Lucier's statement in paragraph 819 of the Annex as meaning that the 0 to 1 in a million risk is caused by the *total amount of oestrogens in treated meat*. It is clear that Dr. Lucier stated that this risk is caused by the small fraction of oestrogens that is *added for growth promotion purposes*. However, this mistake on the part of the Panel in interpreting Dr. Lucier's statement does not constitute a *deliberate* disregard of evidence or *gross* negligence amounting to bad faith. The Panel also failed to refer to certain other statements made by Dr. Lucier. It seems to us that these statements either merely clarify the statement discussed above or are of a general nature. The Panel cannot realistically refer to all statements made by the experts advising it and should be allowed a substantial margin of discretion as to which statements are useful to refer to explicitly. The same thing may be said with regard to the claim by the European Communities that the Panel failed to quote certain statements by Dr. Ritter and Dr. McLean.[111]

139. Second, it is claimed that the Panel manifestly distorted the views of Dr. André when it said that he did not contest the statements made by the other Panel experts on the safety of the hormones in dispute.[112] To the contrary, according to the European Communities, the views expressed by Dr. André support the scientific opinions presented by the EC scientists.[113] Whether or not the views of Dr. André support the statements made by the other Panel experts or the opinions expressed by the EC scientists may be an issue of fact; it does require some technical expertise to deal with it. However, even if the Panel has interpreted the views of Dr. André incorrectly, we see no reason, and no reason was advanced, to consider this mistake as a *deliberate disregard* or *distortion* of evidence.

140. Third, it is claimed that the Panel manifestly distorted the scientific evidence by considering that the 1995 EC Scientific Conference amounted to a risk

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[108] EC's appellant's submission, para. 350.
[109] EC's appellant's submission, para. 347.
[110] See, in particular, footnote 331 of the US Panel Report and footnote 437 of the Canada Panel Report.
[111] See the statements of Dr. Ritter in paras. 322, 743 and 782, and the statement of Dr. McLean in para. 824, of the Annex to the US and Canada Panel Reports.
[112] See footnote 348 of the US Panel Report and footnote 455 of the Canada Panel Report.
[113] See, in particular, paras. 6.99 to 6.101 of the US Panel Report and paras. 6.98 to 6.100 of the Canada Panel Report.

assessment in the sense of Articles 5.1-5.2. However, we note that the Panel does not state that the 1995 EC Conference amounted to a risk assessment. The Panel includes this Conference in the listing of scientific evidence concerning the hormones at issue referred to by the European Communities.[114] With regard to the reports mentioned in this list, the Panel states that several of these reports appear to meet the minimum requirements of a risk assessment, referring to the Lamming Report and the 1988 and 1989 JECFA Reports.[115] The Panel does not, however, refer to the 1995 EC Conference. The Panel discusses the scientific conclusions to be drawn from the 1995 EC Scientific Conference but this does not amount to designating the Conference as a risk assessment.[116]

141. Fourth, the European Communities contends that the distinction made by the Panel between studies that generally relate to the hormones in dispute and studies that specifically address residues in food of these hormones when used for growth promotion purposes is a distinction devised by the Panel for the sole purpose of rejecting the relevance of the 1987 IARC Monographs in this case and amounts to a distortion of relevant scientific evidence.[117] We note, however, that the Panel did consider the 1987 IARC Monographs but held that they could not be regarded as part of a risk assessment for the hormones at issue because the Monographs do not address the carcinogenic potential of these hormones when used specifically for growth promotion purposes or with respect to residue levels comparable to those present after such use[118], or the potential for adverse effects arising from the presence *in food* of residues of the hormones in dispute or from residue levels comparable to those present in food. The Panel's distinction between general and specific studies and its treatment of the 1987 IARC Monographs does not, therefore, appear arbitrary. Furthermore, we note that the Panel concluded, in the alternative, that the Monographs have been taken into account in, and do not contradict, the other studies referred to by the European Communities, in particular the 1988 and 1989 JECFA Reports.[119] We believe that the Panel's treatment of the 1987 IARC Monographs does not amount to a distortion of evidence.

142. Fifth, the European Communities submits that the Panel made no attempt whatsoever to discuss "the scientific views and evidence presented by the other EC scientists" and therefore violated Article 11 of the DSU.[120] It is our understanding that the European Communities refers here to the articles and opinions of individual scientists that are included in the Panel's list of scientific evidence

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[114] US Panel Report. para. 8.108; Canada Panel Report, para 8.111. The 1995 EC Conference Proceedings were submitted by the European Communities itself as annexes to its first submission to the Panel in both the US and Canada proceedings.
[115] US Panel Report, para. 8.111; Canada Panel Report, para. 8.114.
[116] US Panel Report, para. 8.123; Canada Panel Report, para. 8.126.
[117] EC's appellant's submission, para. 368.
[118] US Panel Report, para. 8.127; Canada Panel Report, para. 8.130.
[119] US Panel Report, para. 8.129; Canada Panel Report, para. 8.132.
[120] EC's appellant's submission, para. 380.

referred to by the European Communities.[121] We note that, contrary to what the European Communities claims, the Panel does discuss these articles and opinions of individual scientists. The Panel Report included a summary discussion of these articles and opinions.[122] However, as the Panel explains, the scientific evidence included in these articles and opinions relates to the carcinogenic or genotoxic potential of entire categories of hormones or the hormones at issue in general; not when used specifically for growth promotion purposes or with respect to residue levels comparable to those present in meat after such use. In our opinion, the Panel's treatment of the articles and opinions of individual scientists, like its treatment of the 1987 IARC Monographs, does not amount to a distortion of evidence.

C. Evidence with Regard to the Issue of Control

143. With regard to the issue of control, the European Communities contends that the Panel failed to take into account the evidence submitted by the European Communities[123] and ignored statements made by some of its own experts.[124] We observe that the Panel did indeed not explicitly refer to all the evidence regarding the issue of control before it. The Panel had found that the risks related to the general problems of control should not be taken into account in risk assessment[125] and accordingly did not refer extensively to the evidence regarding the issue of control. Furthermore, we note that the Panel, subsequently and in the alternative, concluded that even if the issue of control, and the evidence relating to that issue, could be taken into account, the European Communities had not supplied *convincing* evidence. The Panel, it appears, excluded that evidence on the *legal ground* of non-relevancy; as will be seen later, the Panel erred in law in holding the evidence non-relevant. Nevertheless, it did examine the evidence.[126]

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[121] US Panel Report, para. 8.108; Canada Panel Report, para. 8.111.

[122] US Panel Report, para. 8.130; Canada Panel Report, para. 8.133. The Panel itself refers to some of the articles and opinions in paras. 4.131-4.136 and 4.180 of the US Panel Report, and paras. 4.154-4.166 of the Canada Panel Report.

[123] The European Communities contends that it submitted convincing specific evidence to the Panel that control would be more difficult under a regime where the hormones in dispute were allowed (under specific conditions of use) than under the current EC regime where the hormones in dispute are banned. It also contends that it submitted clear evidence to the Panel, specifying the risks for human health that the inadequate control of these hormones can pose and that in the United States and Canada there were instances in which the MRL's were not respected. Finally the European Communities submitted evidence relating the practical and technical difficulties that are specific to control of hormones. EC's appellant's submission, paras. 403-433.

[124] EC's appellant's submission, para. 416. The European Communities submits that, for example, Dr. André's reference to misuse in France (see para. 168 of the Annex to the US and Canada Panel Reports) and Dr. McLean's statement on the difficulty of controlling treatment of animals (see para. 474 of the Annex to the US and Canada Panel Reports) were not taken into account by the Panel.

[125] US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

[126] US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

144. The European Communities also claims that the Panel incorrectly quoted the statements of its experts.[127] Referring to a number of specific statements[128], the Panel stated that the experts advising the Panel made clear that the potential for abuse under a regime where the hormones in dispute are allowed under specified conditions and under the current regime where they are banned, would be comparable. The European Communities submits that in the statements referred to by the Panel, the experts either explicitly stated they were speculating or added strong reservations to their opinions. After reading these statements carefully, we come to the conclusion that the Panel did not in fact represent the opinions of its experts accurately. However, this mistake does not amount to the egregious disregarding or distorting of evidence before the Panel.

D. Evidence on Article 5.5

145. The European Communities claims that in finding that the difference in its levels of protection in respect of five of the hormones at issue and in respect of carbadox and olaquindox is arbitrary or unjustifiable[129], the Panel did not take into account the evidence before it.[130] We note that the Panel considered in detail each of the arguments and related evidence referred to by the European Communities on this particular point.[131] Although the Panel did not agree with the arguments advanced by the European Communities, we do not believe that in doing so, the Panel arbitrarily ignored or manifestly distorted the evidence before it. We deal with these arguments below in some detail.[132]

IX. CERTAIN PROCEDURES ADOPTED BY THE PANEL

A. The Selection and Use of Experts

146. The European Communities considers that in its selection and use of experts, the Panel has violated Article 11.2 of the *SPS Agreement* and Articles 11, 13.2 and Appendix 4 of the DSU.[133] We note that the Panel decided to request

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127 EC's appellant's submission, para. 419.
128 US Panel Report, footnote 362; Canada Panel Report, footnote 469.
129 US Panel Report, para. 8.238; Canada Panel Report, para. 8.241.
130 The European Communities argues that it had advanced six reasons why this distinction is not arbitrary or unjustifiable but the Panel rejected all these reasons, and in doing so, it failed to take into account the evidence before it. The reasons advanced by the European Communities were the following: first, that carbadox and olaquindox are not hormones and have a different mode of action; second, that carbadox and olaquindox act as growth promoters by combating the development of bacteria; third, that carbadox and olaquindox are only available in prepared feedstuffs in predetermined dosages; fourth, that there are no alternatives to carbadox and olaquindox; fifth, that carbadox cannot be abused; and sixth, that carbadox is used in very small quantities and is hardly absorbed. EC's appellant's submission, paras. 529-548.
131 US Panel Report, paras. 8.231-8.238; Canada Panel Report, paras. 8.234-8.240.
132 See paras. 227-235 of this Report.
133 EC's appellant's submission, para. 587.

the opinion of experts on certain scientific and other technical matters raised by the parties to the dispute, and rather than establishing an experts review group, the Panel considered it more useful to leave open the possibility of receiving a range of opinions from the experts in their individual capacity. The Panel stresses, among other things, that:

> We considered, however, that neither Article 11.2 of the SPS Agreement nor Article 13.2 of the DSU limits our right to seek information from *individual* experts as provided for in Article 11.2, first sentence, of the SPS Agreement and Articles 13.1 and 13.2, first sentence, of the DSU.[134]

147. We agree with the Panel. Both Article 11.2 of the *SPS Agreement* and Article 13 of the DSU enable panels to seek information and advice as they deem appropriate in a particular case. Article 11.2 of the *SPS Agreement* states:

> In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group. (underlining added)

Article 13 of the DSU provides, in relevant part:

> 1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate ...
>
> 2. Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to the dispute, a panel *may* request an advisory report in writing from an experts review group ... (underlining added)

We find that in disputes involving scientific or technical issues, neither Article 11.2 of the *SPS Agreement*, nor Article 13 of the DSU prevents panels from consulting with individual experts. Rather, both the *SPS Agreement* and the DSU leave to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate.

148. Both Article 11.2 of the *SPS Agreement* and Article 13.2 of the DSU require panels to consult with the parties to the dispute during the selection of the experts. However, it is not claimed by any of the participants in this appeal that the Panel did not consult with them when appointing the experts. Moreover, it is uncontested that the experts have been selected in accordance with procedures on which all the participants have previously agreed.[135] It is similarly uncontested

[134] US Panel Report, para. 8.7; Canada Panel Report, para. 8.7.
[135] US Panel Report, paras. 6.1-6.10; Canada Panel Report, paras. 6.1-6.9.

that, among the experts consulted by the Panel, there are nationals from each of the parties to the dispute. The rules and procedures set forth in Appendix 4 of the DSU apply in situations in which expert review groups have been established. However, this is not the situation in this particular case. Consequently, once the panel has decided to request the opinion of individual scientific experts, there is no legal obstacle to the panel drawing up, in consultation with the parties to the dispute, *ad hoc* rules for those particular proceedings.

149. We conclude, therefore, that in its selection and use of experts, the Panel has not acted inconsistently with Articles 11, 13.2 and Appendix 4 of the DSU and Article 11.2 of the *SPS Agreement*.

