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India - Patent Protection for Pharmaceutical and Agricultural Chemical Products

Complaint by the European Communities and their member States

Report of the Panel

The report of the Panel on India – Patent Protection for Pharmaceutical and Agricultural Chemical Products is being circulated to all Members, pursuant to the DSU. The report is being circulated as an unrestricted document from 24 August 1998 pursuant to the Procedures for the Circulation and Derestriction of WTO Documents (WT/L/160/Rev.1). Members are reminded that in accordance with the DSU only parties to the dispute may appeal a panel report, an appeal shall be limited to issues of law covered in the panel report and legal interpretations developed by the panel, and that there shall be no ex parte communications with the panel or Appellate Body concerning matters under consideration by the panel or Appellate Body.

(ii)

Note by the Secretariat: This Panel Report shall be adopted by the Dispute Settlement Body (DSB) within 60 days after the date of its circulation unless a party to the dispute decides to appeal or the DSB decides by consensus not to adopt the report. If the Panel Report is appealed to the Appellate Body, it shall not be considered for adoption by the DSB until after the completion of the appeal. Information on the current status of the Panel Report is available from the WTO Secretariat.

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I. INTRODUCTION

1.1 On 28 April 1997, the European Communities and their member 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 for the grant of exclusive marketing rights for such products (WT/DS79/1). No mutually satisfactory solution was reached in these consultations, held on 14 May 1997. The European Communities and their member States requested the Dispute Settlement Body (DSB), in a communication dated 9 September 1997, to establish a panel to examine the matter (WT/DS79/2).¹ At its meeting of 16 October 1997, the DSB agreed to establish a panel with standard terms of reference in accordance with Article 6 of the DSU. The United States reserved third party rights.

1.2 In document WT/DS79/3 of 27 November 1997, the DSB was informed of the terms of reference and the composition of the Panel. Due to the absence of agreement between the parties to the dispute on the composition of the Panel, the composition of the Panel was determined by the Director-General pursuant to Article 8.7 of the DSU. Informing the parties to the dispute that he had determined the composition of the Panel pursuant to Article 10.4 of the DSU, taking into account the fact that the European Communities and their member States had been a third party to the panel proceeding on "India - Patent Protection for Pharmaceutical and Agricultural Chemical Products" (WT/DS50 - complaint by the United States) and the measures at issue in the present dispute had already been the subject of the earlier proceeding, the Director-General appointed the same Panel members as in the earlier dispute (with the exception of the chairman of the original panel who was no longer available).

Terms of reference

"To examine, in the light of the relevant provisions of the covered agreements cited by the European Communities and their member States in document WT/DS79/2, the matter referred to the DSB by the European Communities and their member 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. Stuart Harbinson
Panelists: Mr. Douglas Chester
Mr. Yanyong Phuangrath

1.3 The Panel heard the parties to the dispute on 24 March and 29 April 1998. The interim report was issued to the parties on 19 June 1998. Only India requested the Panel to review parts of the interim report; no request was received to hold an additional meeting.

¹ See Annex 1 to this report.

II. FACTUAL ASPECTS

Indian legal system and practice

2.1 The following summarizes the key points of the information provided to the Panel on the general principles in Indian law governing the impact of treaty obligations on domestic law and the power of the executive to implement such obligations:

- 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. Although not self-executing under Indian law, implementation of a treaty does not require fresh legislative or executive action if existing administrative regulations or statutory or constitutional provisions permit the implementation of the treaty in question. The Indian courts may construe, in this context, statutory or constitutional provisions that pre-exist a treaty obligation in order to render them consistent with such a treaty obligation.
- The Directive Principles of State Policy as enshrined in Article 51 of the Indian Constitution enjoin upon the State to endeavour, inter alia, to foster respect for international law and treaty obligations in the dealings of organized people with one another. It is a fundamental principle of statutory interpretation in Indian domestic law that, wherever possible, a statutory provision must be interpreted consistently with India's international obligations, whether under customary international law or an international treaty or convention. If the terms of the legislation are not clear and are reasonably capable of more than one meaning, the treaty itself becomes relevant, for there is a prima facie presumption that Parliament does not intend to act in breach of international law, including therein a specific treaty obligation; and if one of the meanings which can reasonably be ascribed to the legislation is consonant with the treaty obligations and another or others are not, the meaning which is consonant is to be preferred.
- A treaty may be implemented by the exercise of executive power. However, where implementation of a treaty requires legislation, the legislative power belongs, under Article 253 of the Indian Constitution, exclusively to Parliament. Where the Constitution does not require action to be taken only by legislation or there is no existing law to fetter the executive power of the Union (or a State, as the case may be), the Government would not only be free to take such action by an executive order or to lay down a policy for the making of such executive orders, but also to change such orders or the policy itself, as often as the Government so requires. The executive power of the Government of India to enter into, and implement, treaties is derived from the legislative power of the Union of India incorporated in Articles 246 and 253 read with Entry 14 of List I of the Seventh Schedule of the Indian Constitution. The Government also has executive power over "patents, inventions and designs", which fall under Entry 49 of List I.
- Article 123, clause 1 of the Indian Constitution 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".

- Article 73 of the Indian Constitution confers upon the Government of India executive power over all subjects in which Parliament has legislative competence. 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."

The executive powers of the Union and State Governments are co-extensive with their respective legislative powers (Articles 73 and 162 of the Indian Constitution). The executive power of the Government extends to matters with regard to which Parliament can make laws. The executive power of the Centre extends also to the exercise of such rights, authority and jurisdiction as are exercisable by the Government of India by virtue of a treaty or agreement (Article 73(1)(b) of the Indian Constitution). If the statutory provisions are silent on a point, the executive can fill up the gaps or supplement the rules or implement the policy by issuing administrative instructions not inconsistent with the rules already framed.

- Under Article 226 of the Indian Constitution, the High Court² has the power of "judicial legislative and administrative action", which includes the power to review administrative regulations or instructions on the ground that they violate statutory provisions. In exercising this authority, the main principles guiding the High Court are:

- According to a well-established principle of Indian administrative law, administrative instructions cannot be issued on any matter which is the subject of legislation. Wherever there is no statutory provision or where there are gaps in any enactment, the same can be provided or bridged by issue of necessary administrative instructions. The only rider on the authority to issue such administrative instructions is that there should be no statutory provision either expressly or by necessary implications to the contrary.
- Administrative acts done in the purported exercise of a statutory power can be invalidated by the Court, if constitutional limits or statutory powers have been transgressed. However, where an administrative act is done, not in the

² The High Court is the highest court in each State and is the intermediate appellate court in India's unified system of courts.

purported exercise of a statutory power, but in the exercise of the executive power of a State, the doctrine of ultra vires is inapplicable to it, and courts have no supervision and control over such instructions, though they may be binding on the subordinate officials departmentally.

- Judicial review in respect of administrative acts not done in the purported exercise of a statutory power, but in the exercise of the executive power, is directed towards its manner and mode, and not the administrative decision taken on merits. The standard for this review is whether the exercise of the discretionary power has been "unfair", "arbitrary" or "malafide".
- Neither will the Supreme Court or High Courts interfere or adjudicate upon government policy matters, unless fundamental principles of law have been violated.

The Patents (Amendment) Ordinance 1994 and the Patents (Amendment) Bill 1995

2.2 On 31 December 1994, the President of India promulgated the Patents (Amendment) Ordinance, 1994, to amend the Patents Act of 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).³ This Ordinance was issued in exercise of the powers conferred upon the President by clause (1) of Article 123 of the Indian Constitution. 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. During this period, 125 applications had been received and filed.

2.3 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 Article 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 measures 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).

2.4 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.

³ 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.

Article 70.8 of the TRIPS Agreement

2.5 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, following interdepartmental consultations, to instruct the patent offices in India to continue, after the lapse of the Ordinance, to receive patent applications for pharmaceutical and agricultural chemical products under the existing provisions of the Patents Act of 1970 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. While India informed the Panel of the provisions under which such applications were being received and stored under the Patents Act of 1970, 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.

2.6 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 of 1970 in accordance with the requirements of the World Trade Organization; 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.⁴

2.7 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 of 1970 are subject to the same fee as any other patent application being received and allotted a filing date and advertised, on a weekly basis, in the Gazette of India 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 applications⁵ are, however, unlike other patent applications, being allotted a special identification number internally, stored separately and not referred by the Controller to an examiner as specified in Section 12 of the Act. The notification in the Gazette does not distinguish between applications that are the subject of these administrative arrangements and other patent applications.

2.8 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 of 1970.

2.9 For the purposes of the case in hand, the main aspects of the provisions of the Patents Act of 1970 which are of relevance to the case in hand are as follows⁶:

- 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

⁴ The full text of the question and answer is reflected in Annex 2 of this report.

⁵ Applications which contain both product and process claims in respect of inventions in the pharmaceutical or agricultural chemical area are subject to the same administrative arrangements as applications with only product claims.

⁶ The full text of the provisions of the Patents Act of relevance to the case in hand can be found at Annex 3 of this report.

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 filed⁷ in respect of an application for a patent, the application 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.

2.10 India informed the Panel that, between 1 January 1995 and 31 January 1998, a total of 2,212 patent applications for pharmaceutical and agricultural chemical products had been received and published in the Gazette of India. None of these applications, nor the mechanism for receiving and storing them, has been the subject of a legal challenge in court as to their validity under Indian law. About one half of these applications had been made by EC companies.⁸

Article 70.9 of the TRIPS Agreement

2.11 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 European Communities and their member States requested the Panel, given the particular circumstances of this case, in which the measures at issue had already been examined by this Panel

⁷ 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.

⁸ India informed the Panel that, between 1 January 1995 and 31 January 1998, of these 2,212 applications, 55 were received in the month of January 1998. By 31 January 1998, EC companies had submitted 1,056 of these applications, of which 32 in the month of January 1998.

and by the Appellate Body in an earlier dispute (WT/DS50) to which the European Communities and their member States had been a third party, to extend its findings in the earlier dispute, as modified by the Appellate Body, to the European Communities and their member States as the complainant in the present proceeding and, on this basis, to make the following rulings, findings and recommendations:

Article 70.8 of the TRIPS Agreement

- (a) That India had not complied with its obligations under Article 70.8(a) of the TRIPS Agreement to establish "a means" that adequately preserved novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period provided for in Article 65 of the TRIPS Agreement.

Article 70.9 of the TRIPS Agreement

- (b) That India had not complied with its obligations under Article 70.9 of the TRIPS Agreement.

Article 70.8 and 70.9 of the TRIPS Agreement

- (c) That the DSB request India to bring its legal régime for patent protection of pharmaceutical and agricultural chemical products into conformity with India's obligations under Article 70.8 and 70.9 of the TRIPS Agreement.

3.2 India requested the Panel to reject the complaints of the European Communities and their member States on the basis of the following findings:

I. That the complaints are not admissible

Articles 9.1 and 10.4 of the DSU

- (a) The complaints of the European Communities and their member States are inconsistent with the rules of the DSU on multiple complainants, in particular Articles 9.1 and 10.4, according to which multiple complaints should be submitted to a single panel "whenever feasible" or "whenever possible", because the same matter has already been the subject of a panel procedure (WT/DS50) and there were neither legal, procedural nor factual reasons that had prevented the European Communities and their member States from bringing their complaint jointly with the earlier case initiated by the United States, or at least at the same time as the United States.

II. That, if the Panel were to find the complaints admissible

Article 70.8 of the TRIPS Agreement

- (a) The evidence adduced in the present proceeding does not demonstrate that "mailbox" applications can be challenged in India's courts and that India's "mailbox" system⁹ fails to provide a sound legal basis to preserve the novelty of the inventions and the priority of the date of the applications.

Article 70.9 of the TRIPS Agreement

- (b) Article 70.9, interpreted in accordance with Article 31 of the Vienna Convention on the Law of Treaties and the principles of interpretation enunciated by the Appellate Body in the earlier case (WT/DS50), does not require the establishment of a mechanism to provide for the grant of exclusive marketing rights before such rights are due.

Article 70.8 and 70.9 of the TRIPS Agreement

- (c) India has not acted inconsistently with Article 70.8(a) and 70.9.

⁹ The term "mailbox system" is used in this Panel report as shorthand for the means 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.

IV. ARGUMENTS OF THE PARTIES

Articles 9.1 and 10.4 of the DSU

4.1 The European Communities and their member States argued that, given the particular circumstances of this case, in which the measures at issue had already been examined by this Panel and by the Appellate Body in an earlier dispute (WT/DS50), to which the European Communities and their member States had been a third party, the Panel should extend its findings in the earlier dispute, as modified by the Appellate Body, to the European Communities and their member States as the complainant in the present proceeding. The following points were advanced in support of this argument:

- Since the DSB had adopted the Panel report and the Appellate Body report in the earlier dispute¹⁰ dealing with the same measures at its meeting of 16 January 1998 no change in factual circumstances had occurred. The domestic legal situation in India had not changed and, in particular, no amendment to the Patents Act of 1970 had been enacted in India in order to provide for an appropriate means to file applications for patents for inventions of pharmaceutical and agricultural chemical products pursuant to Article 70.8 of the TRIPS Agreement; nor had the same Act been amended in order to provide for the possibility to grant exclusive marketing rights pursuant to Article 70.9 of the TRIPS Agreement.
- It was neither necessary nor appropriate to repeat all the legal arguments that had already been put before this Panel when it dealt with the United States' complaint. Article 10.4 of the DSU specifically provided that a third party considering that a measure already the subject of a panel proceeding nullified or impaired benefits accruing to it under a covered agreement was entitled to bring its complaint on that measure before the original panel. This provision was designed to serve continuity, consistency and procedural economy in the WTO dispute settlement system. Therefore, a re-examination of the elements of the complaint in all legal detail would go against the very purpose of Article 10.4 of the DSU.
- The present complaint was in all aspects identical, from a legal point of view, with the earlier complaint submitted by the United States. It would entail a repetitive exercise of formalistic exchanges of views, which would be entirely futile given that the legal situation had already been clarified by the adoption of the earlier Panel and Appellate Body reports. It would also amount to a re-hearing of the case and would thus give the parties to the dispute the opportunity of having the equivalent of a further appeal not foreseen in any provision of the DSU.
- In view of the fact that the Panel and the Appellate Body had already found in the earlier dispute that the present Indian domestic régime concerning the patent protection of pharmaceutical and agricultural chemical products was inconsistent with India's obligations under Article 70.8 and 70.9 of the TRIPS Agreement, it followed pursuant to Article 3.8 of the DSU that there was a presumption according to which this breach of the relevant WTO rules by India had an adverse affect on the European Communities and their member States as the other party to this dispute. In these circumstances, the burden was on India to rebut the presumption according to which India's present domestic régime for the patent protection of pharmaceutical and agricultural chemical products nullified or impaired benefits accruing to

¹⁰ Documents WT/DS50/R and WT/DS50/AB/R, respectively

the European Communities and their member States under Article 70.8 and 70.9 of the TRIPS Agreement.