B. Additional Third Party Rights to the United States and Canada

150. The European Communities contends that, notwithstanding its protest that these decisions affected its rights of defence, the Panel took a number of decisions granting additional third party rights to Canada and the United States which are not justified by Article 9.3 of the DSU, are inconsistent with Articles 7.1, 7.2, 18.2 and 10.3 thereof, and were not granted to the other third parties.[136] We recall that the European Communities refers to the following decisions of the Panel: first, to hold a joint meeting with scientific experts; second, to give access to all of the information submitted in the United States' proceeding to Canada; third, to give access to all of the information submitted in the Canadian proceeding to the United States; and fourth, to invite the United States to observe and make a statement at the second substantive meeting in the proceeding initiated by Canada.

151. Article 9.3 of the DSU reads as follows:

> If more than one panel is established to examine the complaints related to the same matter, to the greatest extent possible the same persons shall serve as panelists on each of the separate panels and the timetable for the panel process in such disputes shall be harmonized.

After examining the procedural course of the two disputes, we consider that four aspects should be underlined. First, both proceedings dealt with the same matter. Second, all the parties to both disputes agreed that the same panelists would serve on both proceedings. Third, although the proceeding initiated by Canada started several months after the proceeding started by the United States, the Panel managed to finish the Panel Reports at the same time. Fourth, given the fact that the same panelists were conducting two proceedings dealing with the same matter, neither Canada nor the United States were ordinary third parties in each other's complaint.

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[136] EC's appellant's submission, paras. 605 and 612.

152. With respect to the decision of the Panel to hold a joint meeting with scientific experts, the Panel explains as follows:

> Prior to our meeting with scientific experts, we decided to hold that meeting jointly for both this Panel, requested by Canada, and the parallel panel requested by the United States. This decision stemmed from the similarities of the two cases (the same EC measures are at issue and both cases are dealt with by the same panel members), our decision to use the same scientific experts in both cases and the fact that we had already decided to invite Canada and the United States to participate in the meeting with scientific experts in each of the two cases. In addition, we considered that, from a practical perspective, there was a need to avoid repetition of arguments and/or questions at our meetings with the scientific experts. The European Communities objected to this decision arguing that one joint meeting with experts, instead of two separate meetings, was likely to affect its procedural rights of defence. Where it made precise claims of prejudice to its rights of defence, we took corrective action.[137]

We consider the explanation of the Panel quite reasonable, and its decision to hold a joint meeting with the scientific experts consistent with the letter and spirit of Article 9.3 of the DSU. Clearly, it would be an uneconomical use of time and resources to force the Panel to hold two successive but separate meetings gathering the same group of experts twice, expressing their views twice regarding the same scientific and technical matters related to the same contested EC measures. We do not believe that the Panel has erred by addressing the EC procedural objections only where the European Communities could make a precise claim of prejudice. It is evident to us that a procedural objection raised by a party to a dispute should be sufficiently specific to enable the panel to address it.[138]

153. The decision of the Panel to use and provide all information to the parties in both disputes was taken in view of its previous decision to hold a joint meeting with the experts.[139] The European Communities asserts that it cannot see how providing information in one of the proceedings to a party in the other helps to harmonize timetables.[140] We can see a relation between timetable harmonization within the meaning of Article 9.3 of the DSU and economy of effort. In disputes where the evaluation of scientific data and opinions plays a significant role, the

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[137] Canada Panel Report, para. 8.18. See also US Panel Report, para. 8.14.

[138] Furthermore, the DSU, and in particular its Appendix 3, leave panels a margin of discretion to deal, always in accordance with due process, with specific situations that may arise in a particular case and that are not explicitly regulated. Within this context, an appellant requesting the Appellate Body to reverse a panel's ruling on matters of procedure must demonstrate the prejudice generated by such legal ruling.

[139] US Panel Report, para. 8.15; Canada Panel Report, para. 8.19.

[140] EC's appellant's submission, para. 610.

panel that is established later can benefit from the information gathered in the context of the proceedings of the panel established earlier. Having access to a common pool of information enables the panel and the parties to save time by avoiding duplication of the compilation and analysis of information already presented in the other proceeding.[141] Article 3.3 of the DSU recognizes the importance of avoiding unnecessary delays in the dispute settlement process and states that the prompt settlement of a dispute is essential to the effective functioning of the WTO. In this particular case, the Panel tried to avoid unnecessary delays, making an effort to comply with the letter and spirit of Article 9.3 of the DSU. Indeed, as noted earlier, despite the fact that the Canadian proceeding was initiated several months later than that of the United States, the Panel managed to finish both Panel Reports at the same time.

154. Regarding the participation of the United States in the second substantive meeting of the Panel requested by Canada, the Panel states:

> This decision was, *inter alia*, based on the fact that our second meeting was held the day after our joint meeting with the scientific experts and that the parties to this dispute would, therefore, most likely comment on, and draw conclusions from, the evidence submitted by these experts to be considered in both cases. Since in the panel requested by the United States the second meeting was held before the joint meeting with scientific experts, we considered it appropriate, in order to safeguard the rights of the United States in the proceeding it requested, to grant the United States the opportunity to observe our second meeting in this case and to make a brief statement at the end of that meeting.[142]

The explanation of the Panel appears reasonable to us. If the Panel had not given the United States an opportunity to participate in the second substantive meeting of the proceedings initiated by Canada, the United States would not have had the same degree of opportunity to comment on the views expressed by the scientific experts that the European Communities and Canada enjoyed. Although Article 12.1 and Appendix 3 of the DSU do not specifically require the Panel to grant this opportunity to the United States, we believe that this decision falls within the sound discretion and authority of the Panel, particularly if the Panel considers it necessary for ensuring to all parties due process of law. In this regard, we note that in *European Communities - Bananas*[143], the panel considered that particular circumstances justified the grant to third parties of rights somewhat broader than those explicitly envisaged in Article 10 and Appendix 3 of the DSU. We conclude that, in the case before us, circumstances justified the Panel's decision to

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[141] Moreover, in the proceeding initiated by Canada, the European Communities made references to materials that it had previously submitted in the proceeding initiated by the United States. Canada's appellee's submission, para. 216.

[142] Canada Panel Report, para. 8.20.

[143] Adopted 25 September 1997, WT/DS27/AB/R.

allow the United States to participate in the second substantive meeting of the proceedings initiated by Canada.

C. The Difference Between Legal Claims and Arguments

155. Arguing that panels are not entitled to make findings beyond what has been requested by the parties, the European Communities asserts that the Panel has erred by basing the main part of its reasoning on Article 5.5 of the *SPS Agreement* on a claim that the complainants had not made.[144] According to the European Communities, the complainants did not complain of a supposed difference of treatment between artificially added or exogenous natural and synthetic hormones when used for growth promotion purposes compared with the naturally present endogenous hormones in untreated meat and other foods (such as milk, cabbage, broccoli or eggs). The European Communities states that nowhere in the sections of the Panel Reports summarising the arguments on Article 5.5 is there any mention of such an argument.

156. Considering that in the request for the establishment of a panel in the proceeding initiated by the United States[145], as well as in the proceeding started by Canada[146], both complainants have included a claim that the EC ban is inconsistent with Article 5 of the *SPS Agreement*, we believe that the objection of the European Communities overlooks the distinction between legal claims made by the complainant and arguments used by that complainant to sustain its legal claims. In *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* we said:

> We stated ... 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. That past practice required that a claim had to be included in the documents referred to, or contained in, 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

[144] EC's appellant's submission, paras. 495 and 594.
[145] WT/DS26/6, 25 April 1996.
[146] WT/DS48/5, 17 September 1996.

> first and second panel meetings with the parties as a case proceeds.[147] (footnotes omitted)

Panels are inhibited from addressing legal claims falling outside their terms of reference. However, nothing in the DSU limits the faculty of a panel freely to use arguments submitted by any of the parties - or to develop its own legal reasoning - to support its own findings and conclusions on the matter under its consideration. A panel might well be unable to carry out an objective assessment of the matter, as mandated by Article 11 of the DSU, if in its reasoning it had to restrict itself solely to arguments presented by the parties to the dispute. Given that in this particular case both complainants claimed that the EC measures were inconsistent with Article 5.5 of the *SPS Agreement*, we conclude that the Panel did not make any legal finding beyond those requested by the parties.

X. THE INTERPRETATION OF ARTICLES 3.1 AND 3.3 OF THE *SPS AGREEMENT*

157. The European Communities appeals from the conclusion of the Panel that the European Communities, by maintaining SPS measures which are not based on existing international standards without justification under Article 3.3 of the *SPS Agreement*, has acted inconsistently with the requirements contained in Article 3.1 of that Agreement.

158. It will be seen below that the Panel is actually saying that the European Communities acted inconsistently with the requirements of both Articles 3.1 and 3.3 of the *SPS Agreement*, a position that flows from the Panel's view of a supposed "general rule - exception" relationship between Articles 3.1 and 3.3, a view we have indicated we do not share.[148]

159. The above conclusion of the Panel has three components: first, international standards, guidelines and recommendations exist in respect of meat and meat products derived from cattle to which five of the hormones involved have been administered for growth promotion purposes; secondly, the EC measures involved here are not based on the relevant international standards, guidelines and recommendations developed by Codex, because such measures are not in conformity with those standards, guidelines and recommendations; and thirdly, the EC measures are "not justified under", that is, do not comply with the requirements of Article 3.3. *En route* to its above-mentioned conclusion, the Panel developed three legal interpretations, which have all been appealed by the European Communities and which need to be addressed: the first relates to the meaning of "based on" as used in Article 3.1; the second is concerned with the relationship between Articles 3.1, 3.2 and 3.3 of the *SPS Agreement*; and the third

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[147] Adopted 16 January 1998, WT/DS50/AB/R, para. 88.
[148] See paras. 104 and 106 of this Report.

relates to the requirements of Article 3.3 of the *SPS Agreement*. As may be expected, the Panel's three interpretations are intertwined.

A. The Meaning of "Based On" as Used in Article 3.1 of the SPS Agreement

160. Article 3.1 provides:

> To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

161. Addressing the meaning of "based on", the Panel constructs the following interpretations:

> The SPS Agreement does not explicitly define the words *based on* as used in Article 3.1. However, Article 3.2, which introduces a presumption of consistency with both the SPS Agreement and GATT for sanitary measures which *conform to* international standards, equates measures *based on* international standards with measures which *conform to* such standards. Article 3.3, in turn, explicitly relates the definition of sanitary measures *based on* international standards to the level of sanitary protection achieved by these measures. Article 3.3 stipulates the conditions to be met for a Member to enact or maintain certain sanitary measures which are *not* based on international standards. It applies more specifically to measures "which result in a *higher level* of sanitary ... protection than would be achieved by measures based on the relevant international standards" or measures "which result in a *level* of sanitary ... protection *different* from that which would be achieved by measures based on international standards". One of the determining factors in deciding whether a measure is *based on* an international standard is, therefore, the level of protection that measure achieves. According to Article 3.3 all measures which *are* based on a given international standard should in principle achieve the *same* level of sanitary protection. Therefore, if an international standard reflects a specific level of sanitary protection and a sanitary measure implies a *different* level, that measure cannot be considered to be *based on* the international standard.
>
> We find, therefore, that for a sanitary measure to be *based on* an international standard in accordance with Article 3.1, that *measure* needs to reflect the same level of sanitary protection as the *standard*. In this dispute a comparison thus needs to be made between the level of protection reflected in the EC measures in dispute and

> that reflected in the Codex standards for each of the five hormones at issue.[149] (underlining added)

162. We read the Panel's interpretation that Article 3.2 "equates" measures "based on" international standards with measures which "conform to" such standards, as signifying that "based on" and "conform to" are identical in meaning. The Panel is thus saying that, henceforth, SPS measures of Members *must* "conform to" Codex standards, guidelines and recommendations.

163. We are unable to accept this interpretation of the Panel. In the first place, the ordinary meaning of "based on" is quite different from the plain or natural import of "conform to". A thing is commonly said to be "based on" another thing when the former "stands" or is "founded" or "built" upon or "is supported by" the latter.[150] In contrast, much more is required before one thing may be regarded as "conform[ing] to" another: the former must "comply with", "yield or show compliance" with the latter. The reference of "conform to" is to "correspondence in form or manner", to "compliance with" or "acquiescence", to "follow[ing] in form or nature".[151] A measure that "conforms to" and incorporates a Codex standard is, of course, "based on" that standard. A measure, however, based on the same standard might not conform to that standard, as where only some, not all, of the elements of the standard are incorporated into the measure.

164. In the second place, "based on" and "conform to" are used in different articles, as well as in differing paragraphs of the same article. Thus, Article 2.2 uses "based on", while Article 2.4 employs "conform to". Article 3.1 requires the Members to "base" their SPS measures on international standards; however, Article 3.2 speaks of measures which "conform to" international standards. Article 3.3 once again refers to measures "based on" international standards. The implication arises that the choice and use of different words in different places in the *SPS Agreement* are deliberate, and that the different words are designed to convey different meanings. A treaty interpreter is not entitled to assume that such usage was merely inadvertent on the part of the Members who negotiated and wrote that Agreement.[152] Canada has suggested the use of different terms was "accidental" in this case, but has offered no convincing argument to support its suggestion. We do not believe this suggestion has overturned the inference of deliberate choice.