4.2 India, in response, requested the Panel to dismiss the complaint of the European Communities and their member States as inconsistent with the rules of the DSU on multiple complainants, in particular Articles 9.1 and 10.4. It advanced the following points in support of this view:

Successive complaints based on the same facts and legal claims were unprecedented

- It had been the consistent practice of both the Contracting Parties to GATT 1947 and the Members of the WTO to bring complaints based on the same facts, claims and arguments either jointly before the same panel or at least concurrently for examination by panels composed of the same persons. About one third of the panels established to date by the DSB had examined complaints submitted by two or more WTO Members jointly or concurrently. Seven WTO panels had examined joint or concurrent complaints, altogether representing 22 complaints. If each of these 22 complaints had instead been examined individually, the amount of resources spent by the WTO and its Members on settling these disputes would have tripled.

- The United States and the EC had reacted in the past with hostility to attempts by other Contracting Parties to GATT 1947 or Members of the WTO to re-litigate a matter, even when the subsequent complaint was justified. The United States had thus objected at the March 1991 meeting of the GATT 1947 Council to the establishment of a panel on Denial of Most-favoured-nation Treatment as to Imports of Non-rubber Footwear from Brazil because "this matter had already been adjudicated" by a panel established under the Tokyo Round Subsidies Agreement, even though Brazil had made legal claims in the second proceeding under the GATT that it could not have made under the Subsidies Agreement.¹¹ Equally hostile had been the EC's reaction to the request for consultations on its régime for the importation, sale and distribution of bananas by Panama in October 1997. The EC had described Panama's initiation of the dispute settlement procedures on a matter on which a panel had already ruled as an abuse of the dispute settlement procedures, even though Panama had not been a WTO Member when the original panel had been established and could therefore not have joined the earlier complaint.¹²

An unmitigated right to bring successive complaints by different parties based on the same facts and legal claims would entail serious risks for the multilateral trade order

- In the WTO, the danger of unnecessary re-litigation of the same matter arose mainly from the multilateral nature of the obligations at issue. In principle, each Member had the same obligations towards each of the other Members. The WTO presently had 132 Members. In theory, an allegation of non-compliance against one Member could therefore give rise to 131 different complaints by all the other Members. If multiple complaints were submitted to the same panel few problems arose; if they were brought successively before different panels, the confusion and waste of resources were great.

¹¹ Document C/M/248, pages 9-16

¹² Document WT/DS105/1. Panama became a Member of the WTO on 6 September 1997. The panel which examined the Bananas case was established on 8 May 1996 (WT/DS27/7).

- The objective of the proceedings under the DSU, just as those of any other system of legal adjudication, was to settle disputes by giving panels and the Appellate Body the authority to determine facts, to find the applicable law and to apply the law to the facts. Legal proceedings were troublesome and costly, not only for the parties to the dispute but to society in general. Henry M. Herman had written in 1886:

"Interest republicae ut sit finis litium, is an old maxim deeply fixed in the law of fundamentals; that it concerns the state that there be an end to litigation. This maxim has wide application; it . . . is obviously based on common sense and sound policy. For if matters which have been solemnly decided are to be drawn again into controversy; if facts, once solemnly affirmed, are to be again denied whenever the affirmant sees his opportunity, there can never be an end to litigation and confusion."

For these reasons, all legal systems had developed principles to ensure that the same matter was not unnecessarily re-litigated, among which the principles of *res judicata* and *stare decisis*.

- However, since the principle of *res judicata* did not apply if the parties to the dispute were different and the principle of *stare decisis* did not apply in the WTO to the interpretations of a panel or the Appellate Body, if successive multiple complaints by different Members on the same matter were to be admitted and examined as separate new cases, it would engender the danger of contradictory decisions and the waste of resources would be tremendous.¹³ If a panel ruled in one case in favour of the defendant, other complainants could bring the same case again and again before different panels with a different composition until a complainant "scored a hit".

(i) The principle of *res judicata* applied only when the parties to the dispute were the same¹⁴ and could therefore not prevent repeated disputes between different WTO Members on the same matter. In fact, the DSU explicitly recognized in Articles 9 and 10 the right of each Member to assert its rights individually. The principle of *stare decisis* also did not prevent multiple complaints on the same matter because this principle had not been applied in GATT/WTO jurisprudence. Thus, the 1989 GATT panel on EEC - Restrictions on Imports of Dessert Apples (Complaint by Chile) had noted that a previous panel, in 1980, had reported on a complaint involving a similar set of GATT issues but that it "did not feel it was legally bound by all the details and legal reasoning of the 1980 Panel report".¹⁵

(ii) The issue of the binding nature of panel decisions had arisen in the WTO for the first time in the complaint on Japan - Taxes on Alcoholic Beverages. The panel had decided this issue in the light of Article 31.3(b) of the Vienna Convention on the Law of Treaties, according to which there shall be taken into account in the interpretation of a treaty "any subsequent practice in the application of the treaty

¹³ The WTO currently does not levy any fees on complainants that might induce them not to engage in re-litigation. The Member which fails to bring its complaint jointly or concurrently with another Member can therefore now impose the financial consequences of its inaction on the WTO and its membership.

¹⁴ See, for example, Robert C. Casad, *Res Judicata*, West Publishing Co., St. Paul, Minn., 1976, page 2.

¹⁵ BISD 36S/123-124

which establishes the agreement of the parties regarding its interpretation". The panel had concluded that "... panel reports adopted by the GATT CONTRACTING PARTIES and the WTO Dispute Settlement Body constitute subsequent practice in a specific case by virtue of the decision to adopt them". The Appellate Body had reversed this finding and pointed out that "an isolated act is generally not sufficient to establish subsequent practice; it is a sequence of acts establishing the agreement of the practice that is relevant". It had further noted that "the generally-accepted view under GATT 1947 was that the conclusions and recommendations in an adopted panel report bound the parties in that particular case, but subsequent panels did not feel legally bound by the details and reasoning of a previous panel report". The Appellate Body had further pointed out that Article IX:2 of the WTO Agreement provided that "The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements". In the view of the Appellate Body, this clause provided the only possibility to adopt definitive interpretations. According to the Appellate Body, "The fact that such an 'exclusive authority' in interpreting the treaty has been established so specifically in the WTO Agreement is reason enough to conclude that such authority does not exist by implication or by inadvertence elsewhere".¹⁶

Articles 9 and 10 of the DSU required multiple complainants to submit their case to the same panel whenever feasible

- The drafters of the DSU had addressed the problem of multiple complaints on the same matter in Article 9.1 of the DSU, which provided:

"Where more than one Member requests the establishment of a panel related to the same matter, a single panel may be established to examine these complaints taking into account the rights of all Members concerned. A single panel should be established to examine such complaints whenever feasible."

The issue was also addressed in Article 10.4, which stated:

"If a third party considers that a measure already the subject of a panel proceeding nullifies or impairs benefits accruing to it under any covered agreement, that Member may have recourse to normal dispute settlement procedures under this Understanding. Such a dispute shall be referred to the original panel wherever possible."

These provisions made clear that another Member's complaint, by itself, did not foreclose a new complaint. Both joint and successive complaints by different Members, before the same panel or different panels, were therefore in principle allowed. However, Articles 9 and 10 also attached an important condition to the right to resubmit the same matter to a panel, by stipulating that "a single panel shall be established whenever feasible". The same proviso was contained in Article 10.4, according to which a dispute on a measure already under litigation must be referred to the same panel "wherever possible". Articles 9 and 10 therefore balance two conflicting objectives: on the one hand, each complainant must have the right to bring its own case, make its own claims and develop its own arguments; on the other hand, each defendant and the WTO must be protected against completely unnecessary re-litigation. The

¹⁶ Appellate Body report on Japan - Taxes on Alcoholic Beverages, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, Section E

compromise the drafters had found was logical and based on common sense: when complaints could be joined, they must be joined; when a third party could submit its complaint about a measure to a panel that examined the same measure, it must do so.

- The obligations under Articles 9.1 and 10.4 were expressed in the passive voice ("A single panel shall be established ..."; "Such a dispute shall be referred to ..."). The Articles therefore did not make clear to whom they were addressed: were the obligations established for the organs and officers of the WTO - in particular, the DSB and the Director-General - or for the Members of the WTO, or for both? This interpretative issue must be resolved in the light of the purpose of these provisions, which was to avoid unnecessary re-litigation. This purpose could not be achieved if the responsibility to ensure the joint or concurrent examination of multiple complaints fell exclusively on the organs and officers of the WTO. The DSB must establish a panel "if the complaining party so requests" whether or not that request was justified, and the DSB could therefore not effectively prevent unnecessary re-litigation. Equally, the Director-General was obliged under Article 8.7 to determine the composition of a panel "at the request of either party" irrespective of the nature of the complaint.

- The Panel had the responsibility to determine the admissibility of the EC complaints in the light of the provisions of Articles 9.1 and 10.4 of the DSU. In this regard, it should be recalled that the WTO panel on European Communities - Regime for the Importation, Sale and Distribution of Bananas had examined whether the authority to determine whether a request for the establishment of a panel met the requirements of Article 6.2 of the DSU rested with the DSB or with the panel. The panel had ruled that it had the authority:

"Because of the application of the 'reverse' consensus decision-making applicable in the case of panel establishment in the DSB, the DSB is not likely to be an effective body for resolving disputes over whether a request for the establishment of a panel meets the requirements of Article 6.2 of the DSU. Therefore, as a practical matter only the panel established on the basis of the request (and thereafter the Appellate Body) can perform that function."¹⁷

The reasoning of that panel applied equally to the question of whether a complaint met the requirements of Articles 9.1 and 10.4 of the DSU.

- It might therefore be concluded that Articles 9.1 and 10.4 could achieve their purpose only if the duty to submit multiple complaints to a single panel whenever possible was interpreted as a duty falling on both the WTO and its membership, and panels declared complaints that did not meet the requirements of these provisions as inadmissible. The present Panel was the first to address this issue and therefore had the important task of resolving it in the light of its broad systemic implications.

- It should be noted that India was not arguing against the submission of successive complaints on the same matter by different WTO Members in all cases. Successive complaints might be unavoidable and therefore legitimate for a variety of reasons. There might be legal reasons. For instance, the complainant might wish to make claims that went further than those made in the earlier proceeding. There might be procedural reasons. Thus,

¹⁷ Report of the panel on European Communities - Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/R/ECU, paragraph 7.26

the complainant might not have been a WTO Member when the original complaint had been brought, as noted above for Panama in the Bananas case. There might be factual reasons. For instance, the parties to the earlier dispute might have reached a settlement. The interpretation of Articles 9 and 10 suggested above would not curtail the legitimate exercise of the fundamental right of a WTO Member to a new and separate examination of its complaint when the need arose but would prevent only the needless, and therefore abusive, delay in the exercise of this right.

- The EC's exercise of the right to bring a new complaint on the same matter that had already been the subject of an earlier proceeding was abusive. As the EC itself admitted, its complaint was "in all aspects identical, from a legal point of view, with the earlier complaint submitted by the United States". Not a single new fact, claim or argument was presented by the EC. India had obligations under Article 70.8 and Article 70.9 not only with respect to the United States but with respect to all Members of the WTO, including the EC. Moreover, Article 4 of the TRIPS Agreement obliged India to implement its obligations under these provisions on a most-favoured-nation basis. India could therefore have only one "mailbox" system and only one mechanism for the granting of exclusive marketing rights, and these must be equally applicable to all Members of the WTO. Any change that India might make to implement the recommendations of the Panel in the earlier dispute, as modified by the Appellate Body, would therefore necessarily benefit not only the United States but also the European Communities and their member States. The only purpose of the EC's complaint was thus to obtain rights under Article 22.2 of the DSU, which the EC could easily have obtained by submitting its complaint jointly or concurrently with the United States. The EC had presented no reasons of a legal, procedural or factual nature that justified its decision to seek these rights belatedly in a separate proceeding.

- The question before the Panel was essentially the following: do complainants have an unlimited right to delay the initiation of proceedings or do defendants and the WTO have the right to be protected against unnecessary re-litigation? The EC's complaints amounted to unwarranted harassment, entailing a waste of the WTO's limited human and financial resources, as well as those of India. If the EC's approach to re-litigation were sanctioned by this Panel, and if Articles 9 and 10 of the DSU provided no point at which judicial proceedings in the WTO must stop, the WTO could easily become one vast scene of litigation, disturbance and ill will.

- The Appellate Body had stated in another context that "The WTO rules are not so rigid or so inflexible as not to leave room for reasoned judgements in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world".¹⁸ India invited the Panel to approach the novel and important interpretative issue before it in that spirit.