165. In the third place, the object and purpose of Article 3 run counter to the Panel's interpretation. That purpose, Article 3.1 states, is "[t]o harmonize [SPS] measures on as wide a basis as possible ...". The preamble of the *SPS Agreement*

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[149] US Panel Report, paras. 8.72 and 8.73; Canada Panel Report, paras. 8.75 and 8.76.

[150] L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles* (Clarendon Press), Vol. I, p. 187.

[151] L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles* (Clarendon Press), Vol. I, p. 477.

[152] Appellate Body Report, *United States - Underwear*, adopted 25 February 1997, WT/DS24/AB/R, DSR 1997:I, 11 at 25.

also records that the Members "[d]esir[e] to *further the use of harmonized [SPS] measures between Members* on the basis of international standards, guidelines and recommendations developed by the relevant international organizations ...". (emphasis added) Article 12.1 created a Committee on Sanitary and Phytosanitary Measures and gave it the task, *inter alia*, of "furtherance of its objectives, in particular with respect to harmonization" and (in Article 12.2) to "encourage the use of international standards, guidelines and recommendations by all Members". It is clear to us that harmonization of SPS measures of Members on the basis of international standards is projected in the Agreement, as a *goal*, yet to be realized *in the future*. To read Article 3.1 as requiring Members to harmonize their SPS measures *by conforming those measures with international standards*, guidelines and recommendations, *in the here and now*, is, in effect, to vest such international standards, guidelines and recommendations (which are by the terms of the Codex *recommendatory* in form and nature[153]) with *obligatory* force and effect. The Panel's interpretation of Article 3.1 would, in other words, transform those standards, guidelines and recommendations into binding *norms*. But, as already noted, the *SPS Agreement* itself sets out no indication of any intent on the part of the Members to do so. We cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation by mandating *conformity* or *compliance with* such standards, guidelines and recommendations.[154] To sustain such an assumption and to warrant such a far-reaching interpretation, treaty language far more specific and compelling than that found in Article 3 of the *SPS Agreement* would be necessary.

166. Accordingly, we disagree with the Panel's interpretation that "based on" means the same thing as "conform to".

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[153] US Panel Report, para. 8.59; Canada Panel Report, para. 8.62.

[154] The interpretative principle of *in dubio mitius*, widely recognized in international law as a "supplementary means of interpretation", has been expressed in the following terms:

> "The principle of *in dubio mitius* applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties."

R. Jennings and A. Watts (eds.), *Oppenheim's International Law*, 9th ed., Vol. I (Longman, 1992), p. 1278. The relevant case law includes: *Nuclear Tests Case (Australia v. France)*, (1974), *I.C.J. Reports*, p. 267 (International Court of Justice); *Access of Polish War Vessels to the Port of Danzig* (1931) PCIJ Rep., Series A/B, No.43, p. 142 (Permanent Court of International Justice); *USA-France Air Transport Services Arbitration* (1963), 38 *International Law Reports* 243 (Arbitral Tribunal); *De Pascale Claim* (1961), 40 *International Law Reports* 250 (Italian - United States Conciliation Commission). See also: I. Brownlie, *Principles of Public International Law*, 4th ed. (Clarendon Press, 1990), p. 631; C. Rousseau, *Droit International Public*, Vol. I (1990), p. 273; D. Carreau, *Droit International*, 4th ed. (Editions A. Pedone, 1994), p. 142; M. Díez de Velasco, *Instituciones de Derecho Internacional Público*, 9th ed., Vol. I (Editorial Tecnos, 1991), pp. 163-164; and B. Conforti, *Diritto Internazionale*, 3rd ed. (Editoriale Scientifica, 1987), pp. 99-100.

167. After having erroneously "equated" measures "based on" an international standard with measures that "conform to" that standard[155], the Panel proceeds to Article 3.3. According to the Panel, Article 3.3 "explicitly relates" the "definition of sanitary measures *based on* international standards to the level of sanitary protection achieved by those measures". The Panel then interprets Article 3.3 as saying that "all measures which are based on a given international standard should *in principle* achieve the *same* level of sanitary protection", and argues *a contrario* that "if a sanitary measure implies a *different* level (from that reflected in an international standard), that measure cannot be considered to be *based on* the international standard". The Panel concludes that, under Article 3.1, "for a sanitary measure to be *based on* an international standard ..., that *measure* needs to reflect the same level of sanitary protection as the *standard*".[156]

168. It appears to us that the Panel reads much more into Article 3.3 than can be reasonably supported by the actual text of Article 3.3. Moreover, the Panel's entire analysis rests on its flawed premise that "based on", as used in Articles 3.1 and 3.3, means the same thing as "conform to" as used in Article 3.2. As already noted, we are compelled to reject this premise as an error in law. The correctness of the rest of the Panel's intricate interpretation and examination of the consequences of the Panel's litmus test, however, have to be left for another day and another case.

B. Relationship Between Articles 3.1, 3.2 and 3.3 of the SPS Agreement

169. We turn to the relationship between Articles 3.1, 3.2 and 3.3 of the *SPS Agreement*. As observed earlier, the Panel assimilated Articles 3.1 and 3.2 to one another, designating the product as the "general rule", and contraposed that product to Article 3.3 which denoted the "exception". This view appears to us an erroneous representation of the differing situations that may arise under Article 3, that is, where a relevant international standard, guideline or recommendation exists.

170. Under Article 3.2 of the *SPS Agreement*, a Member may decide to promulgate an SPS measure that conforms to an international standard. Such a measure would embody the international standard completely and, for practical purposes, converts it into a municipal standard. Such a measure enjoys the benefit of a presumption (albeit a rebuttable one) that it is consistent with the relevant provisions of the *SPS Agreement* and of the GATT 1994.

171. Under Article 3.1 of the *SPS Agreement*, a Member may choose to establish an SPS measure that is based on the existing relevant international standard, guideline or recommendation. Such a measure may adopt some, not necessarily

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[155] US Panel Report, para. 8.72; Canada Panel Report, para. 8.75.
[156] US Panel Report, para. 8.73; Canada Panel Report, para. 8.76.

all, of the elements of the international standard. The Member imposing this measure does not benefit from the presumption of consistency set up in Article 3.2; but, as earlier observed, the Member is not penalized by exemption of a complaining Member from the normal burden of showing a *prima facie* case of inconsistency with Article 3.1 or any other relevant article of the *SPS Agreement* or of the GATT 1994.

172. Under Article 3.3 of the *SPS Agreement*, a Member may decide to set for itself a level of protection different from that implicit in the international standard, and to implement or embody that level of protection in a measure not "based on" the international standard. The Member's appropriate level of protection may be higher than that implied in the international standard. The right of a Member to determine its own appropriate level of sanitary protection is an important right. This is made clear in the sixth preambular paragraph of the *SPS Agreement*:

> *Members*,
>
> ...
>
> *Desiring* to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health; (underlining added)

As noted earlier, this right of a Member to establish its own level of sanitary protection under Article 3.3 of the *SPS Agreement* is an autonomous right and *not* an "exception" from a "general obligation" under Article 3.1.

C. The Requirements of Article 3.3 of the SPS Agreement

173. The right of a Member to define its appropriate level of protection is not, however, an absolute or unqualified right. Article 3.3 also makes this clear:

> Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[2] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures

based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

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[2] For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

174. The European Communities argues that there are two situations covered by Article 3.3 and that its SPS measures are within the first of these situations.[157] It is claimed that the European Communities has maintained SPS measures "which result in a higher level of ... protection than would be achieved by measures based on the relevant" Codex standard, guideline or recommendation, for which measures "there is a scientific justification".[158] It is also, accordingly, argued that the requirement of a risk assessment under Article 5.1 does not apply to the European Communities. At the same time, it is emphasized that the EC measures have satisfied the requirements of Article 2.2.[159]

175. Article 3.3 is evidently not a model of clarity in drafting and communication. The use of the disjunctive "or" does indicate that two situations are intended to be covered. These are the introduction or maintenance of SPS measures which result in a higher level of protection:

(a) "if there is a scientific justification"; or

(b) "as a consequence of the level of ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5".

It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that "all measures which result in a [higher] level of ... protection", that is to say, measures falling within situation (a) as well as those falling within situation (b), be "not inconsistent with any other provision of [the SPS] Agreement". "Any other provision of this Agreement" textually includes Article 5. Secondly, the footnote to Article 3.3, while attached to the end of the first sentence, defines "scientific justification" as an "examination and evaluation of available scientific information in conformity with relevant provisions of this Agreement ...". This examination and evaluation would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the *SPS Agreement*.

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157 EC's appellant's submission, paras. 240-244.
158 *SPS Agreement*, Article 3.3.
159 EC's appellee's submission, para. 88.

176. On balance, we agree with the Panel's finding that although the European Communities has established for itself a level of protection higher, or more exacting, than the level of protection implied in the relevant Codex standards, guidelines or recommendations, the European Communities was bound to comply with the requirements established in Article 5.1. We are not unaware that this finding tends to suggest that the distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real. Its involved and layered language actually leaves us with no choice.

177. Consideration of the object and purpose of Article 3 and of the *SPS Agreement* as a whole reinforces our belief that compliance with Article 5.1 was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection. In generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of Members on as wide a basis as possible, while recognizing and safeguarding, at the same time, the right and duty of Members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between Members or as a disguised restriction on international trade, without preventing Members from adopting or enforcing measures which are both "necessary to protect" human life or health and "based on scientific principles", and without requiring them to change their appropriate level of protection. The requirements of a risk assessment under Article 5.1, as well as of "sufficient scientific evidence" under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings. We conclude that the Panel's finding that the European Communities is required by Article 3.3 to comply with the requirements of Article 5.1 is correct and, accordingly, dismiss the appeal of the European Communities from that ruling of the Panel.

XI. THE READING OF ARTICLES 5.1 AND 5.2 OF THE *SPS AGREEMENT*: BASING SPS MEASURES ON A RISK ASSESSMENT

178. We turn to the appeal of European Communities from the Panel's conclusion that, by maintaining SPS measures which are not based on a risk assessment, the European Communities acted inconsistently with the requirements contained in Article 5.1 of the *SPS Agreement*.

179. Article 5.1 of the *SPS Agreement* provides:

> Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. (underlining added)

A. The Interpretation of "Risk Assessment"

180. At the outset, two preliminary considerations need to be brought out. The first is that the Panel considered that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 of the *SPS Agreement*[160], which reads as follows:

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. (underlining added)

We agree with this general consideration and would also stress that Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1: the elements that define the basic obligation set out in Article 2.2 impart meaning to Article 5.1.

181. The second preliminary consideration relates to the Panel's effort to distinguish between "risk assessment" and "risk management". The Panel observed that an assessment of risk is, at least with respect to risks to human life and health, a "scientific" examination of data and factual studies; it is not, in the view of the Panel, a "policy" exercise involving social value judgments made by political bodies.[161] The Panel describes the latter as "non-scientific" and as pertaining to "risk management" rather than to "risk assessment".[162] We must stress, in this connection, that Article 5 and Annex A of the *SPS Agreement* speak of "risk assessment" only and that the term "risk management" is not to be found either in Article 5 or in any other provision of the *SPS Agreement*. Thus, the Panel's distinction, which it apparently employs to achieve or support what appears to be a restrictive notion of risk assessment, has no textual basis. The fundamental rule of treaty interpretation requires a treaty interpreter to read and interpret the words actually used by the agreement under examination, and not words which the interpreter may feel should have been used.

1. Risk Assessment and the Notion of "Risk"

182. Paragraph 4 of Annex A of the *SPS Agreement* sets out the treaty definition of risk assessment: This definition, to the extent pertinent to the present appeal, speaks of:

> ... the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs. (underlining added)

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[160] US Panel Report, para. 8.93; Canada Panel Report, para. 8.96.
[161] US Panel Report, para. 8.94; Canada Panel Report, para. 8.97.
[162] US Panel Report, para. 8.95; Canada Panel Report, para. 8.98.

183. Interpreting the above definition, the Panel elaborates risk assessment as a two-step process that "should (i) *identify* the *adverse effects* on human health (if any) arising from the presence of the hormones at issue when used as growth promoters *in meat* ..., and (ii) if any such adverse effects exist, *evaluate* the *potential* or probability of occurrence of such effects".[163]

184. The European Communities appeals from the above interpretation as involving an erroneous notion of risk and risk assessment. Although the utility of a two-step analysis may be debated, it does not appear to us to be substantially wrong. What needs to be pointed out at this stage is that the Panel's use of "probability" as an alternative term for "potential" creates a significant concern. The ordinary meaning of "potential" relates to "possibility" and is different from the ordinary meaning of "probability".[164] "Probability" implies a higher degree or a threshold of potentiality or possibility. It thus appears that here the Panel introduces a quantitative dimension to the notion of risk.