4.3 The European Communities and their member States disagreed with India on the interpretation of Articles 9 and 10 of the DSU and advanced the following arguments in this regard:

- Article 9 addressed a situation where there was more than one complainant in a dispute settlement procedure. It did not, however, contain any obligation on WTO Members to make a complaint at a given point in time. Nor did it address the situation of a WTO Member that had requested to be a third party in a given dispute settlement procedure. This

¹⁸ Appellate Body Report on Japan - Taxes on Alcoholic Beverages, (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R)

situation was addressed exclusively in Article 10. Article 10.4, which was relevant for the present case, specifically provided that a third party might become a complainant on the measure already the subject of a panel proceeding. It was obvious from this language that Article 10.4 addressed a situation with successive panel proceedings, like in the present case, since a WTO Member could not possibly be a complainant and a third party in one and the same procedure. Moreover, there was no provision in Article 10.4, neither explicit nor implied, which would prevent a third party from requesting the establishment of a panel after the conclusion of the earlier panel proceeding.

- There might be good reasons why a WTO Member wished to become a complainant with regard to a measure already the subject of a panel proceeding after having been a third party to that earlier panel.¹⁹ The procedural rights of third parties were much more limited than those of complainants. In particular, pursuant to Article 10.3 of the DSU, third parties shall receive the submissions of the (other) parties to the dispute to the first meeting of the panel. This implied that third parties did not have access to any other submission of the parties to the dispute. Pursuant to paragraphs 6 and 12(b) of Appendix 3 to the DSU, third parties were heard in a separate session, but did not participate otherwise in the meetings of the panel with the parties to the dispute. Pursuant to Article 17.4 of the DSU, only parties to the dispute, not third parties, may appeal a panel report. Finally, pursuant to Article 22.2 of the DSU, under the conditions set out in that provision, "any party having invoked the dispute settlement procedures may request authorization from the DSB to suspend the application to the Member concerned of concessions or other obligations under the covered agreements". As was apparent from this provision, the DSB could not grant such authorization to a third party, since it had not "invoked the dispute settlement procedures". If a third party wished to be released from these limitations, its only option was to become a complainant in its own right.

- Moreover, contrary to India's position in the present dispute, the DSU did not contain any obligation for a WTO Member to request dispute settlement procedures at a given point in time, at least as long as the measures at issue giving rise to the dispute continued to apply.

¹⁹ In response to a question from the Panel, the EC explained that, in 1996 and at the beginning of 1997, the European Communities and their member States were engaged in intensive discussions with India with a view to convince the Indian authorities to take the necessary steps for a correct implementation of its obligations under Article 70.8 and 70.9 of the TRIPS Agreement. Until that time, the EC was confident that India was preparing the necessary steps concerning the implementation of its obligations under these provisions without awaiting the end of the ongoing dispute settlement procedure (WT/DS50). When it became clear that India was not in fact taking the necessary steps to implement the above provisions expeditiously, the EC requested consultations under the DSU. The request for these consultations was submitted to India on 28 April 1997 and was circulated to WTO Members on 6 May 1997 (document WT/DS79/1). Consultations were held on 14 May 1997. While these consultations failed to lead to a mutually acceptable solution, it was felt that the EC's position had been sufficiently clarified so that India could have no doubt that the EC were willing to pursue the dispute settlement procedure further if necessary. Again, it was the impression of the EC that by means of additional informal contacts it would be possible to avoid further steps in the formal dispute settlement procedure. This was based also on the EC's experience, particularly in the TRIPS context, that satisfactory solutions are very often found on the basis of informal contacts before resorting to a formal panel process. In addition, at the time of the EC's formal consultations with India in May 1997, the panel process in the dispute between the United States and India (WT/DS50) was well advanced and it would have been difficult for the EC to join this ongoing dispute as a complainant, since the EC had chosen earlier on to act as a third party in that dispute. The EC does not believe that a party can be a complainant and a third party in the same panel procedure. This reading of the relevant DSU provisions is reinforced by the wording of Article 10.4 which in the view of the EC envisages successive procedures. As becomes clear from the above, the EC did not make the same policy choice as the United States, namely to resort to early dispute settlement procedures once the problem had been identified. Rather, the EC used all available channels in order to come to a mutually satisfactory solution without submitting the matter to WTO dispute settlement. Unfortunately, these efforts failed and the EC was left with no other option than to request the establishment of a panel as a complainant in order to be able to protect its interests in the context of the enforcement provisions of the DSU (Articles 21 and 22), since these provisions require the party seeking implementation of a panel report to have resorted to dispute settlement procedures as a complainant rather than a third party (Article 22.2 DSU).

Article 3.7 of the DSU specifically provided that "[b]efore bringing a case, Members shall exercise their judgement as to whether action under these procedures would be fruitful". On the basis of this provision, the Appellate Body had found in *European Communities - Regime for the Importation, Sale and Distribution of Bananas*²⁰ that WTO Members enjoyed broad discretion whether to bring a case against another Member under the DSU. This discretion necessarily also included the choice of the appropriate timing of a complaint. Launching a dispute settlement procedure was an important policy decision that was influenced by a large number of factors. The WTO was a Members-driven organization where Members enjoyed discretion whether or not to resort to a particular form of action under the covered agreements. Members might follow different strategies concerning the appropriate action in case of violations of WTO obligations by other Members. On this basis, a Member might choose a different timing of a complaint under the DSU for a measure already the subject of an earlier panel proceeding. This possibility was specifically addressed and recognized in Article 10.4 of the DSU, which would be stripped of any useful meaning if India's approach, according to which Members had an obligation to join a complaint under Article 9 if they wanted to bring a dispute on measures on which another Member was already complaining, were correct. As the Appellate Body had found in *United States - Standards for Reformulated and Conventional Gasoline*²¹, one of the corollaries of the "general rule of interpretation" contained in Article 31 of the Vienna Convention on the Law of Treaties was that "interpretation must give meaning and effect to all terms of a treaty. An interpreter was not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility".

- Contrary to India's allegations, the present case could not be compared with cases in which other WTO Members had been acting as multiple complainants rather than third parties. Moreover, by contrast to the situation in the *Bananas* dispute, where Panama had attempted to get involved in the implementation of the DSB recommendations and rulings of a dispute settlement procedure in which it had not participated, the EC did not claim to be entitled to a particular role with regard to the implementation of the recommendations and rulings of the DSB in the earlier dispute launched by the United States in which they were a third party (WT/DS50). The present case was in fact as yet without precedent in WTO practice. However, this situation was specifically addressed and resolved in Article 10.4 of the DSU.

4.4 India, in response, recalled that it had explicitly recognized that Members had the right to decide whether and when to bring a complaint, including Members that had been a third party in a previous proceeding. However, India's argument had been that the purpose of the second sentences of Articles 9.1 and 10.4 of the DSU was to ensure that different Members with similar complaints submit them concurrently to the same panel and that this purpose could not be achieved if these provisions were interpreted as addressing only the situation in which such Members had already decided to submit their complaints concurrently. The EC did not respond to this point at all. It also did not explain why it could not bring its complaint jointly with the United States. It merely stated that it had made different procedural choices. Implicit in the EC's contention was the claim that Articles 9.1 and 10.4, notwithstanding the explicit wording of their second sentences, were no bar to the institution of a successive complaint in respect of a measure which had been the subject-matter of an earlier proceeding. However, it was India's contention that this claim of the EC in respect of

²⁰ Report of 9 September 1997 (document WT/DS27/AB/R, paragraph 135)

²¹ Report of 29 April 1996 (document WT/DS2/AB/R, page 23)

Articles 9.1 and 10.4 would encourage unnecessary and avoidable litigation, which the present complaint of the EC clearly did. The EC attempted to distinguish the case of the successive complaint by Panama on the EC's banana régime from the present case by claiming that Panama "had attempted to get involved in the implementation of the DSB recommendations and rulings of a dispute settlement procedure in which it had not participated". However, was this not precisely what the EC was trying to do in the present case? The EC's attempt to distinguish Panama's course of action from its own could not hide the fact that in this case the EC was submitting India to a legal harassment to which the EC would not wish to be submitted itself.

4.5 India further made the following points in relation to Article 9.1 of the DSU:

- The first sentence of Article 9.1 of the DSU authorized the DSB to establish a single panel to examine multiple complaints. As far as the present case was concerned, this sentence made clear that the DSB would have had the authority to establish a single panel if the United States and the EC had submitted their requests for the establishment of a panel contemporaneously. The second sentence of Article 9.1 went further and stipulated the referral of multiple complaints to a single panel whenever feasible. Since the DSB could establish a single panel to examine multiple complaints related to the same matter only when these were submitted contemporaneously, the second sentence implied the duty to bring such complaints contemporaneously whenever feasible.

- Articles 9 and 10 balanced two conflicting objectives: on the one hand, each complainant must have the right to bring its own case, make its own claims and develop its own arguments; on the other hand, each defendant and the WTO must be protected against completely unnecessary re-litigation. The compromise the drafters had found was logical and based on common sense: when complaints could be joined, they must be joined; when a third party could submit its complaint about a measure to a panel that examined the same measure, it must do so.

4.6 Addressing the points that India had made with regard to Articles 9.1 and 10.4 of the DSU, the European Communities and their member States stated the following:

- India claimed that Article 9.1, second sentence, of the DSU created a duty to submit disputes regarding the same matter by different WTO Members simultaneously to the same panel. This reading of Article 9.1 of the DSU was clearly wrong. Article 9 dealt, in accordance with its title, with a situation in which more than one complainant requested the establishment of a panel on the same matter. Paragraph 1 of that provision was concerned with situations in which such requests were made simultaneously by several complainants. The first sentence of that paragraph allowed several WTO Members to request a single panel in such situations, while the second sentence encouraged the DSB to resort to the establishment of a single panel whenever feasible. Paragraph 3 dealt with a situation in which requests for the establishment of a panel on the same matter were made successively, but at a time when the first panel had not yet completed its work. In such situations, more than one panel would have to be established. This provision clearly demonstrated that there could be no obligation for WTO Members to request the establishment of a single panel on the same matter, since otherwise Article 9.3 would be superfluous. In WTO practice, Article 9.3 had already been used on several occasions, specifically in two disputes concerning the

EC.²² These disputes demonstrated that there was no obligation for several Members to submit their requests for the establishment of a panel on the same matter simultaneously.

- In any case, the present dispute was governed by the procedural rule laid down in Article 10.4 of the DSU. That provision explicitly dealt with the situation at hand and required the dispute to be referred to the original panel. The term "original panel" was a term of art used elsewhere in the DSU, namely in Articles 21.5 and 22.6, where it clearly dealt with procedures which by their very nature could not be simultaneous with the procedure which the "original panel" had been handling in the first place. The procedures referred to in these latter provisions only occurred at the implementation stage of a dispute in which the "original panel" by necessity had already circulated its report on the substance of the case. In other words, the term "original panel" was used where the DSU referred to a panel having already dealt with the same issue in an earlier procedure in which it had already completed its work. India submitted that its interpretation of Article 9.1, which created a duty on WTO Members to submit disputes simultaneously to the same panel, applied *mutatis mutandis* to Article 10.4. The EC did not agree with India's interpretation of Article 9.1. To seek to apply this interpretation in addition to Article 10.4, which had a different purpose, was obviously far-fetched.

- The EC was, for these reasons, of the view that India's reading of Articles 9.1, second sentence, and 10.4, second sentence, of the DSU was wrong and should be rejected by the Panel. In this context, the EC had already drawn the attention of the Panel to the first sentence of Article 3.7 of the DSU which - as had been confirmed by the Appellate Body in the Bananas case²³ - gave Members broad discretion whether to launch a dispute settlement case, which necessarily included the discretion to decide on the timing of a dispute settlement procedure.

Normal dispute settlement procedures

4.7 India took the view that, in the alternative, if the Panel were to consider that Article 10.4 of the DSU entitled the European Communities and their member States to bring their complaints, the Panel would be obliged to apply the "normal dispute settlement procedures", as stipulated in Article 10.4, and make an objective assessment of the facts and arguments presented in the present proceedings, as required under Article 11 of the DSU. To support its view that it would have to be given the benefit of the normal dispute settlement procedures, if the EC complaints were found to be consistent with rules of the DSU on multiple complainants, India advanced the following arguments:

- The EC based its right to re-litigation on the first sentence of Article 10.4 of the DSU, which provided:

"If a third party considers that a measure already the subject of a panel proceeding nullifies or impairs benefits accruing to it under any covered

²² Cf. the requests for the establishment of a panel by Canada on the one hand and by Chile and Peru on the other hand in the dispute on European Communities - Trade Description of Scallops (WT/DS7/7 and WT/DS12/7 and WT/DS14/6) and the requests by the United States on the one hand and Canada on the other hand in the dispute on European Communities - Measures concerning Meat and Meat Products (Hormones) (WT/DS26/6 and WT/DS48/5).

²³ Cf. Appellate Body report on European Communities - Régime for the Importation, Sale and Distribution of Bananas (WT/DS27/AB/R), paragraph 135

agreement, that Member may have recourse to normal dispute settlement procedures under this Understanding."

The EC was thus requesting this Panel to go through the "normal dispute settlement procedures" under the DSU for a purpose for which these procedures had obviously not been designed. The role of a panel was to determine facts, to find the applicable law and to apply the law to the facts. But the EC was not requesting this Panel to perform these functions. It was merely requesting the Panel to perform the mechanical function of formally extending a ruling made in an earlier panel proceeding to the present complaint.