185. In its discussion on a statement made by Dr. Lucier at the joint meeting with the experts in February 1997[165], the Panel states the risk referred to by this expert is an estimate which "... only represents a statistical range of 0 to 1 in a million, not a scientifically identified risk".[166] The European Communities protests vigorously that, by doing so, the Panel is in effect requiring a Member carrying out a risk assessment to quantify the potential for adverse effects on human health.[167]

186. It is not clear in what sense the Panel uses the term "scientifically identified risk". The Panel also frequently uses the term "identifiable risk"[168], and does not define this term either. The Panel might arguably have used the terms "scientifically identified risk" and "identifiable risk" simply to refer to an ascertainable risk: if a risk is not ascertainable, how does a Member ever know or demonstrate that it exists? In one part of its Reports, the Panel opposes a requirement of an "identifiable risk" to the uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not *ever* have adverse health effects.[169] We agree with the Panel that this theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed. In another part of its Reports, however, the Panel appeared to be using the term "sci-

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[163] US Panel Report, para. 8.98; Canada Panel Report, para. 8.101.

[164] The dictionary meaning of "potential" is "that which is possible as opposed to actual; a possibility"; L. Brown (ed.), *The New Shorter Oxford English Dictionary on Historical Principles*, Vol. 2, p. 2310 (Clarendon Press, 1993). In contrast, "probability" refers to "degrees of likelihood; the appearance of truth, or likelihood of being realized", and "a thing judged likely to be true, to exist, or to happen"; *Id*., p. 2362.

[165] Para. 819 of the Annex to the US and Canada Panel Reports.

[166] US Panel Report, footnote 331; Canada Panel Report, footnote 437.

[167] EC's appellant's submission, paras. 392-397.

[168] US Panel Report, paras. 8.124, 8.134, 8.136, 8.151, 8.153, 8.161, 8.162; Canada Panel Report, paras. 8.127, 8.137, 8.139, 8.154, 8.156, 8.164, 8.165.

[169] US Panel Report, paras. 8.152-8.153; Canada Panel Report, paras. 8.155-8.156.

entifically identified risk" to prescribe implicitly that a certain *magnitude* or threshold level of risk be demonstrated in a risk assessment if an SPS measure based thereon is to be regarded as consistent with Article 5.1.[170] To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the *SPS Agreement*. A panel is authorized only to determine whether a given SPS measure is "based on" a risk assessment. As will be elaborated below, this means that a panel has to determine whether an SPS measure is sufficiently supported or reasonably warranted by the risk assessment.

2. Factors to be Considered in Carrying Out a Risk Assessment

187. Article 5.2 of the *SPS Agreement* provides an indication of the factors that should be taken into account in the assessment of risk. Article 5.2 states that:

> In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

The listing in Article 5.2 begins with "available scientific evidence"; this, however, is only the beginning. We note in this connection that the Panel states that, for purposes of the EC measures in dispute, a risk assessment required by Article 5.1 is "a *scientific* process aimed at establishing the *scientific* basis for the sanitary measure a Member intends to take".[171] To the extent that the Panel intended to refer to a process characterized by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions, the Panel's statement is unexceptionable.[172] However, to the extent that the Panel purports to exclude from the scope of a risk assessment in the sense of Article 5.1, all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error. Some of the kinds of factors listed in Article

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[170] US Panel Report, footnote 331; Canada Panel Report, footnote 437.

[171] US Panel Report, para. 8.107; Canada Panel Report, para. 8.110.

[172] "The ordinary meaning of 'scientific', as provided by dictionary definitions, includes 'of, relating to, or used in science', 'broadly, having or appearing to have an exact, objective, factual, systematic or methodological basis', 'of, relating to, or exhibiting the methods or principles of science' and 'of, pertaining to, using, or based on the methodology of science'. Dictionary definitions of 'science' include 'the observation, identification, description, experimental investigation, and theoretical explanation of natural phenomena', 'any methodological activity, discipline, or study', and 'knowledge attained through study or practice'". (footnotes omitted) *United States' Statement of Administrative Action, Uruguay Round Agreements Act*, 203d Congress, 2d Session, House Document 103-316, Vol. 1, 27 September 1994, p. 90.

5.2 such as "relevant processes and production methods" and "relevant inspection, sampling and testing methods" are not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology. Furthermore, there is nothing to indicate that the listing of factors that may be taken into account in a risk assessment of Article 5.2 was intended to be a closed list. It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.

B. The Interpretation of "Based On"

1. A "Minimum Procedural Requirement" in Article 5.1?

188. Although it expressly recognizes that Article 5.1 does *not* contain any specific procedural requirements for a Member to base its sanitary measures on a risk assessment, the Panel nevertheless proceeds to declare that "there is a minimum procedural requirement contained in Article 5.1". That requirement is that "the Member imposing a sanitary measure needs to submit evidence that at least it actually *took into account* a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as *based on* a risk assessment".[173] The Panel goes on to state that the European Communities did not provide any evidence that the studies it referred to or the scientific conclusions reached therein "*have actually been taken into account by the competent EC institutions* either when it *enacted* those measures (in 1981 and 1988) or *at any later point in time*".[174] (emphasis added) Thereupon, the Panel holds that such studies could not be considered as part of a risk assessment on which the European Communities based its measures in dispute. Concluding that the European Communities had not met its burden of proving that it had satisfied the "minimum procedural requirement" it had found in Article 5.1, the Panel holds the EC measures as inconsistent with the requirements of Article 5.1.

189. We are bound to note that, as the Panel itself acknowledges, no textual basis exists in Article 5 of the *SPS Agreement* for such a "minimum procedural requirement". The term "based on", when applied as a "minimum procedural requirement" by the Panel, may be seen to refer to a human action, such as particular human individuals "taking into account" a document described as a risk assessment. Thus, "take into account" is apparently used by the Panel to refer to some subjectivity which, at some time, may be present in particular individuals but that, in the end, may be totally rejected by those individuals. We believe that "based on" is appropriately taken to refer to a certain *objective relationship* be-

[173] US Panel Report, para. 8.113; Canada Panel Report, para. 8.116.
[174] US Panel Report, para. 8.114; Canada Panel Report, para. 8.117.

tween two elements, that is to say, to an *objective situation* that persists and is observable between an SPS measure and a risk assessment. Such a reference is certainly embraced in the ordinary meaning of the words "based on" and, when considered in context and in the light of the object and purpose of Article 5.1 of the *SPS Agreement*, may be seen to be more appropriate than "taking into account". We do not share the Panel's interpretative construction and believe it is unnecessary and an error of law as well.

190. Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measures be "based on an assessment, as appropriate for the circumstances ...". The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization. The "minimum procedural requirement" constructed by the Panel, could well lead to the elimination or disregard of available scientific evidence that rationally supports the SPS measure being examined. This risk of exclusion of available scientific evidence may be particularly significant for the bulk of SPS measures which were put in place before the effective date of the *WTO Agreement* and that have been simply maintained thereafter.

191. In the course of demanding evidence that EC authorities actually "took into account" certain scientific studies, the Panel refers to the preambles of the EC Directives here involved. The Panel notes that such preambles did not mention any of the scientific studies referred to by the European Communities in the panel proceedings. Preambles of legislative or quasi-legislative acts and administrative regulations commonly fulfil requirements of the internal legal orders of WTO Members. Such preambles are certainly not required by the *SPS Agreement*; they are not normally used to demonstrate that a Member has complied with its obligations under international agreements. The absence of any mention of scientific studies in the preliminary sections of the EC Directives does not, therefore, prove anything so far as the present case is concerned.

2. Substantive Requirement of Article 5.1 - Rational Relationship Between an SPS Measure and a Risk Assessment

192. Having posited a "minimum procedural requirement" of Article 5.1, the Panel turns to the "substantive requirements" of Article 5.1 to determine whether the EC measures at issue are "based on" a risk assessment. In the Panel's view, those "substantive requirements" involve two kinds of operations: first, identifying the scientific conclusions reached in the risk assessment and the scientific conclusions implicit in the SPS measures; and secondly, examining those scientific conclusions to determine whether or not one set of conclusions matches, i.e.

conforms with, the second set of conclusions.[175] Applying the "substantive requirements" it finds in Article 5.1, the Panel holds that the scientific conclusions implicit in the EC measures do not conform with any of the scientific conclusions reached in the scientific studies the European Communities had submitted as evidence.[176]

193. We consider that, in principle, the Panel's approach of examining the scientific conclusions implicit in the SPS measure under consideration and the scientific conclusion yielded by a risk assessment is a useful approach. The relationship between those two sets of conclusions is certainly relevant; they cannot, however, be assigned relevance to the exclusion of everything else. We believe that Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the *SPS Agreement*, requires that the results of the risk assessment must sufficiently warrant - that is to say, reasonably support - the SPS measure at stake. The requirement that an SPS measure be "based on" a risk assessment is a substantive requirement that there be a rational relationship between the measure and the risk assessment.

194. We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure. The risk assessment could set out both the prevailing view representing the "mainstream" of scientific opinion, as well as the opinions of scientists taking a divergent view. Article 5.1 does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community. In some cases, the very existence of divergent views presented by qualified scientists who have investigated the particular issue at hand may indicate a state of scientific uncertainty. Sometimes the divergence may indicate a roughly equal balance of scientific opinion, which may itself be a form of scientific uncertainty. In most cases, responsible and representative governments tend to base their legislative and administrative measures on "mainstream" scientific opinion. In other cases, equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety. Determination of the presence or absence of that relationship can only be done on a case-to-case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects.

195. We turn now to the application by the Panel of the substantive requirements of Article 5.1 to the EC measures at stake in the present case. The Panel

[175] US Panel Report, para. 8.117; Canada Panel Report, para. 8.120.
[176] US Panel Report, para. 8.137; Canada Panel Report, para. 8.140.

lists the following scientific material to which the European Communities referred in respect of the hormones here involved (except MGA):

- the 1982 Report of the EC Scientific Veterinary Committee, Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the Report of the Scientific Group on Anabolic Agents in Animal Production ("Lamming Report");
- the 1983 Symposium on Anabolics in Animal Production of the *Office international des epizooties* ("OIE") ("1983 OIE Symposium");
- the 1987 Monographs of the International Agency for Research on Cancer ("IARC") on the Evaluation of Carcinogenic Risks to Humans, Supplement 7 ("1987 IARC Monographs");
- the 1988 and 1989 JECFA Reports;
- the 1995 European Communities Scientific Conference on Growth Promotion in Meat Production ("1995 EC Scientific Conference");
- articles and opinions by individual scientists relevant to the use of hormones (three articles in the journal Science, one article in the International Journal of Health Service, one report in The Veterinary Record and separate scientific opinions of Dr. H. Adlercreutz, Dr. E. Cavalieri, Dr. S.S. Epstein, Dr. J.G. Liehr, Dr. M. Metzler, Dr. Perez-Comas and Dr. A. Pinter, all of whom were part of the EC delegation at [the] joint meeting with experts).[177]

196. Several of the above scientific reports appeared to the Panel to meet the minimum requirements of a risk assessment, in particular, the Lamming Report and the 1988 and 1989 JECFA Reports. The Panel assumes accordingly that the European Communities had demonstrated the existence of a risk assessment carried out in accordance with Article 5 of the *SPS Agreement*.[178] At the same time, the Panel finds that the conclusion of these scientific reports is that the use of the hormones at issue (except MGA) for growth promotion purposes is "safe". The Panel states:

> ... none of the scientific evidence referred to by the European Communities which specifically addresses the safety of some or all of the hormones in dispute when used for growth promotion, indicates that an identifiable risk arises for human health from such use of these hormones if good practice is

[177] US Panel Report, para. 8.108; Canada Panel Report, para. 8.111.
[178] US Panel Report, para. 8.111; Canada Panel Report, para. 8.114.

> followed. All of the scientific studies outlined above came to the conclusion that the use of the hormones at issue (all but MGA, for which no evidence was submitted) for growth promotion purposes is safe; most of these studies adding that this conclusion assumes that good practice is followed.[179]

197. Prescinding from the difficulty raised by the Panel's use of the term "identifiable risk", we agree that the scientific reports listed above do not rationally support the EC import prohibition.[180]

198. With regard to the scientific opinion expressed by Dr. Lucier at the joint meeting with the experts, and as set out in paragraph 819 of the Annex to the US and Canada Panel Reports[181], we should note that this opinion by Dr. Lucier does not purport to be the result of scientific studies carried out by him or under his supervision focusing specifically on residues of hormones in meat from cattle fattened with such hormones.[182] Accordingly, it appears that the single divergent opinion expressed by Dr. Lucier is not reasonably sufficient to overturn the contrary conclusions reached in the scientific studies referred to by the European Communities that related specifically to residues of the hormones in meat from cattle to which hormones had been administered for growth promotion.