- The EC had conceded that a re-litigation of the case would have systemic and practical problems, when stating that "... a re-examination of the elements of the complaint in all legal detail would go against the very purpose of Article 10.4 of the DSU. It would entail a repetitive exercise of formalistic exchanges of views which would be entirely futile given that the legal situation has already been clarified by the adoption of the earlier panel and Appellate Body reports. It would also amount to a re-hearing of the case and would thus give the parties to the dispute the opportunity of having the equivalent of a further appeal not foreseen in any provision of the DSU ..." This statement was contradictory. The EC first claimed that it had the right to resort to the "normal dispute settlement procedures" referred to in Article 10.4, notwithstanding the fact that its complaint was "in all respects identical, from a legal point of view, with the earlier complaint submitted by the United States"; however, it then claimed that the application of the normal dispute settlement procedures "would be entirely futile", "amount to a re-hearing of the case" and create the opportunity of "having the equivalent of a further appeal". The EC thus interpreted Article 10.4 as conferring upon it a right whose exercise was futile and dangerous for the multilateral trading system.

- The implication of the EC's argumentation was that Article 10.4 should be interpreted as giving the EC the right to bring a new complaint and as barring India from submitting new arguments or new facts. This could not possibly be so. The Panel must either dismiss the complaint "as entirely futile" or re-examine the matter as a new case in accordance with the "normal dispute settlement procedures"; it could not first permit the complaint and then deny the defendant the application of the normal dispute settlement procedures on the ground that this would be entirely futile. The reasons that the EC advanced to deny India the right to normal dispute settlement procedures were the very reasons that called for a dismissal of its complaint. How could the EC reasonably expect any Member of the WTO to cooperate in one-sided procedures violating the most basic principles of procedural justice?

4.8 The European Communities and their member States said that they recognized that normal dispute settlement procedures were applicable in the present case. They remained, however, of the view that points dealt with in the earlier dispute on the same subject should not be re-litigated in the present dispute. The referral of this dispute to the original panel served the purpose of ensuring consistency and procedural economy. Why would the parties have to repeat all the factual allegations and legal arguments already submitted in the earlier dispute? The Panel was familiar with them and had already made its findings on them, as much as the Appellate Body in the context of India's appeal in the earlier dispute. The purpose of referring the dispute back to the original panel must be to limit the debate to any new or unknown facts or new arguments on which the Panel had not yet had an opportunity to make any findings, i.e the Panel should concentrate on any new or so far unknown factual allegations and legal arguments. If it were otherwise, the danger of lack of consistency and of a wasting of resources would be inevitable. In any case, panels should recognize earlier panel and

Appellate Body reports as relevant for the solution of a subsequent dispute in accordance with the Appellate Body report in *Japan - Taxation of Alcoholic Beverages*.²⁴

4.9 As regards the approach the Panel should take when applying the normal dispute settlement procedures under Article 10.4 in the present case, India made the following points:

- The ruling in the previous case on Article 70.8 was based on the findings that the evidence submitted by India had not been sufficient to rebut the presumption created by the evidence adduced by the United States that the Indian mailbox system was inconsistent with Indian law. In the present case, India had submitted evidence on the domestic situation that it had not submitted in the previous case and had requested the Panel to engage in further fact-finding. The facts before this Panel were therefore different. It was irrelevant whether or not India had changed in patent régime; relevant was only whether the evidence adduced by India in the present proceeding was sufficient to rebut whatever presumption the evidence submitted by the EC had created. As confirmed by the Appellate Body, a panel could not interpret domestic law but must examine the applications of the domestic law. In such an examination an important new element to be considered was the fact that since the initiation of the United States' complaint (WT/DS50) about two years ago not even one attempt had been made to challenge any of the mailbox applications while a total number of over 2,000 applications had been submitted.

- There was a significant difference between being guided "by the Appellate Body's decision", as the United States suggested in its third party submission in the present dispute, and being guided by the Appellate Body's reasoning in the previous and other cases. If this Panel were to declare that the Appellate Body had already decided the matter and that an independent examination of the facts and arguments in the present case was therefore not necessary, it would effectively declare the matter *res judicata* and deny India its procedural rights under the normal dispute settlement procedures. The Panel could not logically first admit the complaint and then declare the matter before it to have been decided by the Appellate Body.

- If the Panel were to be guided by the reasoning of the Appellate Body in the previous and other cases, it would proceed as all panels under the normal dispute settlement procedures did, using the reasoning in the previous case as a precedent. India was in fact urging the Panel to use the Appellate Body's reasoning in the previous case as a precedent, in particular as regards the inappropriateness of: (a) using the principle of predictability of conditions of competition as a basis for expanding the scope of Article 70.8 and 70.9; (b) basing a finding of inconsistency with the TRIPS Agreement on an interpretation of Indian law rather than an examination of the application of Indian law; and (c) expanding the obligations under Article 70.9 beyond the terms of this provision.

Article 70.8(a) of the TRIPS Agreement

4.10 The European Communities and their member States argued that, in view of the fact that the Panel and the Appellate Body had already found in the earlier dispute that the present Indian domestic régime concerning the patent protection of pharmaceutical and agricultural chemical products was inconsistent with India's obligations under Article 70.8 of the TRIPS Agreement, it followed pursuant to Article 3.8 of the DSU that there was a presumption according to which this breach of the relevant WTO rules by India had an adverse affect on the European Communities and

²⁴ Report of 4 October 1996 (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, at page 14)

their member States as the other party to this dispute. In these circumstances, the burden was on India to rebut the presumption according to which India's present domestic régime for the patent protection of pharmaceutical and agricultural chemical products nullified or impaired benefits accruing to the European Communities and their member States under Article 70.8 of the TRIPS Agreement.

4.11 India argued that the Panel was not called upon to determine whether the mailbox system that India had established was consistent with Indian law but whether India, in applying that law, was acting in conformity with Article 70.8(a) of the TRIPS Agreement.

- The EC was relying on the municipal law of India to prove its claim that a competitor could obtain a judicial order to force the Patent Office to examine and reject a mailbox application and thereby make it ineligible for future patent protection. It was recognized that "'municipal law' has to be proved by the party relying on such a law in an international proceeding".²⁵ It was thus for the EC to demonstrate that the domestic law of India was such as to entail a violation of the obligations under Article 70.8(a). It was also recognized that an international tribunal could not interpret municipal law; it must treat it as a fact to be established by the party relying on it.²⁶

- On this issue the Appellate Body had noted in its report on the previous case²⁷:

"In public international law, an international tribunal may treat municipal law in several ways.²⁸ 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."²⁹ (emphasis by the Appellate Body)

²⁵ Mojtaba Kazazi, *Burden of Proof and Related Issues: A Study on Evidence Before International Tribunals*, Kluwer Law International, 1996, page 368

²⁶ *Id.*

²⁷ Document WT/DS50/AB/R, paragraph 65

²⁸ See, for example, I. Brownlie, *Principles of Public International Law*, 4th ed. (Clarendon Press, 1990), pages 40-42.

²⁹ [1926], PCIJ Rep., Series A, No. 7, page 19

- General international law, GATT 1947 precedents and the above ruling of the Appellate Body all pointed in the same direction: the Panel was not called upon to interpret Indian law; it was to give judgement on the question of whether India, in applying that law, had acted in accordance with Article 70.8(a) of the TRIPS Agreement. India submitted that a distinction must be made between: (i) evaluating the application of an Indian statute or regulations to determine whether it violated WTO provisions; and (ii) deciding the purely municipal law issue of whether a measure applied by India was valid under its domestic law. The first was clearly necessary for the WTO to function effectively; the second was the responsibility of the Government of India, namely, upholding India's Constitution and its laws as a sovereign government. In India's view, in its report the Appellate Body had overlooked this central distinction.

4.12 According to India, the EC bore the burden of proving that India had failed to establish a mailbox system meeting the requirements of Article 70.8(a) of the TRIPS Agreement and not merely that there were reasonable doubts that it had failed to do so.

- In the previous case, the United States and India had advanced conflicting views on whether a competitor could obtain a judicial order to force the Patent Office to examine and reject a mailbox application. The United States had claimed that this was possible, while India had pointed out that it was not. Faced with these conflicting claims, the Panel had ruled 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".³⁰ The Panel had also ruled that:

"... even if the 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. 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."³¹

- The Panel had found that the Indian Supreme Court decisions which India had provided to it only established that India's "reliance on an administrative practice regarding the handling of pharmaceutical and chemical product applications is not unconstitutional". However, according to the Panel, this evidence adduced by India did not demonstrate that "a court will uphold the validity of administrative actions which apparently contradict mandatory legislation".³² It had concluded for these reasons that, notwithstanding India's commitment to adapt its legislation on pharmaceutical and agricultural chemical products by the end of the transitional period, "there would remain doubt during the transitional period regarding the eligibility of these products for future patent protection".³³

- The Panel thus had not found that the evidence submitted to it demonstrated that mailbox applications would be invalidated under Indian law. However, on the basis of its

³⁰ Document WT/DS50/R, paragraph 7.35

³¹ Document WT/DS50/R, paragraph 7.37

³² Document WT/DS50/R, paragraph 7.37

³³ Document WT/DS50/R, paragraph 7.38

interpretation of that law, it had found that there was "a certain degree of legal insecurity" and "doubt" because of an "apparent" contradiction with mandatory law. These doubts were in the view of the Panel sufficient to find the Indian mailbox system to be contrary to Article 70.8(a) because that provision required India to "eliminate any reasonable doubts" that the mailbox applications and the patents based on them would not be invalidated. The Panel had thus interpreted into the TRIPS Agreement the requirement that a Member must eliminate any reasonable doubts that it had met the requirements set out in that Agreement.

- By ruling that India - the party subject to Article 70.8(a) - must remove any reasonable doubts regarding its mailbox system, the Panel effectively had relieved the United States - the party claiming a violation of Article 70.8(a) - of the burden of adducing evidence that the violation had occurred. This shift of the burden of proof on to India would imply that the party claiming a violation of Article 70.8(a) must merely prove that there were reasonable doubts suggesting such a violation. It was then for the defending party to dispel those doubts. By proceeding in this manner, the Panel had applied a standard of proof to the evidence to be adduced by the defending party that no State with courts entitled to review administrative actions could meet. India considered for these reasons that the Panel's interpretation of Article 70.8(a) was not only substantively incorrect but also violated established principles governing the burden and standard of proof. India had appealed therefore both from the substantive finding and from its implications for the distribution of the burden of proof and the standard of proof.

- While the Appellate Body had first ruled that Article 70.8(a) did not comprise the obligation to eliminate "reasonable doubts" that mailbox applications would be invalidated, it nonetheless subsequently declared it sufficient for the Panel to have concluded from the evidence that it - the Panel - had "reasonable doubts" that such invalidation could occur.

- The Appellate Body had reversed the substantive finding of the Panel by ruling:

"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'.³⁴ 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."³⁵

³⁴ Id.

³⁵ Document WT/DS50/AB/R, paragraph 58

To India's great surprise, however, the Appellate Body had upheld the Panel's ruling on the distribution of the burden of proof. It had found:

"... the United States put forward evidence and arguments that India's 'administrative instructions' pertaining to mailbox applications were legally insufficient to prevail over the application of certain mandatory provisions of the Patents Act. India put forward rebuttal evidence and arguments. India misinterprets what the Panel said about 'reasonable doubts'. The Panel did not require the United States merely to raise 'reasonable doubts' before the burden shifted to India. Rather, after properly requiring the United States to establish a prima facie case and after hearing India's rebuttal evidence and arguments, the Panel concluded that it had 'reasonable doubts' that the 'administrative instructions' would prevail over the mandatory provisions of the Patents Act if a challenge were brought in an Indian court."³⁶

It was difficult to reconcile the two statements in the underlined portions of the above extracts from the Appellate Body report. The Appellate Body first ruled that Article 70.8(a) did not comprise the obligation to eliminate "reasonable doubts" that mailbox applications would be invalidated. However, the Appellate Body subsequently declared it sufficient for the Panel to have concluded from the evidence that it - the Panel - had "reasonable doubts" that such invalidation could occur. The findings of the Panel were consistent: it had interpreted Article 70.8(a) to require India to eliminate any reasonable doubts as to the validity of mailbox applications and it had consequently considered a demonstration that there were such doubts to be sufficient. The Appellate Body had ruled that India did not have to eliminate any reasonable doubts but then effectively reversed that ruling by considering a demonstration of doubts to be sufficient.

4.13 India further advanced that Members should be given the benefit of the doubt on their own interpretations of their municipal law and that the Panel and the Appellate Body had failed to apply the principle that the conformity of the internal law of each State with its treaty obligations must be presumed.

Whether interpretations of municipal law were correct was to be determined by domestic courts

- India's arguments before the Panel in the present case amounted to the following. The implementation of the TRIPS Agreement would require administrative, regulatory, and legislative actions - or choices amongst them - based on interpretations by the executive authorities of Members of their regulations, statutes and constitution. Whether such interpretations were correct could only be determined by domestic courts. India's position was that panels and the Appellate Body should give a Member the benefit of the doubt on its interpretation of its own law unless there was evidence - such as a court decision - that the Member's interpretation of its own law was manifestly incorrect. Members had the legitimate

³⁶ Document WT/DS50/AB/R, paragraph 74

expectation that the interpretation of their municipal law would be left to their domestic courts.

- As a matter of policy also, this was a wise approach for panels to follow. Panels had special expertise in the area of WTO/GATT law which they did not have in the area of a Member's domestic law. Accordingly, they should give Members the benefit of the doubt on their determinations under their domestic law. This was not the same as deferring to a Member's interpretations of WTO provisions or deferring to a Member's determination on whether a particular factual situation met the WTO standard for imposing anti-dumping duties or for imposing quantitative restrictions under Article 6 of the Agreement on Textiles and Clothing. Thus, the view of the Panel in *United States - Restrictions on Imports of Cotton and Man-Made Fibre Underwear*³⁷ - that a "policy of total deference to the findings of national authorities could not ensure an objective assessment as foreseen by Article 11" of the *Dispute Settlement Understanding* - was clearly distinguishable from the present case. India was not advocating a policy of deference: India recommended merely that not only should the burden of showing that a measure taken by a Member to comply with its WTO obligations was invalid under its domestic law be placed firmly on the Member challenging the validity of such a measure, but Members should also be given the benefit of the doubt on their own interpretations of their municipal law, as previous GATT panels had ruled.

- Otherwise, if panels resorted too quickly to adjudicating upon the validity of a Member's actions under its domestic law, an anomalous situation could result where a particular action of a Member stood invalidated on a panel's interpretation of the Member's domestic law but was upheld by the Member's domestic courts. Also, panels should not permit the WTO to be turned into a forum for adjudicating upon the validity of Members' measures under their domestic law.

The Panel and the Appellate Body had failed to apply the principle that the conformity of the internal law of each State with its treaty obligations must be presumed

- The Appellate Body had found in the previous case that the evidence adduced by the United States had established the "presumption" that India's "mailbox system" was inconsistent with its Patents Act and that India had not submitted evidence rebutting that presumption. This use of a "presumption" was contrary to established principles of international law.³⁸

- The practice of GATT 1947 panels had been consistent with the principle for the settlement of disputes by international tribunals according to which the conformity of the internal law of each state with its treaty obligations must be presumed and a party whose

³⁷ Document WT/DS24/R, paragraph 7.10

³⁸ See Mojtaba Kazazi, *Burden of Proof and Related Issues: A Study on Evidence Before International Tribunals*, Kluwer Law International, 1996, page 242. According to Kazazi this principle is reflected in Article 27 of the Vienna Convention on the Law of Treaties, according to which a party to a treaty may not "invoke the provisions of its internal law as justification for its failure to perform the treaty". For a summary of the current state of WTO case law on the issue of the burden of proof and on presumptions, see the panel report on *Argentina - Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items*, WT/DS56/R, paragraphs 6.34-6.40.

internal law was claimed to be inconsistent with its treaty obligations must therefore be given the benefit of the doubt regarding the interpretation of its internal law.³⁹

- In the previous case, these principles had not been observed. Before the previous Panel, the United States had pointed to certain provisions of the Patents Act that were capable of different interpretations. The Panel and the Appellate Body had considered that the United States had, by adducing this evidence, created a "presumption" that India's mailbox system was inconsistent with its Patents Act. After an "examination" of the Patents Act, the Appellate Body had concluded that India's "explanations" had not persuaded it that mailbox applications would survive legal challenge under the Patents Act.

- It was an established principle of law, confirmed repeatedly by the Appellate Body, that a party claiming a violation of a provision of the WTO Agreement by another Member must assert and prove its claim and that the defendant enjoyed the benefit of the doubt when the interpretation of its domestic law was at issue. The task of the EC was consequently to prove that India's mailbox system was inconsistent with Indian law and that a mailbox application could therefore be successfully challenged in an Indian court. It was not sufficient for it to submit evidence merely casting doubt on that consistency in the minds of the Panelists. The Appellate Body had failed to apply that principle of law in the previous case. India suggested that the Panel be guided by the principles enunciated by the Appellate Body and not by the failure to apply them in a single instance.

4.14 According to India, the Panel and the Appellate Body, in examining the complaint by the United States in the earlier case, had improperly based their conclusions on their interpretation of Indian law.

- In the previous case, the Panel had ruled, on the basis of its own interpretation of the provisions of the Patents Act, that the mailbox system was inconsistent with mandatory requirements of the Patents Act⁴⁰ or "apparently" inconsistent.⁴¹ It did not examine whether India, in applying its Patents Act, had established a mailbox system, but whether the Patents Act permitted it to do so. And the Panel did not determine whether a competitor had, in fact, obtained a judicial order to reject a mailbox application but concluded on the basis of its own assessment of Indian law that an Indian court hypothetically might do so, assuming that a competitor mounted a legal challenge to India's mailbox in a competent Indian court. However, the Panel failed to note that basic principles of standing and ripeness⁴² applicable in Indian law stood in the way of such a court order.⁴³

³⁹ See, for example, report of the panel on United States - Measures Affecting Alcoholic and Malt Beverages, adopted on 19 June 1992, BISD 39S/206, 284-287, 296-297; and the report of the panel on United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco, adopted on 12 August 1994, DS44/R, paragraph 75; see also document L/5863 concerning an unadopted GATT panel report, dated 17 September 1985, paragraphs 58 and 59 ("gold coins").

⁴⁰ Document WT/DS50/R, paragraph 7.35

⁴¹ Document WT/DS50/R, paragraph 7.37

⁴² See further under paragraph 4.17 below.

⁴³ Document WT/DS50/R, paragraph 7.37

- The Appellate Body had not acted in accordance with the principle it had itself enunciated. Rather than examining how India had applied its law on the basis of the interpretation of that law by the Indian authorities, the Appellate Body had based its conclusions on its own interpretation of municipal law. It had ruled as follows:

"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.⁴⁴ And, like the Panel, we are not persuaded that India's 'administrative instructions' would prevail over the contradictory mandatory provisions of the Patents Act.⁴⁵ We note also that, in issuing these 'administrative instructions', the Government of India did not avail itself of the provisions of section 159 of the Patents Act, which allows the Central Government 'to make rules for carrying out the provisions of [the] Act' or section 160 of the Patents Act, which requires that such rules be laid before each House of the Indian Parliament. We are told by India that such rule making 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.

"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."⁴⁶

- The rulings of the Appellate Body were contradictory. It first confirmed that an international tribunal could not interpret domestic law but could only examine the application of that law. This should have led the Appellate Body to examine such questions as: has India established a mailbox system; have mailbox applications been challenged in Indian courts; has any Indian court declared a mailbox application invalid? The fact that India had received 1924 mailbox applications between 1 January 1995 and 15 October 1997, not one of which had been rejected or invalidated, should have been central to the Appellate Body's considerations. Instead, the Appellate Body had interpreted Indian law and examined the questions: is the mailbox system consistent with India's Patents Act; can mailbox applications be challenged under Indian law in Indian courts; can mailbox applications be declared invalid under Indian law? The central finding of the Appellate Body on which it based its conclusion was: "we are not persuaded that India's "administrative instructions" would survive a legal challenge under the Patents Act". It was thus on the basis of its own

⁴⁴ Document WT/DS50/R, paragraph 7.35

⁴⁵ Document WT/DS50/R, paragraph 7.37

⁴⁶ Document WT/DS50/AB/R, paragraphs 69-70

interpretation of the Patents Act, rather than an assessment of the application of that Act, that the Appellate Body had ruled against India.

- The Appellate Body had justified this seeming contradiction as follows:

"It is clear that an examination of the relevant aspects of Indian municipal law and, in particular, the relevant provisions of the Patents Act as they relate to the 'administrative instructions', is essential to determining whether India has complied with its obligations under Article 70.8(a). ... 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."⁴⁷

These formulations disguised the Appellate Body's approach to the municipal law of India and misrepresented the issue that had been before the Appellate Body. India had not claimed or implied that only India "can assess whether Indian law is consistent with India's obligations under the WTO Agreement". India did assert, however, that only its courts could determine whether the application of the Patents Act by the Government of India was consistent with Indian law and that the role of WTO panels and the Appellate Body was to judge whether India's application of its law was consistent with its WTO obligations. This did not mean that Members wishing to challenge the implementation of WTO obligations under domestic law were defenseless. It merely meant that it was not sufficient for them to base their claims merely on one possible interpretation of the domestic law, as the EC was doing in this case. If the parties to a dispute advanced different interpretations of domestic law and the interpretation of that law had not been settled by the domestic courts, the party whose law was at issue should be given the benefit of the doubt. It was in the interest of all Members of the WTO that this principle be applied. Each Member's economic interests were adequately protected if panels, whenever the interpretation of the domestic law had not yet been settled by municipal courts, examined how the defendant's domestic authorities actually applied the defendant's domestic law to products, services and service suppliers or holders of intellectual property rights from the complainant. No Member would wish to be told by a panel or the Appellate Body, as India had been told in the previous case, that it was violating its own domestic law.

4.15 India also argued that the interpretation by the Panel and Appellate Body of Indian law in the earlier case had been incorrect.

- The Patents Act required the Controller to refer patent applications to an examiner; it did not, however, specify the time-frame within which the Controller must do so. The Indian authorities were of the view that, given their broad powers under the Indian Constitution in the field of intellectual property and in the implementation of international treaties, they could use the resulting discretion to postpone the referral of applications for pharmaceutical and agricultural chemical products until 2005 because such products would in any case be patentable only then.

⁴⁷ Document WT/DS50/AB/R, paragraph 66

- The Indian authorities were further of the view that the principle of ripeness consistently applied by Indian courts prevented any legal challenge to mailbox applications because these conferred only a potential, future right.⁴⁸ The Appellate Body, in an incomplete assessment of that legal situation, concluded that it was not convinced that the Indian authorities were acting in accordance with Indian law. The Appellate Body conducted what it called "an examination of the relevant aspects of Indian municipal law" and declared that it was not persuaded by the "explanations" given by India. In fact, the "examination" of Indian law had been an interpretation of that law and the "explanations" rejected had been the interpretations of that law by the Indian authorities.

4.16 India further advanced that the mailbox system it had established was consistent with Indian law.

- Section 6 of the Patents Act permitted the receipt of any application for a patent that related to an "invention". Section 2(1)(j) of the Patents Act defined an invention to include "any new and useful substance produced by manufacture" and "any new and useful improvement of them". This definition was broad enough to include new pharmaceutical and agricultural chemical products.

- Section 3 of the Patents Act set forth certain categories of inventions or alleged inventions which were not considered inventions within the meaning of the Act. Since pharmaceutical and agricultural chemical products per se were not excluded under Section 3, they were "inventions" in respect of which applications might be received under Section 6 of the Act.

- Section 5 of the Act recognized that there might be an invention in relation to a pharmaceutical or agricultural chemical product, but provided that such an invention was patentable only with respect to the process by which it was made and not with respect to the product itself. Therefore, Section 5 of the Patents Act only prohibited the grant of a patent for such a product, not the receipt of an application for a patent for such a product.

- Accordingly, Section 6 of the Patents Act as interpreted and applied administratively did provide a "means" for the receipt of applications for product patents for pharmaceuticals and agricultural chemicals. These applications were being identified and placed in a separate category by the Patent Offices and were not being examined. They were also being allotted a filing date, a serial number and a title, which would entitle them to priority when pharmaceutical and agricultural chemical product patents were finally granted. Further, they were not being rejected because they were not being referred by the Controller of Patents to examiners for examination under Section 12(1) of the Patents Act. This was because, following interdepartmental consultations, the Indian executive authorities had issued administrative instructions to the Controller of Patents not to refer mailbox applications for examination by an examiner until the Patents Act was amended to provide for product patents for pharmaceutical and agricultural chemical products.

- Contrary to the assertions of the Panel and the Appellate Body in the previous case, there was no conflict between the above exercise of executive power under Article 73 of India's Constitution and Section 12(1) of the Patents Act. Although Section 12(1) mandated that the Controller must refer all applications to an examiner, it did not specify any time for

⁴⁸ See further under paragraph 4.17 below.

doing so. In light of this statutory silence, the executive power of the Government of India extended to specifying a reasonable time for referring applications for examination in order to fulfil India's obligations under Article 70.8(a). Therefore, there was no conflict between the administrative instructions in question and Section 12(1) of the Patents Act. This followed from the fundamental principle of statutory interpretation in Indian domestic law that a statutory provision must be interpreted consistently with India's international obligations, whether under customary international law or an international treaty or convention. In this context, Justice G.P. Singh, one of the leading authorities on the principles of statutory interpretation in India and a former Chief Justice of the High Court of the State of Madhya Pradesh, had stated as follows⁴⁹:

"If the terms of the legislation are not clear ... and are reasonably capable of more than one meaning, the treaty itself becomes relevant, for there is a prima facie presumption that Parliament does not intend to act in breach of international law, including therein a specific treaty obligation; and if one of the meanings which can reasonably be ascribed to the legislation is consonant with the treaty obligations and another or others are not, the meaning which is consonant is to be preferred.⁵⁰ Article 19 of the Universal Declaration of Human Rights which declares that everyone has a right to freedom of opinion and expression 'regardless of frontiers' was referred to in holding that the right of freedom of speech and expression guaranteed by Article 19(1)(a) of the Constitution is not restricted to the territory of India.⁵¹ And, Article 11 of the International Covenant on Civil and Political Rights, which provides that no one shall be imprisoned merely on the ground of inability to fulfil a contractual obligation has greatly influenced the court in giving a limited meaning to section 51 and order 21 Rule 37 of the Code of Civil Procedure.⁵² If States are parties to a convention which permits a foreigner when sentenced to imprisonment for a crime to be transferred to the State of which he is the citizen for serving out the sentence on humanitarian grounds, it may not be proper to detain him under a preventive detention law instead of prosecuting him for a criminal offence as that will deprive him of the beneficial provisions of the convention of being transferred to his home State."⁵³

This principle of statutory interpretation held good even if the statute in question pre-existed the treaty obligation.⁵⁴

⁴⁹ Justice G. P. Singh, *Principles of Statutory Interpretation*, Wadhwa & Co., Nagpur, 6th ed., 1996, pages 380-81

⁵⁰ *Salamon v. Commr. of Customs and Excise*, (1996) All ER 871 (CA), page 875, etc.