199. The European Communities laid particular emphasis on the 1987 IARC Monographs and the articles and opinions of individual scientists referred to above.[183] The Panel notes, however, that the scientific evidence set out in these Monographs and these articles and opinions relates to the carcinogenic potential of entire *categories* of hormones, or of the hormones at issue *in general*. The

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[179] US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

[180] In paras. 97-109 of this Report, we conclude that the Panel mistakenly required that the European Communities take on the burden of proof that its measures related to the hormones involved here, except MGA, are based on a risk assessment. We determine that the United States and Canada have to make a *prima facie* case that these measures are *not* based on a risk assessment. However, after careful consideration of the panel record, we are satisfied that the United States and Canada, although not required to do so by the Panel, did, in fact, make this *prima facie* case that the SPS measures related to the hormones involved here, except MGA, are not based on a risk assessment.

[181] This paragraph reads in relevant part:

> For every million women alive in the United States, Canada, Europe today, about a 110,000 of those women will get breast cancer. This is obviously a tremendous public health issue. Of those 110,000 women get breast cancer, maybe several thousand of them are related to the total intake of exogenous oestrogens from every source, including eggs, meat, phyto-oestrogens, fungal oestrogens, the whole body burden of exogenous oestrogens. And by my estimates one of those 110,000 would come from eating meat containing oestrogens as a growth promoter, if used as prescribed.

[182] Assuming that Dr. Lucier's estimate is realistic, it is noteworthy that there could be up to 371 persons who, under the conditions identified by Dr. Lucier, would get cancer in the Member States of the European Union. The total population of the Member States of the European Union in 1995 was 371 million.

[183] Para. 195 of this Report.

Monographs and the articles and opinions are, in other words, in the nature of general studies of or statements on the carcinogenic potential of the named hormones. The Monographs and the articles and opinions of individual scientists have not evaluated the carcinogenic potential of those hormones when used specifically *for growth promotion purposes*. Moreover, they do not evaluate the specific potential for carcinogenic effects arising from the presence *in "food"*, more specifically, "meat or meat products" of residues of the hormones in dispute. The Panel also notes that, according to the scientific experts advising the Panel, the data and studies set out in these 1987 Monographs have been taken into account in the 1988 and 1989 JECFA Reports and that the conclusions reached by the 1987 IARC Monographs are complementary to, rather than contradictory of, the conclusions of the JECFA Reports.[184] The Panel concludes that these Monographs and these articles and opinions are insufficient to support the EC measures at issue in this case.

200. We believe that the above findings of the Panel are justified. The 1987 IARC Monographs and the articles and opinions of individual scientists submitted by the European Communities constitute general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake - the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes - as is required by paragraph 4 of Annex A of the *SPS Agreement*. Those general studies, are in other words, relevant but do not appear to be sufficiently specific to the case at hand.

201. With regard to risk assessment concerning MGA, the European Communities referred to the 1987 IARC Monographs. These Monographs deal with, *inter alia*, the category of progestins of which the hormone progesterone is a member. The European Communities argues that because MGA is an anabolic agent which mimics the action of progesterone, the scientific studies and experiments relied on by the 1987 IARC Monographs were highly relevant.[185] However, the Monographs and the articles and opinions of the individual scientists did not include any study that demonstrated how closely related MGA is chemically and pharmacologically to other progestins and what effects MGA residues would actually have on human beings when such residues are ingested along with meat from cattle to which MGA has been administered for growth promotion purposes. It must be recalled in this connection that none of the other scientific material submitted by the European Communities referred to MGA, and that no international standard, guideline or recommendation has been developed by Codex relating specifically to MGA. The United States and Canada declined to submit any assessment of MGA upon the ground that the material they were

[184] US Panel Report, para. 8.129; Canada Panel Report, para. 8.132.
[185] EC's appellant's submission, para. 179 *ff*.

aware of was proprietary and confidential in nature. In other words, there was an almost complete absence of evidence on MGA in the panel proceedings. We therefore uphold the Panel's finding that there was no risk assessment with regard to MGA.

202. The evidence referred to above by the European Communities related to the biochemical risk arising from the ingestion by human beings of residues of the five hormones here involved in treated meat, where such hormones had been administered to the cattle in accordance with good veterinary practice.[186] The European Communities also referred to distinguishable but closely related risks - risks arising from failure to observe the requirements of good veterinary practice, in combination with multiple problems relating to detection and control of such abusive failure, in the administration of hormones to cattle for growth promotion.

203. The Panel considers this type of risk and examines the arguments made by the European Communities but finds no assessment of such kind of risk. Ultimately, the Panel rejects those arguments principally on *a priori* grounds. First, to the Panel, the provisions of Article 5.2 relating to "relevant inspection, sampling and testing methods":

> ... do not seem to cover the general problem of control (such as the problem of ensuring the observance of good practice) which can exist for any substance. The risks related to the general problem of control do not seem to be specific to the substance at issue but to the economic or social incidence related to a substance or its particular use (such as economic incentives for abuse). These non-scientific factors should, therefore not be taken into account in a risk assessment but in *risk management*.[187] (underlining added)

Moreover, the Panel finds that, assuming these factors could be taken into account in a risk assessment, the European Communities has not provided convincing evidence that the control or prevention of abuse of the hormones here involved is more difficult than the control of other veterinary drugs, the use of which is allowed in the European Communities. Further, the European Communities has not provided evidence that control would be more difficult under a regime where the use of the hormones in dispute is allowed under specific conditions than under the current EC regime of total prohibition both domestically and

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[186] Although the term used in the Codex Standards for the three natural hormones is *good animal husbandry practice* (Section I, MRLs, *Codex Alimentarius*, Vol. 3, pp. 7, 12 and 14), the Glossary of Terms and Definitions of the *Codex Alimentarius* does not contain this term. Instead, it defines the concept:

> "Good Practice in the Use of Veterinary Drugs (GPVD): Is the official recommended or authorized usage including withdrawal periods, approved by national authorities, of veterinary drugs under practical conditions".

We will therefore use the term *good veterinary practice* as a shorthand expression of the concept defined in the *Codex Alimentarius*.

[187] US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

in respect of imported meat. The Panel concludes by saying that banning the use of a substance does not necessarily offer better protection of human health than other means of regulating its use.[188]

204. The European Communities appeals from these findings of the Panel principally on two grounds: firstly, that the Panel has misinterpreted Article 5.2 of the *SPS Agreement*; secondly, that the Panel has disregarded and distorted the evidence submitted by the European Communities.[189]

205. In respect of the first ground, we agree with the European Communities that the Panel has indeed misconceived the scope of application of Article 5.2. It should be recalled that Article 5.2 states that in the assessment of risks, Members shall take into account, in addition to "available scientific evidence", "relevant processes and production methods; [and] relevant inspection, sampling and testing methods". We note also that Article 8 requires Members to "observe the provisions of Annex C in the operation of control, inspection and approval procedures ...". The footnote in Annex C states that "control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification". We consider that this language is amply sufficient to authorize the taking into account of risks arising from failure to comply with the requirements of good veterinary practice in the administration of hormones for growth promotion purposes, as well as risks arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice.

206. Most, if not all, of the scientific studies referred to by the European Communities, in respect of the five hormones involved here, concluded that their use for growth promotion purposes is "safe"[190], if the hormones are administered in accordance with the requirements of good veterinary practice. Where the condition of observance of good veterinary practice (which is much the same condition attached to the standards, guidelines and recommendations of Codex with respect to the use of the five hormones for growth promotion) is *not* followed, the logical inference is that the use of such hormones for growth promotion purposes may or may not be "safe".[191] The *SPS Agreement* requires assessment of the potential for adverse effects on human health arising from the presence of contaminants and toxins in food. We consider that the object and purpose of the *SPS Agreement* justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be. We do not mean to suggest that risks arising from potential abuse in the administration of controlled substances and from control problems need to be, or should be, evaluated by risk assessors in each and every case. When and if risks of these types do in fact arise,

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188 US Panel Report, para. 8.146; Canada Panel Report, para. 8.149.

189 EC's appellant's submission, para. 399 and 401.

190 US Panel Report, para. 8.124; Canada Panel Report, para. 8.127.

191 This point was clearly brought out during the oral hearing and both the United States and Canada expressed agreement with this inference. See footnote 186 of this Report concerning the usage of the terms "good veterinary practice" and "good animal husbandry practice".

risk assessors may examine and evaluate them. Clearly, the necessity or propriety of examination and evaluation of such risks would have to be addressed on a case-by-case basis. What, in our view, is a fundamental legal error is to exclude, on an *a priori* basis, any such risks from the scope of application of Articles 5.1 and 5.2. We disagree with the Panel's suggestion that exclusion of risks resulting from the combination of potential abuse and difficulties of control is justified by distinguishing between "risk assessment" and "risk management". As earlier noted, the concept of "risk management" is not mentioned in any provision of the *SPS Agreement* and, as such, cannot be used to sustain a more restrictive interpretation of "risk assessment" than is justified by the actual terms of Article 5.2, Article 8 and Annex C of the *SPS Agreement*.

207. The question that arises, therefore, is whether the European Communities did, in fact, submit a risk assessment demonstrating and evaluating the existence and level of risk arising in the present case from abusive use of hormones and the difficulties of control of the administration of hormones for growth promotion purposes, within the United States and Canada as exporting countries, and at the frontiers of the European Communities as an importing country. Here, we must agree with the finding of the Panel that the European Communities in fact restricted itself to pointing out the condition of administration of hormones "in accordance with good practice" "without further providing an assessment of the potential adverse effects related to non compliance with such practice".[192] The record of the panel proceedings shows that the risk arising from abusive use of hormones for growth promotion combined with control problems for the hormones at issue, may have been examined on two occasions in a scientific manner. The first occasion may have occurred at the proceedings before the Committee of Inquiry into the Problem of Quality in the Meat Sector established by the European Parliament, the results of which constituted the basis of the Pimenta Report of 1989. However, none of the original studies and evidence put before the Committee of Inquiry was submitted to the Panel. The second occasion could have been the 1995 EC Scientific Conference on Growth Promotion in Meat Production. One of the three workshops of this Conference examined specifically the problems of "detection and control". However, only one of the studies presented to the workshop discussed systematically some of the problems arising from the combination of potential abuse and problems of control of hormones and other substances.[193] The study presented a theoretical framework for the systematic analysis of such problems, but did not itself investigate and evaluate the actual problems that have arisen at the borders of the European Communities or within the United States, Canada and other countries exporting meat and meat products to the European Communities. At best, this study may represent the beginning of an assessment of such risks.

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[192] US Panel Report, para. 8.143; Canada Panel Report, para. 8.146.

[193] B. Jülicher, "Sampling Strategies", in *Proceedings of the Scientific Conference on Growth Promotion in Meat Production*, Brussels, 29 November to 1 December 1995, pp. 521-540.

208. In the absence of any other relevant documentation, we find that the European Communities did not actually proceed to an assessment, within the meaning of Articles 5.1 and 5.2, of the risks arising from the failure of observance of good veterinary practice combined with problems of control of the use of hormones for growth promotion purposes. The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel. We affirm, therefore, the ultimate conclusion of the Panel that the EC import prohibition is not based on a risk assessment within the meaning of Articles 5.1 and 5.2 of the *SPS Agreement* and is, therefore, inconsistent with the requirements of Article 5.1.

209. Since we have concluded above[194] that an SPS measure, to be consistent with Article 3.3, has to comply with, *inter alia*, the requirements contained in Article 5.1, it follows that the EC measures at issue, by failing to comply with Article 5.1, are also inconsistent with Article 3.3 of the *SPS Agreement*.

XII. THE READING OF ARTICLE 5.5 OF THE *SPS AGREEMENT*: CONSISTENCY OF LEVELS OF PROTECTION AND RESULTING DISCRIMINATION OR DISGUISED RESTRICTION ON INTERNATIONAL TRADE

210. The European Communities also appeals from the conclusion of the Panel[195] that, by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers appropriate in different situations which result in discrimination or a disguised restriction on international trade, the European Communities acted inconsistently with the requirements set out in Article 5.5 of the *SPS Agreement*.[196]

A. General Considerations: the Elements of Article 5.5

211. Article 5.5 of the *SPS Agreement* needs to be quoted in full:

> With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different

[194] See para. 177 of this Report.
[195] EC's appellant's submission, para. 448.
[196] US Panel Report, paras. 8.206, 8.218, 8.244, 8.266 and 8.269; Canada Panel Report, paras. 8.209, 8.221, 8.247, 8.269 and 8.272.

> situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

212. Article 5.5 must be read in context. An important part of that context is Article 2.3 of the *SPS Agreement*, which provides as follows:

> Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

When read together with Article 2.3, Article 5.5 may be seen to be marking out and elaborating a particular route leading to the same destination set out in Article 2.3.

213. The objective of Article 5.5 is formulated as the "achieving [of] consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection". Clearly, the desired consistency is defined as a goal to be achieved in the future. To assist in the realization of that objective, the Committee on Sanitary and Phytosanitary Measures is to develop *guidelines for the practical implementation of Article 5.5*, bearing in mind, among other things, that ordinarily, people do not voluntarily expose themselves to health risks. Thus, we agree with the Panel's view that the statement of that goal does not establish a *legal obligation* of consistency of appropriate levels of protection. We think, too, that the goal set is not absolute or perfect consistency, since governments establish their appropriate levels of protection frequently on an *ad hoc* basis and over time, as different risks present themselves at different times. It is only arbitrary or unjustifiable inconsistencies that are to be avoided.

214. Close inspection of Article 5.5 indicates that a complaint of violation of this Article must show the presence of three distinct elements. The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those *levels of protection* exhibit arbitrary or unjustifiable differences ("distinctions" in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the *measure* embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade.

215. We consider the above three elements of Article 5.5 to be cumulative in nature; all of them must be demonstrated to be present if violation of Article 5.5 is to be found. In particular, both the second and third elements must be found. The second element alone would not suffice. The third element must also be demonstrably present: the implementing measure must be shown to be applied in such a manner as to result in discrimination or a disguised restriction on international trade. The presence of the second element - the arbitrary or unjustifiable character of differences in *levels of protection* considered by a Member as appropriate in differing situations - may in practical effect operate as a "warning" signal that the implementing *measure* in its application *might* be a discriminatory measure or *might* be a restriction on international trade disguised as an SPS measure for the protection of human life or health. Nevertheless, the measure itself needs to be examined and appraised and, in the context of the differing levels of protection, shown to result in discrimination or a disguised restriction on international trade.

B. Different Levels of Protection in Different Situations

216. We examine the first element set out in Article 5.5, namely, that a Member has established different levels of protection which it regards as appropriate for itself in differing situations. The Panel, interpreting the term "different situations", states in effect that situations involving the same substance or the same adverse health effect may be compared to one another.[197] The European Communities protests this interpretation as erroneous: while it agrees that there must be some common element (e.g. the substance or drug, or the health risk), it argues that such common element is not necessarily sufficient to ensure a rational comparison.[198]

217. There appears no need to examine this matter at any length. Clearly, comparison of *several* levels of sanitary protection deemed appropriate by a Member is necessary if a panel's inquiry under Article 5.5 is to proceed at all. The situations exhibiting differing levels of protection cannot, of course, be compared unless they are comparable, that is, unless they present some common element or elements sufficient to render them comparable. If the situations proposed to be examined are *totally* different from one another, they would not be rationally comparable and the differences in levels of protection cannot be examined for arbitrariness.

218. In examining the EC measures here involved[199] and at least one other SPS measure of the European Communities[200], the Panel finds that several different levels of protection were projected by the European Communities:

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197 US Panel Report, para. 8.176; Canada Panel Report, para. 8.179.
198 EC's appellant's submission, para. 455.
199 See paras. 2-5 of this Report.

(i) the level of protection in respect of natural hormones when used for growth promotion[201];

(ii) the level of protection in respect of natural hormones occurring endogenously in meat and other foods[202];

(iii) the level of protection in respect of natural hormones when used for therapeutic or zootechnical purposes[203];

(iv) the level of protection in respect of synthetic hormones (zeranol and trenbolone) when used for growth promotion[204]; and

(v) the level of protection in respect of carbadox and olaquindox.[205]

C. Arbitrary or Unjustifiable Differences in Levels of Protection

219. The Panel then proceeds to compare level of protection (i) with, firstly, level of protection (ii) and, secondly, with level of protection (iii). Thereafter, the Panel compares levels of protection (i) and (iv) with level of protection (v). The Panel holds that the differences between levels of protection (i) and (iv) on the one hand, and level of protection (ii) on the other, are arbitrary and unjustifiable.[206] It further held that the differences in levels of protection (i) and (iv) on the one hand, and level (v) on the other, are also arbitrary and unjustifiable.[207] In contrast, the Panel does not undertake to compare level of protection (iii) with level of protection (i).[208] We examine below *seriatim* what the Panel has done and the results it has obtained.

220. The Panel first compares the levels of protection established by the European Communities in respect of natural and synthetic hormones when used for growth promotion purposes (levels of protection (i) and (iv)) with the level of protection set by the European Communities in respect of natural hormones occurring endogenously in meat and other natural foods (level of protection (ii)). The Panel finds the difference between these levels of protection "arbitrary" and

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[200] Directive du Conseil 70/524/CEE of 23 November 1970, Official Journal No. L 270, 14 December 1970, p. 1, the Annexes of which are replaced by Commission Directive 91/248/EEC of 12 April 1991, Official Journal No. L 124, 18 May 1991, p. 1.

[201] US Panel Report, para. 8.191; Canada Panel Report, para. 8.194; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

[202] US Panel Report, para. 8.191; Canada Panel Report, para. 8.194; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

[203] US Panel Report, para. 8.191; Canada Panel Report, para. 8.194.

[204] US Panel Report, para. 8.212; Canada Panel Report, para. 8.215.

[205] US Panel Report, para. 8.226 (with respect to carbadox only); Canada Panel Report, para. 8.229; and, with regard to MGA, US Panel Report, para. 8.268; Canada Panel Report, para. 8.271.

[206] US Panel Report, paras. 8.197 and 8.214; Canada Panel Report, paras. 8.200 and 8.217; and, with regard to MGA, US Panel Report, para. 8.265; Canada Panel Report, para. 8.268.

[207] US Panel Report, para. 8.238; Canada Panel Report, para. 8.241; and, with regard to MGA, US Panel Report, para. 8.268; Canada Panel Report, para. 8.271.

[208] US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.

"unjustifiable" basically because, in its view, the European Communities had not provided any reason other than the difference between added hormones and hormones naturally occurring in meat and other foods that have formed part of the human diet for centuries, and had not submitted any evidence that the risk related to natural hormones used as growth promoters is higher than the risk related to endogenous hormones.[209] The Panel adds that the residue level of natural hormones in some natural products (such as eggs and broccoli) is higher than the residue level of hormones administered for growth promotion in treated meat.[210] Furthermore, the Panel states the practical difficulties of detecting the presence of residues of natural hormones in treated meat would also be present in respect of natural hormones occurring endogenously in meat and other foods.[211] The Panel stresses the very marked gap between a "no-residue" level of protection against natural hormones used for growth promotion and the "unlimited-residue" level of protection with regard to hormones occurring naturally in meat and other foods.[212] Much the same reasons are deployed by the Panel in comparing the levels of protection in respect of synthetic hormones used for growth promotion and in respect of natural hormones endogenously occurring in meat and other foods.[213]

221. We do not share the Panel's conclusions that the above differences in levels of protection in respect of added hormones in treated meat and in respect of naturally-occurring hormones in food, are merely arbitrary and unjustifiable. To the contrary, we consider there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods. In respect of the latter, the European Communities simply takes no regulatory action[214]; to require it to prohibit totally the production and consumption of such foods or to limit the residues of naturally-occurring hormones in food, entails such a comprehensive and massive governmental intervention in nature and in the ordinary lives of people as to reduce the comparison itself to an absurdity. The other considerations cited by the Panel, whether taken separately or grouped together, do not justify the Panel's finding of arbitrariness in the difference in the level of protection between added hormones for growth promotion and naturally-occurring hormones in meat and other foods.

222. Because the Panel finds that the difference in the level of protection in respect of the three natural hormones, when used for growth promotion purposes,

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[209] US Panel Report, para. 8.193; Canada Panel Report, para. 8.196.
[210] US Panel Report, para. 8.194; Canada Panel Report, para. 8.197.
[211] US Panel Report, para. 8.195; Canada Panel Report, para. 8.198.
[212] US Panel Report, para. 8.196; Canada Panel Report, para. 8.199.
[213] US Panel Report, paras. 8.213, 8.264 and 8.265; Canada Panel Report, paras. 8.216, 8.267 and 8.268.
[214] It may be questioned whether the European Communities has established at all an appropriate level of protection in respect of naturally-occurring hormones in meat and other foods (i.e. which are part of peoples' daily diet). We have accepted *arguendo* the assumption of the Panel that the European Communities did, for the purposes of this analysis.

and the level of protection in respect of natural hormones present endogenously in meat and other foods is unjustifiable, the Panel regards it as unnecessary to decide whether the difference in the levels of protection set by the European Communities in respect of natural hormones used as growth promoters and in respect of the same hormones when used for therapeutic or zootechnical purposes, is justified.[215] Because, however, we have reached a conclusion different from that of the Panel, we consider it appropriate to complete the Panel's analysis in order that we may be in a position to review the Panel's conclusion concerning consistency with Article 5.5 as a whole. The matter of therapeutic and zootechnical uses of hormones was fully argued before the Panel.[216] Although the failure of the Panel to proceed with this comparison was not expressly appealed by the United States, the United States relies markedly upon the fact that the European Communities treats therapeutic and zootechnical uses of natural hormones differently from growth promotion use of the same hormones.[217]

223. The European Communities has argued that there are two important differences between the administration of hormones for growth promotion purposes and their administration for therapeutic and zootechnical purposes. The first difference concerns the frequency and scale of the treatment.[218] Therapeutic use is occasional as opposed to regular and continuous use that characterizes growth promotion.[219] Therapeutic use is selective as it concerns only individual sick or diseased animals; growth promotion involves the administration of hormones to all herds and all the members of a herd of cattle. Thus, therapeutic use takes place on a small scale and normally involves cattle intended for breeding and not for slaughter; in contrast, the use of these hormones for growth promotion occurs on a much larger scale and is much more difficult and costly to control.[220] Zootechnical use may relate to entire herds but would occur only once a year[221]; it is thus clearly distinguishable from the use of hormones continuously and over long periods of time (apparently most of the lifespan of the animals involved). This difference has been stressed in particular by Dr. André, one of the experts advising the Panel.[222]

224. The second difference concerns the mode of administration of hormones. In order to prevent abuse[223], the European Communities has regulated in sub-

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[215] US Panel Report, para. 8.200; Canada Panel Report, para. 8.203.
[216] See, for example, US Panel Report, paras. 4.63, 4.64, 4.68, 4.69, 4.71, 4.223, 4.224, 4.225, 4.226 and 4.227, and Canada Panel Report, paras. 4.141, 4.147, 4.217, 4.238 and 4.242.
[217] United States' appellant's submission, paras. 26, 27 and 29.
[218] EC's appellee's submission, paras. 82-84.
[219] US Panel Report, para. 4.71; Canada Panel Report, para. 4.242.
[220] US Panel Report, para. 8.198; Canada Panel Report, para. 8.201.
[221] US Panel Report, para. 8.199; Canada Panel Report, para. 8.202.
[222] US Panel Report, paras. 6.183, 6.184 and 6.189; Canada Panel Report, paras. 6.182, 6.183 and 6.188.
[223] See the ninth paragraph of the Preamble of Directive 96/22/EC, dated 29 April 1996, which states:

stantial detail the conditions under which the administration of natural hormones may be authorized by the Member States of the European Union for therapeutic and zootechnical purposes. The hormones must, in the first place, be administered by a veterinarian or under the responsibility of a veterinarian.[224] In addition, Directive 96/22/EC specifies detailed conditions, such as, for example: strict withdrawal periods; administration by injection or, in case of varying disfunctions, by vaginal spirals, but not by implants; clear identification of the individual animal so treated; and recording of the details of treatment by the responsible veterinarian (e.g. type of treatment, type of veterinary drug used or authorized, date of treatment, identity of the animals treated).[225]

225. The conclusion we come to, after consideration of the foregoing factors, is that, on balance, the difference in the levels of protection concerning hormones used for growth promotion purposes, on the one hand, and concerning hormones used for therapeutic and zootechnical purposes, on the other, is not, in itself, "arbitrary or unjustifiable".

226. We turn to the Panel's comparison between the levels of protection set by the European Communities in respect of natural and synthetic hormones for growth promotion and with respect to carbadox and olaquindox.[226] Carbadox and olaquindox are anti-microbial agents or compounds which are mixed with the feed given to piglets (maximum age of four months). According to a report of JECFA[227], submitted to the Panel by the United States, carbadox is a feed additive that is a known genotoxic carcinogen, that is, carbadox *induces* and does not merely promote cancer.[228] The experts advising the Panel confirmed that carbadox was genotoxic in character.