⁵¹ *Maneka Gandhi v. Union of India*, (1978) 1 SCC 248

⁵² *Jolly George Verghese v. Bank of Cochin*, (1980) 2 SCC 360

⁵³ *Kubic Dariusz v. Union of India*, AIR 1990 SC 470

⁵⁴ *People's Union for Civil Liberties v. Union of India*, (1997) 1 SCC 301

- Under Indian law, there was also another independent principle of statutory interpretation, namely that, even where a statutory provision specified a time for performing a statutory duty, the time specified was only directory and not mandatory. Thus, Justice Singh noted that:

"... [W]here a public officer is directed by a statute to perform a duty within a specified time, the cases establish that provisions as to time are only directory ... A provision fixing a time, within which a public officer or authority has to act in performance of a duty, generally means that the statute considers it reasonable for the officer or authority to act within the said period."⁵⁵

Therefore, India submitted that the time within which the Controller of Patents had been instructed to refer the mailbox applications to an examiner - i.e., only after amendment of the Patents Act to provide for product patents for pharmaceutical and agricultural chemicals - was reasonable in light of India's obligation under Article 70.8(a) to establish a mailbox pending the introduction of patent protection for these products.

- Further, Article 73 of India's Constitution conferred upon the Government of India executive power of the widest latitude over all subjects in which Parliament had legislative competence. This power extended to filling lacuna administratively in statutes, rules or regulations.⁵⁶ The executive power of the Government of India to enter into, and implement treaties, was derived from the legislative power of the Union of India incorporated in Articles 246 and 253 read with Entry 14 of List I of the Seventh Schedule of the Indian Constitution.⁵⁷ The Government of India also had executive power over "patents, inventions and designs", which fell under Entry 49 of List I. Based on these powers, the Government of India had decided to store applications for pharmaceutical and agricultural chemical products separately for future action under Article 70.8 and 70.9 of the TRIPS Agreement and to instruct the Controller of Patents not to refer them to an examiner until 2005.

- In addition, the Government of India had also bound itself to observe its obligations under Article 70.8 by virtue of a statement in Parliament. On 2 August 1996, the Government had stated in Parliament as follows:

"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."

Such statements were considered binding upon the Government under the Indian Constitution.

⁵⁵ Justice G. P. Singh, *supra* note 49, pages 244-245

⁵⁶ *Union of India vs. H. R. Patankar and Others*, (1984) Supp. SCC 359; and *J. R. Raghupathy vs. State of A.P.*, (1988) 4 SCC 364

⁵⁷ *Maganbhai v. Union of India*, (1970) 3 SCC 401

4.17 Further, according to India, mailbox applications could not be challenged in Indian courts and invalidated under the Patents Act.⁵⁸

- Contrary to what the Panel had found in the earlier dispute (WT/DS50) on the basis of the limited evidence submitted to it, an Indian court would never examine a request by a competitor to force the Controller of Patents to refer a mailbox application to an examiner for examination. In fact, such a request could not be entertained because basic principles of standing and ripeness dictated the rejection of challenges to contingent, future rights such as those of mailbox applicants to receive patents in the year 2005.⁵⁹ A mailbox application gave an applicant only a right to receive a patent for a pharmaceutical or agricultural chemical product in the future when India would provide for the grant of such patents under its Patents Act. Further, the applicant must satisfy the Patent Office that the applicable criteria for the grant of a patent under the Patents Act were met. Thus, a mailbox application gave an applicant at best a contingent, future right, which - under the principles of standing and ripeness applied in India as in other common law countries - could never be successfully challenged in court. This was confirmed by the fact that none of the mailbox applications which India had received and published in the Gazette of India had been challenged in court.

⁵⁸ In response to a question from the Panel as to whether general Indian law allowed for the possibility of administrative decisions (including decisions not to act in particular circumstances) to be challenged in an administrative tribunal or other judicial body, in particular on grounds of inconsistency with a statutory provision, India informed the Panel that Article 226 of the Indian Constitution has been interpreted as giving the High Court the power of judicial legislative and administrative action. This includes the power to review administrative regulations or instructions on the ground that they violate statutory provisions. The High Court is the highest court in each State and is the intermediate appellate court in India's unified system of courts. In response to a follow-up question from the Panel, India provided more detailed information to the Panel on this review possibility. In exercising this authority, the main principles guiding the High Court are:

- According to a well-established principle of Indian administrative law, administrative instructions cannot be issued on any matter which is the subject of legislation. Wherever there is no statutory provision or where there are gaps in any enactment, the same can be provided or bridged by issue of necessary administrative instructions. The only rider on the authority to issue such administrative instructions is that there should be no statutory provision either expressly or by necessary implications to the contrary.
- Administrative acts done in the purported exercise of a statutory power can be invalidated by the Court, if constitutional limits or statutory powers have been transgressed.
- Judicial review in respect of administrative acts not done in the purported exercise of a statutory power, but in the exercise of the executive power, is directed towards its manner and mode, and not the administrative decision taken on merits. The standard for this review is whether the exercise of the discretionary power has been "unfair", "arbitrary" or "malafide".
- Neither will the Supreme Court or High Courts interfere or adjudicate upon government policy matters, unless fundamental principles of law have been violated.

⁵⁹ In response to a question from the Panel, India informed the Panel that, to demonstrate a proper "cause of action" in a legal challenge to the validity of India's mailbox under Article 226 of the Constitution, a competitor of a mailbox applicant must demonstrate not only that his legal right has been violated as a result of the establishment of the mailbox but also must make a showing of actual damage suffered as a result of the mailbox. A mailbox application would result in the grant of a patent or exclusive marketing right ("EMR") only if and when: (i) India amended the Patents Act to provide for the grant of product patents for pharmaceutical and agricultural chemical products under its Patents Act; and (ii) the mailbox application satisfied any relevant criteria for the grant of a patent or EMR, as the case may be, under the amended Patents Act. Until these conditions were satisfied, no competitor of a mailbox applicant will be able to demonstrate this merely because a mailbox application for a competing product has been received for the grant of a patent or an EMR in the future. Accordingly, an Indian court would reject his legal challenge to India's mailbox on the ground that he cannot demonstrate that he has suffered actual damage.

- The EC had not demonstrated that mailbox applications would not survive legal challenge under the Patents Act.

- Interpretation of domestic laws would inevitably be uncertain until a competent court had spoken. How could a Member in the meantime demonstrate that its authorities were acting on the basis of the correct interpretation? Since mailbox applications could not be challenged in Indian courts, how could India under these circumstances ever rebut a presumption that mailbox applications would not survive challenge in Indian courts?

4.18 Finally, India argued that applications had been received, and continued to be received, by the Patent Office and stored for future action. They were recorded and published in the Gazette of India; therefore, the necessary facts were there to determine the novelty and priority of the inventions in question in accordance with the dates of these applications and to decide on the grant of patents on them when their patentability would be due in accordance with Article 70.8(b) and (c).

- Between 1 January 1995 and 31 January 1998, India had received 2,212 mailbox applications, not one of which had been rejected or invalidated. All mailbox applications - including their serial numbers, dates, name of applicant and the titles - were advertised in the Gazette of India. This advertisement was made irrespective of whether the product for which the patent was sought was patentable. There was nothing in Indian law that prevented the Patent Office from receiving and storing the applications for future action under Article 70.8 of the TRIPS Agreement, and the record of the applications advertised in the Gazette of India could obviously not be erased. The registration, dating, storage and publication of these applications could therefore not be litigated out of existence. There was consequently nothing that could possibly prevent India, when patents were due in accordance with subparagraphs (b) and (c) of Article 70.8, from deciding 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.

4.19 The European Communities and their member States were of the view that India had not advanced any new elements that had not yet been considered in the earlier dispute or that were otherwise relevant for the resolution of the present dispute.

- India basically claimed that Section 5 of its Patents Act prohibited the grant of a patent for pharmaceutical or agricultural chemical products without however prohibiting the filing of an application for such products. India furthermore claimed that, therefore, the filing of an application for such products was possible under Section 6 and, thus, constituted a sufficient "means" for the filing of an application under Article 70.8(a) of the TRIPS Agreement. These arguments were not new, since these provisions of the Indian Patents Act had been submitted to the Panel in the earlier dispute and had not been amended since. They were not relevant, because Section 15(2) of the Indian Patents Act, which was of mandatory nature, instructed the Controller to refuse an application for an invention that was not patentable under the Act. The possibility of the filing of an application that must be refused under a mandatory provision of the domestic legislation of a WTO Member did not constitute an adequate "means" for the filing of an application under Article 70.8(a) of the TRIPS Agreement.

- India moreover claimed that under Section 12(1) of the Indian Patents Act, no time was specified for the referral of an application to an examiner. Therefore, in India's view, there was no conflict between the administrative instructions of the Indian executive authorities to the Controller of Patents and Section 12(1) of the Patents Act. This question

had been extensively discussed in the earlier dispute, in particular in paragraph 7.35 of the Panel report in the earlier dispute and in paragraph 69 of the Appellate Body report in that dispute. The EC believed that everything necessary had already been said with regard to this question. Given this discussion, the EC could not agree with India that the terms of its Patents Act were unclear as to the action to be taken by the Controller once an application had been filed or with regard to the timing of such action. Under these circumstances, the EC could not see the relevance of the statement of Justice G.P. Singh quoted by India in the context of the present dispute. The same went with regard to the argument that statutory time-limits were not mandatory since it was in apparent contradiction with the terms of the Indian Patents Act, which did not allow any delay in the referral of an application to an examiner. In other words, Section 12(1) of the Indian Patents Act simply did not contain a time-limit, since it provided for immediate action; the section started with the word "when", which did not provide for any delay. Again, the EC failed to see a lacuna that could be filled in by administrative instructions.

- The statement made by the Indian Government before the Indian Parliament on 2 August 1996 had already been mentioned in the earlier dispute. Whatever declarations the Indian Government might have made before the Parliament or elsewhere, they did not change the fact that the Indian Patents Act contained in Section 12(1) a mandatory provision requiring the Controller to refer any application to an examiner "[w]hen the complete specification has been filed in respect of an application for a patent". Moreover, as already stated before, Section 15(2) of the Indian Patents Act required the Controller to refuse an application if it appeared to him that the invention claimed in the specification was not patentable under the Act. Both provisions contained the auxiliary "shall", which did not allow the exercise of any discretion by the Controller.

- It was obvious that the Indian authorities themselves had come to the conclusion that the existing Patents Act of 1970 did not suffice to bring India's domestic legislation into conformity with its obligations under Article 70.8(a) of the TRIPS Agreement when they had decided at the end of 1994 to promulgate the Patents (Amendment) Ordinance, 1994, in order to remedy the apparent shortcomings of the existing Patents Act of 1970. For the same reason, India had submitted a Bill to its Parliament aiming at an amendment of the Patents Act of 1970. India's assertion in the present dispute that the Patents Act of 1970 was in compliance with its obligations under Article 70.8 of the TRIPS Agreement, although the proposed amendment had never been enacted, was simply not credible.

- India had also referred to the principles of standing and ripeness which would prevent a challenge in India's courts with a view to force the Controller of Patents to refer a mailbox application to an examiner for examination. Even if this were correct, this did not exclude the possibility of other forms of private disputes concerning the novelty and the priority of a mailbox filing. In particular, the EC could not see any reason why litigation between two or more applicants about the time or the formalities of a filing under Article 70.8(a) of the TRIPS Agreement could not lead to litigation before an Indian court at any time before the year 2005. A dispute on the relevant filing date could, in particular, arise before the year 2005 as a preliminary issue in the context of a court procedure regarding the granting of an exclusive marketing right under Article 70.9 of the TRIPS Agreement. In such court procedures, the fact that there was presently no legal basis in India for the filing of a mailbox application made it impossible, or at least unnecessarily difficult, for an applicant to defend his position in the Indian courts. The fact that so far no mailbox application had been challenged in the Indian courts was in this context irrelevant, since it might be based precisely on the fragile status of such applications in India. Moreover, India did not even contest that

such disputes could arise after the year 2005 and would then have to be judged under the law applicable at the time of filing. In other words, the legal uncertainty created by the present Indian legal situation would be carried forward into the future.

4.20 India replied that, by arguing that India's interpretation of its own laws was incorrect and inviting the Panel to adopt another interpretation of India's Patents Act, the EC again failed to address the basic issue before the Panel.

- According to the consistent jurisprudence of international tribunals, including the Appellate Body, Indian law could not be interpreted by this Panel, but must be treated as a fact. It was therefore not relevant for this Panel whether India had acted consistently with its own laws. The Panel was bound to presume that this was so because only Indian courts could decide that question. What was relevant for this Panel was whether the measures which India had taken were consistent with the TRIPS Agreement, i.e. whether India had applied its laws in such a manner as to provide a means of filing mailbox applications.

- The EC did not contest that India received, published and stored mailbox applications and that all such applications had remained unchallenged. Moreover, the EC confirmed that about one thousand EC companies had made use of India's mailbox system. The EC thus did not deny that India had in fact provided a means of filing patent applications for pharmaceutical and agricultural chemical products.

- The EC's only claim was that this means of filing was inconsistent with Indian law and that, because of the resulting legal uncertainty, the means of filing was also inconsistent with India's obligation under Article 70.8 of the TRIPS Agreement. It was thus perfectly clear from the EC's argumentation that the Panel could make the requested ruling on the alleged inconsistency with the TRIPS Agreement only if it first found the mailbox system to be inconsistent with Indian law. That finding, however, this Panel was not authorized to make.

Article 70.9 of the TRIPS Agreement

4.21 The European Communities and their member States argued that, in view of the fact that the Panel and the Appellate Body had already found in the earlier dispute that the present Indian domestic régime concerning the patent protection of pharmaceutical and agricultural chemical products was inconsistent with India's obligations under Article 70.9 of the TRIPS Agreement, it followed pursuant to Article 3.8 of the DSU that there was a presumption according to which this breach of the relevant WTO rules by India had an adverse affect on the European Communities and their member States as the other party to this dispute. In these circumstances, the burden was on India to rebut the presumption according to which India's present domestic régime for the patent protection of pharmaceutical and agricultural chemical products nullified or impaired benefits accruing to the European Communities and their member States under Article 70.9 of the TRIPS Agreement.

4.22 India argued that the interpretation of Article 70.9 of the TRIPS Agreement by the Panel in the earlier case had not been based on Article 31 of the Vienna Convention on the Law of Treaties and the Panel had incorrectly interpreted Article 70.9 as requiring implementation of its provisions before specified events had occurred.

The terms of Article 70.9

- 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 in accordance with Article 70.8(a) only after the following events had occurred:

- (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.

- There was nothing in the text of Article 70.9 that set out the obligation to make a "system" for the grant of exclusive marketing rights generally available in the domestic law before the events listed in this provision had occurred. The terms of Article 70.9 stipulated that exclusive marketing rights "shall be granted" to specified products. The Panel, however, had interpreted this provision as if it read: "the competent authorities of the Members shall have the authority to grant exclusive marketing rights", i.e. whether or not such rights had to be granted.

- India had not denied the grant of exclusive marketing rights to any product meeting the above conditions. The Panel had faced the same fact in the earlier dispute but had nevertheless concluded that India did not comply with its obligations under Article 70.9 of the TRIPS Agreement because it had failed to establish under its domestic law "a system" that enabled the executive branch of India to grant exclusive marketing rights as of the entry into force of the WTO Agreement.⁶⁰

Context

- That the previous panel had expanded the meaning of Article 70.9 beyond its terms became obvious when the text of Article 70.9 was read in its context. There were many provisions in the TRIPS Agreement which explicitly obliged Members to change their domestic law to permit their authorities to take certain action in favour of interested parties. Thus, according to Articles 42-48 of the TRIPS Agreement, the judicial authorities of Members "shall have the authority" to grant certain rights. Article 51 obliged Members to "adopt procedures" to enable right holders to prevent the release of counterfeited or pirated products from customs. Article 39.2 required Members to give natural and legal persons "the possibility of preventing" the disclosure of information. According to Article 25.1, "Members shall provide for the protection" of certain industrial designs and Article 22.2 obliged Members to "provide the legal means for interested parties to prevent" certain misuses of geographical indications. The terms of all these provisions of the TRIPS Agreement clearly created an obligation to empower the executive authorities to take specified actions before the need to take such actions actually arose. The question for the Panel therefore was: if the drafters had intended Article 70.9 to entail the obligation to create in the domestic law the legal authority for the grant of exclusive marketing rights, why had they not repeated the wording used in one of the numerous provisions that explicitly provided for the creation of the authority to grant rights to interested parties?

⁶⁰ Document WT/DS50/R, paragraph 8.1

- A comparison of the terms of Article 70.9 with those of Article 27 according to which "patents shall be available" for inventions was also revealing. The ordinary meaning of "available" was "obtainable". Article 27 thus clearly created the obligation to make patents obtainable under domestic law before any application for a patent must be accepted. Article 70.9, by contrast, merely stipulated that "exclusive marketing rights shall be granted" to specific products after the occurrence of specified events. There was nothing in these terms that suggested that such rights must be obtainable in the domestic law.
- The Panel had examined Article 70.9 only in the context of Article 27, not any of the other provisions cited above. The relevance of the distinction between "shall be available" and "shall be granted" in the wording of these related provisions was tersely dismissed by the Panel as follows: "The implementation of Article 70.9 requires a system under which applications for exclusive marketing rights can be made"⁶¹ because "an exclusive marketing right cannot be 'granted' in a specific case unless it is 'available' in the first place".⁶²
- The Panel was of course factually correct when pointing out that, after the events set out in Article 70.9 had occurred with respect to a particular product, the distinction between "shall be available" and "shall be granted" lost its practical relevance because a change in domestic law might then in any case be required. However, this begged the question that was before the Panel, namely: does a Member have to make exclusive marketing rights available in its domestic legislation before these events have occurred? It was simply not logical to conclude that exclusive marketing rights must be made available in the domestic legislation before these events because such availability was in any case necessary once the events had occurred.
- There were numerous transitional provisions throughout the various WTO agreements that required action at some point in the future, either when a date had arrived or an event had occurred. Tariff concessions must be reduced in stages.⁶³ Import restrictions on textiles must be removed after a ten-year transitional period.⁶⁴ Developing countries must phase out export subsidies for any product that had reached a certain share of world trade.⁶⁵ These were all obligations that were, just like those under Article 70.8 and 70.9 of the TRIPS Agreement, contingent upon a date or event. If the logic applied by the Panel to Article 70.9 was correct, then all the transitional provisions under the WTO Agreement imposing an obligation as from a future date or event would have to be interpreted to comprise the additional obligation to change the domestic law in anticipation of the future date or event. This was, however, obviously not intended by any of these transitional provisions.
- The Panel, though repeatedly urged to do so by India, had not examined the context of Article 70.9 fully. No reference was made in the Panel's findings to, for instance, Articles 42-48 of the TRIPS Agreement, according to which the judicial authorities of

⁶¹ Document WT/DS50/R, paragraph 7.56

⁶² Document WT/DS50/R, footnote 112

⁶³ Paragraph 2 of the Marrakesh Protocol to the GATT 1994

⁶⁴ Article 9 of the Agreement on Textiles and Clothing

⁶⁵ Article 27.5 and 27.6 of the Agreement on Subsidies and Countervailing Measures ("SCM Agreement")

Members "shall have the authority" to grant certain rights and which thus clearly expressed the notion that the Panel had discovered in Article 70.9. The Panel's failure to examine this central interpretative issue was impermissible. The question therefore remained: if the drafters had intended Article 70.9 to entail the obligation to create in the domestic law the legal authority for the grant of exclusive marketing rights, why had they not repeated the wording used in one of the numerous provisions that explicitly provided for the creation of authority to grant rights?

Object and Purpose

- The Panel was of the view that the purpose of Article 70.9 was to oblige the developing countries concerned to establish as of the entry into force of the WTO Agreement in their domestic law the authority to grant exclusive marketing rights. However, this had not been, and could not possibly have been, the intention of the drafters. The products covered by Article 70.9 of the TRIPS Agreement were mainly pharmaceutical and agricultural chemical products. It took considerable time - often more than ten years - to obtain a patent for such products and the necessary marketing approvals, first in the country of origin and then in the country in which an exclusive marketing right was sought. There was therefore no need to require immediate legislative action and there could therefore not have been cause for urgency in the minds of the developed countries.

- Moreover, Article 70.9 was part of the transitional arrangements of the TRIPS Agreement whose very function was to enable developing countries to postpone legislative changes. Patent protection for pharmaceutical and agricultural chemical products was the most sensitive TRIPS issue in many developing countries. The Panel's interpretation of Article 70.9 had the absurd consequence that the transitional arrangements would allow developing countries to postpone legislative changes in all fields of technology except in the most sensitive ones. Neither developed countries nor developing countries could, therefore, realistically be presumed to have sought an immediate change of domestic law to provide for exclusive marketing rights when negotiating the text of Article 70.9. When the drafters had agreed to stipulate that exclusive marketing rights "shall be granted" after certain events had occurred rather than stipulating that they "shall be made available" immediately, they had clearly meant that legal action ensuring the grant of such rights would be required only in respect of products that had completed the five time-consuming procedural steps listed in Article 70.9.

4.23 India further argued that the Panel had, in the previous case, interpreted Article 70.9 on the basis of the concept of the predictability of conditions of competition and, although it had rejected this concept as a basis for interpreting the TRIPS Agreement, the Appellate Body had failed to reverse the Panel's interpretation.

The concept of predictability of conditions of competition did not justify an interpretation of Article 70.9 according to which there must be a mechanism in place to provide for the grant of exclusive marketing rights before such rights were due

- The Panel claimed that it had interpreted the TRIPS Agreement in accordance with the customary rules of treaty interpretation.⁶⁶ In fact, however, the Panel had neither based its interpretation on the terms of Article 70.9, nor had it taken into account the context and the

⁶⁶ Document WT/DS50/R, paragraph 7.60

transitional nature and purpose of this provision. Instead, it had based its expansive approach essentially on the idea that the function of Article 70.9 was to create predictability as to the future conditions of competition. The Panel had expressed this idea as follows:

"The protection of legitimate expectations is central to creating security and predictability in the multilateral trading system ... When interpreting 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 ... laying down the principle of the protection of conditions of competition from multilateral trade agreements."⁶⁷

- In justifying its broad interpretation of Article 70.9, the Panel had referred to its findings on Article 70.8(a) where it had found that the achievement of "security and predictability ... is one of the central goals of the dispute settlement mechanism" and that the function of the TRIPS Agreement was to create "the predictability needed to plan future trade". If a system for the grant of exclusive marketing rights was non-existent, so the Panel had argued, there was a lack of legal security that was likely to discourage applications for exclusive marketing rights.⁶⁸ The notion of predictability of conditions of competition had thus been the logical foundation of the Panel's decision to turn an obligation which, by its terms, only required actions after certain events had occurred into an obligation to take action immediately.

- In examining India's appeal from the report of the Panel, the Appellate Body had rejected the Panel's reliance on the notion of conditions of competition as a means to expand the obligations under the TRIPS Agreement.⁶⁹ It had ruled:

"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.⁷⁰ At that point in its reasoning, the

⁶⁷ Document WT/DS50/R, paragraph 7.22

⁶⁸ See the references to paragraphs 7.30 and 7.41 in paragraph 7.62 of document WT/DS50/R.

⁶⁹ "The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself." (See document WT/DS50/AB/R, paragraph 45.)

⁷⁰ See, for example, the report of the Working Party on Brazilian Internal Taxes, adopted 30 June 1949, BISD II/181, paragraph 16; Panel Report, United States - Taxes on Petroleum and Certain Imported Substances, adopted 17 June 1987, BISD 34S/136, paragraph 5.1.9; Panel Report, Canada - Administration of the Foreign Investment Review Act, adopted 7 February 1984, BISD 30S/140, paragraph 6.6; Panel Report, Japanese Measures on Imports of Leather, adopted 15/16 May 1984, BISD 31S/94, paragraph 55; Panel Report, Japan - Customs Duties, Taxes and Labeling Practices on Imported Wines and Alcoholic Beverages, adopted 10 November 1987, BISD 34S/83, paragraph 5.11; Panel Report, European Economic Community - Restrictions on Imports of Apples, adopted 22 June 1989, BISD 36S/135, paragraph 5.25; and Panel Report, United States - Measures Affecting the Importation, Internal Sale and Use of Tobacco, adopted 4 October 1994, DS44/R, paragraph 99.

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.

[...]

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

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

"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."⁷¹

"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.

"In United States - Standards for Reformulated and Conventional Gasoline⁷², 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."⁷³

⁷¹ Document WT/DS50/R, paragraph 7.18

⁷² Document WT/DS2/AB/R, adopted 20 May 1996, pages 16-17

⁷³ Document WT/DS50/AB/R, paragraphs 40 and 43

The Appellate Body had failed to reverse the interpretation of Article 70.9 by the Panel even though that interpretation had been based on the notion of predictability of conditions of competition which the Appellate Body had rejected as a basis for interpreting the TRIPS Agreement

- As to Article 70.9 of the TRIPS Agreement, India had submitted the following legal issues to the Appellate Body in accordance with Article 17.6 of the DSU:

"India respectfully requests the Appellate Body to address the following issues:

"- Is the interpretation of Article 70.9 made by the Panel consistent with the ordinary meaning to be given to the terms of Article 70.9 in their context, in particular the context of other provisions which - unlike Article 70.9 - explicitly provide for the creation of the authority to grant rights, such as Articles 42-48?

"- If so, can it be reasonably assumed that the object and purpose of Article 70.9 was the creation of an obligation to provide for the availability of exclusive marketing rights in the domestic law as from the date of entry into force of the WTO Agreement given the fact that it can take ten years or more to complete the procedural steps required to obtain an exclusive marketing right and that Article 70.9 forms part of a series of transitional provisions designed to enable developing countries to postpone legislative actions?

"- If not, does the principle of predictability of competitive relationships justify the Panel's interpretation of Article 70.9?

"- If so, does the principle of predictability of competitive relationships imply that all transitional obligations applicable as from a future date or event entail the immediate obligation to empower the executive authority to meet those obligations? If not, what justifies the creation of this obligation only in respect of Article 70.9?"

- Article 17.12 of the DSU stipulated that "the Appellate Body shall address each of the issues raised in accordance with paragraph 6 during the appellate proceeding". The Appellate Body had carried out this task by making the following findings:

"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.""

"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.

"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.

"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.

"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."

- The Appellate Body's ruling did not contain a single reference to India's extensive argumentation based on the text, context and objective of Article 70.9. Having rejected the notion of predictability of conditions of competition as a basis for expanding the obligations under the TRIPS Agreement beyond its terms, it would have been logical for the Appellate Body to reverse the Panel's ruling on Article 70.9 of the TRIPS Agreement in the previous case because it was founded on that very notion. Instead, the Appellate Body had made findings that were either unexplained or concerned matters which were not in dispute, thereby denying India its procedural rights under Article 17.12 of the DSU.

- The Appellate Body did not explain how Article XVI:4 of the WTO Agreement could determine the scope of the obligations under Article 70.9 of the TRIPS Agreement. Article XVI:4 merely stated how the obligations under the WTO agreements were to be implemented and was therefore relevant only once it had been determined that there was an obligation under one of the WTO agreements that required implementation. The issue before the Appellate Body had been whether there was such an obligation. India had pointed out that there were numerous transitional provisions throughout the various WTO agreements that required action at some point in the future, either when a date had arrived or an event had occurred. If Article XVI:4 of the WTO Agreement was relevant for the interpretation of Article 70.9 of the TRIPS Agreement, then all transitional provisions under the WTO Agreement imposing an obligation as from a future date or event would have to be interpreted to comprise the additional obligation to change the domestic law in anticipation of the future date or event. This was however obviously not intended by any of these transitional provisions. India had specifically requested the Appellate Body to address this issue but the Appellate Body had failed to do so.