227. In the panel proceedings, the European Communities sought to justify the difference in the levels of protection in respect of the natural and synthetic hormones (except MGA) and in respect of carbadox and olaquindox.[229] The Panel responds to these arguments and the European Communities has reiterated its

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> Whereas the prohibition on the use of hormonal substances for fattening purposes should continue to apply; whereas the use of certain substances for therapeutic or zootechnical purposes may be authorized but must be strictly controlled in order to prevent any misuse; (underlining added)

224 US Panel Report, para. 4.69; Canada Panel Report, para. 4.192.

225 US Panel Report, para. 4.69; Canada Panel Report, para. 4.238.

226 EC Directive 70/524/CEE of 23 November 1970 governs the use of additives to animal feed. This Directive allows Member States to permit the use of certain additives listed in Annex I of the Directive, under the conditions there specified. On 12 April 1991, EC Directive 91/248/EEC replaced Annexes I and II of the 1970 Directive with new Annexes. The new Annex I includes the following under the subheading "growth promoters": carbadox and olaquindox.

227 Evaluation of Certain Veterinary Drug Residues in Food: Thirty-sixth Report of the Joint FAO/WHO Expert Committee on Food Additives ("JECFA"), Technical Report Series 799 (World Health Organization, 1990), pp. 45-50.

228 US Panel Report, para. 4.220.

229 US Panel Report, para. 8.229 (with respect to carbadox only); Canada Panel Report, para. 8.232.

original arguments in its appellant's submission.[230] We canvass the arguments of the European Communities and the Panel's responses, which are set out below in very summary form.

228. The first argument of the European Communities is that carbadox and olaquindox are not hormones, but rather anti-microbial agents. The Panel responds that the European Communities has not explained why this difference would itself justify a different regulatory treatment in the light of the carcinogenic potential of both kinds of substances.[231]

229. The second argument of the European Communities is that carbadox and olaquindox only indirectly act as growth promoters by suppressing the development of bacteria and aiding the intestinal flora of piglets, thereby also exerting preventive therapeutic effects; hormones, it is said, have no preventive therapeutic action when used as growth promoters. However, the Panel considers that both the hormones in dispute and carbadox and olaquindox may have therapeutic effects.[232]

230. The European Communities' third argument is that carbadox and olaquindox are only commercially available in prepared feedstuffs (not as injections or implants) in predetermined dosages and, therefore, are less open to abuse. The Panel observes that, according to experts advising it, products containing any of the five hormones at issue for implantation or injection are also packaged in predetermined dosages. The experts add that carbadox as an additive in feedstuffs poses additional risks since it may harm the persons handling the feedstuff.[233]

231. The fourth argument of the European Communities is that there are no alternatives to carbadox or olaquindox available that have the same therapeutic action. The Panel notes that, according to one of the experts, there are readily available alternatives such as oxytetracycline. According to Canada, oxytetracycline has been the subject of a risk assessment by JECFA and Codex has adopted the Acceptable Daily Intakes (ADI) and MRLs recommended by JECFA.[234]

232. The European Communities' fifth argument is that carbadox cannot be abused since it has growth promotion effects only in piglets up to four months old and a fixed withdrawal period of at least 28 days is set in the relevant Directive. In turn, the Panel notes that, according to its expert advisors, there is no assurance that the piglets treated with carbadox would not be slaughtered and that residues of carbadox would not thereby enter the food chain of human beings. The Panel adds that the use of the hormones at issue as growth promoters could similarly be subjected to strict conditions.[235]

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230 EC's appellant's submission, paras. 528-548.
231 US Panel Report, para. 8.231 (with respect to carbadox only); Canada Panel Report, para. 8.234.
232 US Panel Report, para. 8.232 (with respect to carbadox only); Canada Panel Report, para. 8.235.
233 US Panel Report, para. 8.233 (with respect to carbadox only); Canada Panel Report, para. 8.236.
234 US Panel Report, para. 8.234 (with respect to carbadox only); Canada Panel Report, para. 8.237.
235 US Panel Report, para. 8.235; Canada Panel Report, para. 8.238.

233. The sixth argument the European Communities made is that carbadox is used in very small quantities and is hardly absorbed in the piglet's gut with the result that it leaves practically no residues at all in pork meat destined for human consumption. The Panel replies that, according to the experts advising it, once a substance has been administered to an animal, there will always be some residue of this substance or a metabolite left, albeit a very small amount, in the meat of that animal.[236] In this connection, Canada volunteered the comment that, according to a 1991 study commissioned by the European Communities and provided to the Panel, metabolites of carbadox and olaquindox are "nearly completely absorbed in the gut" and that "in using carbadox, a mutagenic or carcinogenic risk for the consumer seems negligible if the withdrawal time is closely respected".[237]

234. The European Communities made a seventh argument which was not repeated in its appeal: the complaining parties limit their claim to one or two substances out of 10,000 to 15,000 veterinary medicinal substances the use of which the European Communities authorizes, which indicates "a remarkable degree of consistency in its levels of sanitary protection".[238] The Panel notes that the European Communities has advised it that the EC Council, by a Decision of 26 February 1996, has already taken action *motu proprio* to review carbadox and olaquindox. To the Panel, the arguments of the European Communities suggest that it acknowledges that the difference in the levels of protection in respect of added hormones and in respect of carbadox and olaquindox may not be justified and should be reviewed.[239]

235. Having reviewed the above arguments and counter-arguments, we must agree with the Panel that the difference in the EC levels of protection in respect of the hormones in dispute when used for growth promotion, on the one hand, and carbadox and olaquindox, on the other, is unjustifiable in the sense of Article 5.5.

D. Resulting in Discrimination or a Disguised Restriction on International Trade

236. In interpreting this last element or requirement of Article 5.5, the Panel recalls the conclusion of the Appellate Body in *United States - Standards for Reformulated and Conventional Gasoline*[240] ("*United States - Gasoline*") to the effect that the terms "arbitrary discrimination", "unjustifiable discrimination" and "disguised restriction on international trade" found in Article XX of the

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[236] US Panel Report, para. 8.236; Canada Panel Report, para. 8.239.
[237] CEAS Consultants (Wye) Ltd. (et. al.), *The Impact on Animal Husbandry in the European Community of the Use of Growth Promoters*, Final Report, Vol. I (1991), cited in Canada's appellee's submission, paras. 180-181.
[238] US Panel Report, para. 8.237; Canada Panel Report, para. 8.240.
[239] US Panel Report, para. 8.237 (with respect to carbadox only); Canada Panel Report, para. 8.240.
[240] Adopted 20 May 1996, WT/DS2/AB/R.

GATT 1994, may be read side-by-side and impart meaning to one another.[241] The Panel also recalls our statement in *Japan - Alcoholic Beverages*[242], and in particular the requirement in Article III:2, second sentence, of the GATT 1994 that dissimilar taxation needs to be "applied ... so as to afford protection to domestic production". It quotes the passage stating, in part, that "[the dissimilar taxation] may be so much more that it will be clear from that very differential that the dissimilar taxation was applied 'so as to afford protection'. In some cases, that may be enough to show a violation".[243] The Panel then renders its interpretation of the last requirement of Article 5.5 of the *SPS Agreement* as follows:

> We consider the reasoning in both Appellate Body Reports to be equally relevant to the relationship between the three elements contained in Article 5.5. All three elements impart meaning to one another. Nevertheless, in order to give effect to all three elements contained in Article 5.5 and giving full meaning to the text and context of this provision, we consider that all three elements need to be distinguished and addressed separately. However, we also agree that in some cases where a Member enacts, for comparable situations, sanitary measures which reflect different levels of protection, the significance of the difference in levels of protection combined with the arbitrariness thereof may be sufficient to conclude that this difference in levels of protection "result[s] in discrimination or a disguised restriction on international trade" in the sense of Article 5.5 (in line with the argument that the magnitude of the very differential of a dissimilar taxation may be enough to conclude that a dissimilar taxation is applied so as to afford protection, as provided for in the second sentence of Article III:2 of GATT.[244] (underlining added)

237. The European Communities urges that the Panel committed several errors of legal interpretation. Firstly, the Panel disregards the alternative character of the three elements of the *chapeau* of Article XX of the GATT 1994, and the fact that the three elements of Article 5.5 of the *SPS Agreement* are additional and cumulative in nature.[245] Secondly, Article III:2, second sentence, of the GATT 1994 is concerned with the impact of a tax on the competitive relations concerning directly competitive or substitutable products. On the other hand, discrimination and disguised restriction in the sense of Article 5.5 of the *SPS Agreement* are entirely different concepts.[246] Thirdly, and as a consequence of its interpretation of Article 5.5, a "discrimination or a disguised restriction on international trade"

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241 US Panel Report, paras. 8.182 and 8.240; Canada Panel Report, paras. 8.185 and 8.243.
242 Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.
243 US Panel Report, para. 8.183; Canada Panel Report, para. 8.186.
244 US Panel Report, para 8.184; Canada Panel Report, para. 8.187.
245 EC's appellant's submission, paras. 471-477.
246 EC's appellant's submission, para. 486.

is not really, for the Panel, a third or additional requirement at all under Article 5.5.[247]

238. We agree with the Panel's view that "all three elements [of Article 5.5] need to be distinguished and addressed separately".[248] We also recall our interpretation that Article 5.5 and, in particular, the terms "discrimination or a disguised restriction on international trade", have to be read in the context of the basic obligations contained in Article 2.3, which requires that "sanitary ... *measures* shall not be *applied in a manner which would constitute a disguised restriction on international trade*". (emphasis added)[249]

239. However, we disagree with the Panel on two points. First, in view of the structural differences between the standards of the *chapeau* of Article XX of the GATT 1994 and the elements of Article 5.5 of the *SPS Agreement*, the reasoning in our Report in *United States - Gasoline*, quoted by Panel, cannot be casually imported into a case involving Article 5.5 of the *SPS Agreement*. Secondly, in our view, it is similarly unjustified to assume applicability of the reasoning of the Appellate Body in *Japan - Alcoholic Beverages*[250] about the inference that may be drawn from the sheer size of a tax differential for the application of Article III:2, second sentence, of the GATT 1994, to the quite different question of whether arbitrary or unjustifiable differences in levels of protection against risks for human life or health, "result in discrimination or a disguised restriction on international trade".[251]

240. In our view, the degree of difference, or the extent of the discrepancy, in the levels of protection, is only one kind of factor which, along with others, may cumulatively lead to the conclusion that discrimination or a disguised restriction on international trade in fact results from the application of a measure or measures embodying one or more of those different levels of protection. Thus, we do not think that the difference between a "no residues" level and "unlimited residues" level is, together with a finding of an arbitrary or unjustifiable difference, sufficient to demonstrate that the third, and most important, requirement of Article 5.5 has been met. It is well to bear in mind that, after all, the difference in levels of protection that is characterizable as arbitrary or unjustifiable is only an element of (indirect) proof that a Member may actually be applying an SPS measure in a manner that discriminates between Members or constitutes a dis-

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247 EC's appellant's submission, para. 491.

248 US Panel Report, para. 8.184; Canada Panel Report, para. 8.187.

249 See para. 212 of this Report.

250 Adopted 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R.

251 The differential involved in *Japan - Alcoholic Beverages* was a tax differential, which is very different from a differential in levels of protection. Unlike a differential in levels of protection, a tax differential is always expressed in quantitative terms and a significant tax differential in favour of domestic products will inevitably affect the competitiveness of imported products and thus afford protection to domestic products. There is a clear and linear relationship between a tax differential and the protection afforded to domestic products. There is, however, no such relationship between a differential in levels of human health protection and discrimination or disguised restriction on trade.

guised restriction on international trade, prohibited by the basic obligations set out in Article 2.3 of the *SPS Agreement*. Evidently, the answer to the question whether arbitrary or unjustifiable differences or distinctions in levels of protection established by a Member do in fact result in discrimination or a disguised restriction on international trade must be sought in the circumstances of each individual case.

241. In the present appeal, it is necessary to address this question only with regard to the difference in the levels of protection established in respect of the hormones in dispute and in respect of carbadox and olaquindox.

242. According to the Panel, the "significance" of the "arbitrary or unjustifiable" distinction in the level of protection concerning the hormones in dispute as compared with the level of protection in respect of carbadox and olaquindox results in discrimination or a disguised restriction on international trade. It bases this finding on: (i) the great difference in the levels of protection, namely, the difference between a "no residue" level for the five hormones at issue when used as growth promoters, as opposed to an "unlimited residue" level for carbadox and olaquindox; (ii) the absence of any plausible justification put forward by the European Communities for this significant difference; and (iii) the nature of the EC measure, i.e., the prohibition of imports, which necessarily restricts international trade.[252]

243. The Panel adduces, in support of its finding, three additional factors: (iv) the objectives (apart from the protection of human health) that it believes the European Communities had in mind in enacting or maintaining the EC ban, as reflected in the preambles of the measures in dispute, the reports of the European Parliament and the opinions rendered by the EC Social and Economic Committee. These include the harmonizing of the regulatory schemes of the different Member States of the European Union and the removal of competitive distortions in and barriers to intra-community trade in beef, and the bringing about of an increase in the consumption of beef, thereby reducing the internal beef surpluses, and providing more favourable treatment to domestic producers[253]; (v) before the import ban came into force (in 1987), the percentage of animals treated for growth promotion with the hormones in dispute was significantly lower in the European Communities than in Canada and the United States. The apparent implication, for the Panel, is that the EC measures constitute *de facto* discrimination against imported beef produced with growth promotion hormones[254]; and (vi) that the hormones at issue are used for growth promotion in the bovine sector "where the European Communities seemingly wants to limit supplies and is arguably less concerned with international competitiveness", whereas carbadox and olaquindox are used for growth promotion in the pork meat sectors "where the European

[252] US Panel Report, para. 8.241; Canada Panel Report, para. 8.244.
[253] US Panel Report, para 8.242; Canada Panel Report, para. 8.245.
[254] US Panel Report, para 8.242; Canada Panel Report, para. 8.245.

Communities has no domestic surpluses and where international competitiveness is a higher priority".[255]

244. In its appeal, the European Communities stresses that the prohibition of the use of hormones for growth promotion purposes applies equally to beef produced within the European Communities and to imports of such beef.[256] It is also emphasized that the predominant motivation for both the prohibition of the domestic use of growth promotion hormones and the prohibition of importation of treated meat, is the protection of the health and safety of its population. No suggestion has been made that the import prohibition of treated meat was the result of lobbying by EC domestic producers of beef. It is also pointed out that legislation (in representative governments) normally reflects multiple objectives. The fact that there was a higher percentage of beef treated with growth promotion hormones in Canada and in the United States, as compared with the European Communities, was simply a reflection of the fact that Canada and the United States had allowed this practice for a long time while the European Communities had not. The long history of the EC Directives should be recalled in this connection. The import prohibition could not have been designed simply to protect beef producers in the European Communities *vis-à-vis* beef producers in the United States and Canada, for beef producers in the European Communities were precisely forbidden to use the same hormones for the same purpose. We note, in this connection, that the prohibition of domestic use also necessarily excludes any exports of treated meat by domestic producers.

245. We do not attribute the same importance as the Panel to the supposed multiple objectives of the European Communities in enacting the EC Directives that set forth the EC measures at issue. The documentation that preceded or accompanied the enactment of the prohibition of the use of hormones for growth promotion and that formed part of the record of the Panel makes clear the depth and extent of the anxieties experienced within the European Communities concerning the results of the general scientific studies (showing the carcinogenicity of hormones), the dangers of abuse (highlighted by scandals relating to black-marketing and smuggling of prohibited veterinary drugs in the European Communities) of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the meat available in its internal market.[257] A major

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[255] US Panel Report, para. 8.243 (with respect to carbadox only); Canada Panel Report, para. 8.246.

[256] EC's appellant's submission, para. 552.

[257] See, for example: Opinion of the Economic and Social Committee of 13 December 1984 on the proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, Official Journal, No. C 44, 15 February 1985, p. 14; Resolution of the European Parliament of 11 October 1985 on the proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, Official Journal No. C 288, 11 November 1985, p. 158; Resolution of the European Parliament of 16 September 1988 on the use of hormones in meat production, Official Journal, No.

problem addressed in the legislative process of the European Communities related to the differences in the internal regulations of various Member States of the European Union (four or five of which permitted, while the rest prohibited, the use for growth promotion of certain hormones), the resulting distortions in competitive conditions in and the existence of barriers to intra-community trade. The necessity for harmonizing the internal regulations of its Member States was a consequence of the European Communities' mandate to establish a common (internal) market in beef.[258] Reduction of any beef surplus through an increase in the consumption of beef within the European Communities, is not only in the interests of EC farmers, but also of non-hormone using farmers in exporting countries. We are unable to share the inference that the Panel apparently draws that the import ban on treated meat and the Community-wide prohibition of the use of the hormones here in dispute for growth promotion purposes in the beef sector were not really designed to protect its population from the risk of cancer, but rather to keep out US and Canadian hormone-treated beef and thereby to protect the domestic beef producers in the European Communities.

246. Our conclusion, therefore, is that the Panel's finding that the "arbitrary or unjustifiable" difference in the EC levels of protection in respect of the hormones at issue on the one hand and in respect of carbadox and olaquindox on the other hand, "result in discrimination or a disguised restriction on international trade", is not supported either by the architecture and structure of the EC Directives here at stake or of the subsequent Directive on carbadox and olaquindox, or by the evidence submitted by the United States and Canada to the Panel. The Panel's finding is itself unjustified and erroneous as a matter of law. Accordingly, we reverse the conclusion of the Panel that the European Communities has acted inconsistently with the requirements set out in Article 5.5 of the *SPS Agreement*.

XIII. APPEALS BY THE UNITED STATES AND CANADA: ARTICLES 2.2 AND ARTICLE 5.6 OF THE *SPS AGREEMENT*

247. The Panel refrained from making findings under Articles 2.2 and 5.6 of the *SPS Agreement*. In respect of Article 2.2, the Panel, having found that the EC measures are inconsistent with Articles 3.1, 5.1 and 5.5, did not believe there was

C 262, 10 October 1988, p. 167; and Resolution of the European Parliament of 14 April 1989 on the USA's refusal to comply with Community legislation on slaughterhouses and hormones, and the consequences of this refusal, Official Journal, No. C 120, 16 May 1989, p. 356. The latter Resolution was based on, *inter alia*, the Pimenta Report, Parts A and B.

[258] Article 7a of the Treaty Establishing the European Community stipulates:

> The Community shall adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992 ...
>
> The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of this Treaty.

any necessity for making a finding on the consistency of the same EC measures with Article 2.2. The Panel, in so concluding, also considered that Articles 3 and 5 provide for more specific rights and obligations than the "basic rights and obligations" set out in Article 2.[259]

248. In respect of Article 5.6, the Panel held that since it had already found the EC level of protection reflected in the EC measure in dispute was adopted in violation of Article 5.5, there was no need to examine whether that same measure is also more trade restrictive than necessary to achieve that level in the sense of Article 5.6.[260]

249. The United States, *qua* appellant, believes the Panel has made all the findings necessary for the purpose and should have declared the EC import prohibition inconsistent with Article 2.2.[261] It is also submitted by the United States that the text of Articles 2, 3 and 5 does not indicate that all of the obligations in Article 2.2 are subsumed under Articles 3 and 5.[262] In respect of Article 5.6, it is similarly urged by the United States that the Panel's findings on Article 5.5 are sufficient to establish that the EC import prohibition is also inconsistent with Article 5.6.[263] Similar submissions are made by Canada as appellant.[264]

250. We agree with the Panel's application of the notion of judicial economy. We have affirmed the Panel's conclusion that the EC measures are inconsistent with Article 5.1 in view of the failure of the European Communities to provide a risk assessment that reasonably supports such measures. Under the circumstances, the necessity or propriety of proceeding to determine whether Article 2.2 of the *SPS Agreement* has also been violated is not at all clear to us. Had we reversed the Panel's conclusion in respect of the inconsistency of the EC measures with Article 5.1, it would have been logically necessary to inquire whether Article 2.2 might nevertheless have been violated. We are, of course, surprised by the fact that the Panel did not begin its analysis of this whole case by focusing on Article 2 that is captioned "Basic Rights and Obligations", an approach that appears logically attractive. We recall the reading that we have given above to Articles 2 and 5 - that Article 2.2 informs Article 5.1, and that similarly Article 2.3 informs Article 5.5 - but believe that further analysis of their relationship should await another case.

251. We have, at the same time, reversed the Panel's conclusion under Article 5.5 of the *SPS Agreement* that the levels of protection set by the European Communities in respect of the use of hormones for growth promotion result in discrimination or a disguised restriction on international trade. However, it cannot be assumed that all the findings of fact necessary to proceed to a determination of

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259 US Panel Report, para 8.271; Canada Panel Report, para. 8.274.
260 US Panel Report, para 8.247; Canada Panel Report, para. 8.250.
261 United States' appellant's submission, para. 4.
262 United States' appellant's submission, para. 18.
263 United States' appellant's submission, para. 20.
264 Canada's appellant's submission, paras. 19-22.

consistency or inconsistency of the EC measures with the requirements of Article 5.6 have been made by the Panel, which Article also provides that "technical and economic feasibility" should be taken into account. There appears all the more reason for refraining from an examination of the legality of the measures under Article 5.6 and for adhering to the prudential dictates of the principle of judicial economy.

252. We consider, therefore, and so hold, that the Panel did not err in refraining from making findings on Articles 2.2 and 5.6 of the *SPS Agreement*.

XIV. FINDINGS AND CONCLUSIONS

253. For the reasons set out in the preceding sections of this Report, the Appellate Body:

(a) reverses the Panel's general interpretative ruling that the *SPS Agreement* allocates the evidentiary burden to the Member imposing an SPS measure, and also reverses the Panel's conclusion that when a Member's measure is not based on an international standard in accordance with Article 3.1, the burden is on that Member to show that its SPS measure is consistent with Article 3.3 of the *SPS Agreement*;

(b) concludes that the Panel applied the appropriate standard of review under the *SPS Agreement*;

(c) upholds the Panel's conclusions that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2, and that the precautionary principle has been incorporated in, *inter alia*, Article 5.7 of the *SPS Agreement*;

(d) upholds the Panel's conclusion that the *SPS Agreement*, and in particular Articles 5.1 and 5.5 thereof, applies to measures that were enacted before the entry into force of the *WTO Agreement*, but that remain in force thereafter;

(e) concludes that the Panel, although it sometimes misinterpreted some of the evidence before it, complied with its obligation under Article 11 of the DSU to make an objective assessment of the facts of the case;

(f) concludes that the procedures followed by the Panel in both proceedings - in the selection and use of experts, in granting additional third party rights to the United States and Canada and in making findings based on arguments not made by the parties - are consistent with the DSU and the *SPS Agreement*;

(g) reverses the Panel's conclusion that the term "based on" as used in Articles 3.1 and 3.3 has the same meaning as the term "conform to" as used in Article 3.2 of the *SPS Agreement*;

(h) modifies the Panel's interpretation of the relationship between Articles 3.1, 3.2 and 3.3 of the *SPS Agreement*, and reverses the Panel's conclusion that the European Communities by maintaining, without justification under Article 3.3, SPS measures which are not based on existing international standards, acted inconsistently with Article 3.1 of the *SPS Agreement*;

(i) upholds the Panel's finding that a measure, to be consistent with the requirements of Article 3.3, must comply with, *inter alia*, the requirements contained in Article 5 of the *SPS Agreement*;

(j) modifies the Panel's interpretation of the concept of "risk assessment" by holding that neither Articles 5.1 and 5.2 nor Annex A.4 of the *SPS Agreement* require a risk assessment to establish a minimum quantifiable magnitude of risk, nor do these provisions exclude *a priori*, from the scope of a risk assessment, factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences;

(k) reverses the Panel's finding that the term "based on" as used in Article 5.1 of the *SPS Agreement* entails a "minimum procedural requirement" that a Member imposing an SPS measure must submit evidence that it actually took into account a risk assessment when it enacted or maintained the measure;

(l) upholds the Panel's finding that the EC measures at issue are inconsistent with the requirements of Article 5.1 of the *SPS Agreement*, but modifies the Panel's interpretation by holding that Article 5.1, read in conjunction with Article 2.2, requires that the results of the risk assessment must sufficiently warrant the SPS measure at stake;

(m) reverses the Panel's findings and conclusions on Article 5.5 of the *SPS Agreement*; and

(n) concludes that the Panel exercised appropriate judicial economy in not making findings on Articles 2.2 and 5.6 of the *SPS Agreement*.

254. The foregoing legal findings and conclusions uphold, modify and reverse the findings and conclusions of the Panel in Parts VIII and IX of the Panel Reports, but leave intact the findings and conclusions of the Panel that were not the subject of this appeal.

255. The Appellate Body *recommends* that the Dispute Settlement Body request the European Communities to bring the SPS measures found in this Report and in the Panel Reports, as modified by this Report, to be inconsistent with the *SPS Agreement* into conformity with the obligations of the European Communities under that Agreement.