- Contrary to what the Appellate Body suggested, the parties to the previous dispute agreed that Article 70.9 entered into effect on the date of entry into force of the WTO Agreement. However, India had claimed that Article 70.9 set out an obligation to accord exclusive marketing rights that was triggered by events which had not yet occurred. At issue before the Appellate Body had thus been the content of Article 70.9, not the date of its entry into force. When the Appellate Body wrote that "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" it turned the issue of content (on which the parties disagreed) into a question of entry into force (on which they agreed).

- From the standpoint of developing country Members, it was distressing that the Appellate Body had not considered it necessary to deal with India's argument that the Panel's interpretation of Article 70.9 had 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. It was also regrettable that the Appellate Body had not taken into account that the Panel's ruling ignored the implicit option available in the TRIPS Agreement to developing countries to cut short the transitional period, if they so chose, and provide for product patents even before the end of the transitional period instead of having to accept the obligation of providing exclusive marketing rights.

4.24 According to India, the Panel faced conflicting signals from the Appellate Body. The Panel could not follow in the present dispute the reasoning in the previous dispute and base its interpretation of Article 70.9 on the notion of predictability of conditions of competition without risking that it would be castigated for misapplying Article 31 of the Vienna Convention and failing to examine the words of the treaty to determine the intention of the parties. However, if the Panel based its interpretation exclusively on the language of Article 70.9 itself, it was bound to arrive at a conclusion that was different from the one reached by the Appellate Body in the previous case. India requested the Panel to resolve this dilemma in the light of the following two rulings of the Appellate Body. The first was:

"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.

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

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

"Furthermore, Article 19.2 of the DSU provides:

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

"These provisions speak for themselves. Unquestionably, both panels and the Appellate Body are bound by them."⁷⁴

The second ruling of the Appellate Body that the Panel should take into account was the following:

"We do not believe that the CONTRACTING PARTIES, in deciding to adopt a panel report, intended that their decision would constitute a definitive interpretation of the relevant provisions of the GATT 1947. Nor do we believe that this is contemplated under GATT 1994. There is a specific cause for this conclusion in the WTO Agreement. Article IX:2 of the WTO Agreement provides: "The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements"... . The fact that such an "exclusive" authority in interpreting the treaty has been established so specifically in the WTO Agreement is reason enough to conclude that such authority does not exist by implication or by inadvertence elsewhere."⁷⁵

It followed from the above that the Panel was strictly bound by the principles of interpretation referred to in Article 3.2 of the DSU, but not by the rulings of panels and the Appellate Body in a single instance and therefore had no option but to base its interpretation of Article 70.9 of the TRIPS Agreement exclusively on Article 31 of the Vienna Convention.

4.25 The European Communities and their member States were of the view that India had not advanced any new elements that had not yet been considered in the earlier dispute or that were otherwise relevant for the resolution of the present dispute.

- India's debate on the implementation of Article 70.9 of the TRIPS Agreement was a replica of its arguments before the Panel and the Appellate Body in the earlier dispute (WT/DS50), as was apparent from the extensive quotations of portions of the Panel and Appellate Body reports in that dispute. The EC was unable to discover any new arguments in India's discussion and therefore referred the Panel to its report and that of the Appellate Body in the earlier dispute. The EC did not believe that the arguments that India was submitting in this context added anything to the debate that had already taken place in the earlier dispute which was equally relevant for the present dispute. Furthermore, no reasonable doubt could exist that the filing date and the validity of the filing could be fundamental issues in the context of exclusive marketing rights granted under Article 70.9 of the TRIPS Agreement in a litigation before an Indian court at any time prior to the year 2005.

- As regards EC companies which were ready to apply for exclusive marketing rights in India, the EC provided to the Panel a copy of a fax, dated 28 April 1998, which it had received from Dr. Alan Hesketh, Manager, Global Intellectual Property, Glaxo Wellcome.⁷⁶

4.26 Commenting on the views expressed by the European Communities and their member States, India noted that the EC had not claimed that India had denied any exclusive marketing rights to European companies and had not refuted India's argument that the terms of Article 70.9 did not require

⁷⁴ Document WT/DS50/AB/R, paragraph 47

⁷⁵ Appellate Body Report on Japan - Taxes on Alcoholic Beverages, Section E (WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R)

⁷⁶ See Annex 4 below.

the establishment of a system for the grant of exclusive marketing rights, but merely required the grant of such rights to particular products meeting specified conditions. India further noted that the EC refused to address the arguments presented by India.

V. ARGUMENTS PRESENTED BY THIRD PARTY

UNITED STATES

Procedural history of the related dispute

5.1 The United States argued in its third party submission that the precise measures and provisions of the WTO Agreement at issue in this dispute had been the subject of a previous WTO dispute settlement proceeding that had concluded very recently. This did not mean that the European Communities and their member States did not have the right to bring this complaint; the DSU did not deny the EC the right to do so. However, the Appellate Body had thoroughly analyzed the legal issues in the case and it was neither necessary nor appropriate for the Panel to repeat that work. The Panel should consider the arguments of the parties, but be guided by the Appellate Body's recent interpretation of the obligations at issue. In accordance with this approach, the Panel should find that India had failed to comply with Article 70.8 and 70.9 of the TRIPS Agreement and recommend that India amend its law to comply with these obligations.

5.2 The United States, describing the procedural history of the earlier dispute (WT/DS50 - United States' complaint against India regarding patent protection for pharmaceuticals and agricultural chemicals), said that the Panel in that dispute had been established by the DSB on 20 November 1996 and had issued its report on 5 September 1997.⁷⁷ In its report, the Panel had found that India had failed to comply with Articles 70.8, 70.9 and 63 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). India had appealed these findings to the Appellate Body, which had upheld the Panel's conclusions with respect to Article 70.8 and 70.9.⁷⁸ The Panel and the Appellate Body had considered India's arguments with respect to the obligations in Article 70.8 and 70.9 of the TRIPS Agreement and, after analysing the text, context, object and purpose of Article 70.8, concluded that the provision required the establishment of a mailbox system that provided a "sound legal basis" for filing product patent applications for pharmaceuticals and agricultural chemicals.⁷⁹ Both the Panel and the Appellate Body had examined the evidence presented regarding India's Patents Act (1970)⁸⁰ and then concluded that India had failed to comply with Article 70.8 of the TRIPS Agreement.⁸¹ With respect to Article 70.9, the Panel and the Appellate Body had determined that this provision required the establishment of a system for granting exclusive marketing rights as of 1 January 1995. By India's own admission, it had not established such a system. Consequently, the Panel and the Appellate Body had found that India had failed to comply with Article 70.9 of the TRIPS Agreement.⁸² The DSB had adopted the Panel and Appellate

⁷⁷ Document WT/DS50/R

⁷⁸ Document WT/DS50/AB/R

⁷⁹ Document WT/DS50/AB/R, paragraph 58; document WT/DS50/R, paragraph 7.28

⁸⁰ Document WT/DS50/AB/R, paragraph 69; document WT/DS50/R, paragraph 7.35

⁸¹ Document WT/DS50/AB/R, paragraph 97; document WT/DS50/R, paragraph 8.1

⁸² Document WT/DS50/AB/R, paragraph 97; document WT/DS50/R, paragraph 8.1

Body reports on 16 January 1998. On 13 February 1998, India had indicated its intention to implement the DSB's recommendations and rulings. India and the United States had not reached an agreement regarding the time in which India would implement these recommendations and rulings; that issue might have to be decided by arbitration in accordance with Article 21.3 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). India thus had not yet amended its law to comply with its obligations under Article 70.8 and 70.9 of the TRIPS Agreement and had not argued in this proceeding that the situation was otherwise.

Under Article 10.4 of the DSU, WTO Members were entitled to bring complaints regarding matters that had been the subject of a previous panel proceeding

5.3 Commenting on India's argument that the Panel should dismiss the EC's complaint on the basis of Articles 9.1 and 10.4 of the DSU, the United States said that these provisions did not support dismissal of the EC's complaint, but rather indicated a pronounced concern for safeguarding the rights of multiple complainants and third parties.

- The text of Article 10.4 did not support India's argument that third parties must join an initial panel proceeding whenever possible. Article 10.4 specifically provided for the possibility of a second panel being established to examine a complaint based on a measure already examined by a previous panel. Article 10.4 referred to "third parties". By definition, a dispute involving a complaint by a third party would be a successive dispute. Under this provision, successive disputes should proceed in accordance with "normal dispute settlement procedures". Nothing in Article 10.4 implied that recourse to normal dispute settlement procedures was limited to third parties that had not been able to present their complaint jointly with the initial complainant.

- As India acknowledged in its first written submission, there might be many reasons why a WTO Member might not initially join a particular dispute settlement proceeding. Regardless of the reason, however, Article 10.4 of the DSU did not deny such a Member the right to resort to the dispute settlement process. In fact, the drafters of Article 10.4 had anticipated situations such as this - where a violation of a WTO agreement had already been established, but nullification or impairment of benefits accruing to a third party had not yet been established - and Article 10.4 was intended to address them. This was the sole purpose of this panel proceeding: to establish the nullification or impairment of benefits accruing to the EC.

- Article 9 of the DSU was entitled "Procedures for Multiple Complainants". Like Article 10.4, the text of Article 9 did not support the mandatory joinder rule suggested by India. Article 9 did not address potential complainants or whether there were any circumstances in which Members must join a dispute as a complainant. It only assumed that there would be situations with multiple complainants and provided procedures to govern such situations.

- There was no support in either the text or negotiating history of the DSU for India's argument that the EC's complaint should be dismissed because it had not been brought at the same time as the United States' complaint. India's interpretation had far-reaching consequences and could result in the denial to a WTO Member of its rights under Articles 10.4 and 22.2 of the DSU. Such a result must be avoided, in accordance with Articles 3.2 and 19.2 of the DSU, which provided that the recommendations or rulings of panels and the Appellate Body could not diminish the rights of WTO Members.

- For the purpose of clarifying the status of the present dispute, the Panel should issue a preliminary ruling rejecting India's request that the complaint of the European Communities and their member States be dismissed as untimely. The Panel should examine the pending complaint under normal dispute settlement procedures.

In examining the complaint brought by the EC, the Panel should apply the interpretation of Article 70.8 and 70.9 of the TRIPS Agreement of the Panel and the Appellate Body in the earlier case

5.4 The United States supported the view of the EC that it was not necessary or appropriate to repeat all of the legal arguments made in the earlier dispute (WT/DS50) in the context of the present proceedings. India had failed to comply with Article 70.8 and 70.9 of the TRIPS Agreement. The Appellate Body had already analysed the obligations in Article 70.8 and 70.9 and determined that India had failed to comply with those obligations. It was undisputed that India had not amended its Patents Act since the Appellate Body had issued its ruling three months ago.

- Under Article 10.4 of the DSU, the Panel should proceed in accordance with "normal dispute settlement procedures". Under normal procedures, it was not necessary for the Panel to approach the legal issues in this case without reference to the work in the earlier dispute. WTO panels could and should be guided by the legal interpretations developed in the context of previous panel proceedings. This was particularly important in a case such as the present one, in which precisely the same measures had recently been the subject of a separate panel proceeding. The relevance of this fact was supported by Article 10.4 of the DSU, which provided that a subsequent dispute regarding a measure should be referred to the "original panel" that had examined the measure. If the original panel proceedings had been essentially irrelevant to the subsequent panel proceedings, there would have been no reason to refer the successive dispute back to the original panel.

- India appeared to seek an entirely redundant proceeding. Despite India's obligation under Article 17.14 of the DSU to accept the Appellate Body's report in the earlier case unconditionally, India's submission gratuitously disparaged the work of the Appellate Body, calling the report "internally inconsistent", "contradictory", "distressing" and "regrettable". In its first written submission, India proceeded to re-argue many of the same points which it had made in the prior appellate proceeding and which the Appellate Body had rejected. India had reiterated these arguments in its criticism of the Appellate Body's report during the DSB meeting on 16 January 1998, when the report had been adopted. These same arguments had now reappeared again.

- India represented in its first written submission that it was presenting "new arguments and new facts" to the Panel and that it was not seeking "a further appeal" from the findings of the Appellate Body or "a rehearing of the previous case". These statements were refuted by the text of India's own submission. The basic arguments presented in the submission were not new and, indeed, much of the submission reiterated in *hac verba* the arguments that India had presented to the Appellate Body in the earlier case. For example, with respect to Article 70.8, pages 23-24 and 28-29 of India's first written submission to this Panel repeated, word-for-word, arguments set out in pages 10-12 and 13-14 of India's submission to the Appellate Body in the earlier case. Regarding Article 70.9, pages 36-39 also appeared to have been copied verbatim from India's appellate submission, pages 18-22. At the third party meeting, the United States added that, moreover, India did not argue that it had modified its patent régime since the Appellate Body's ruling and that, in that situation, the

Panel should be guided by the Appellate Body's decision, not by allegedly new arguments about the same patent régime.

- India should not be permitted to reopen legal issues that had been conclusively determined by a panel and the Appellate Body. Such a result would invite repetitive litigation. Defendants that prevailed on some or all of the issues in a case could find themselves compelled to re-litigate those issues over and over again until they lost. Article 10.4 had been intended to prevent this scenario and reflected the desire of the drafters for finality in dispute settlement proceedings. The drafters had wanted to avoid giving complainants or defendants an incentive to re-litigate disputes to see if different panels would produce different results. If such "panel shopping" did produce different results, the effect on the dispute settlement system would be profoundly destabilizing.

- An important function of the WTO dispute settlement system was "to clarify the existing provisions of [covered] agreements in accordance with customary rules of interpretation of public international law".⁸³ The Appellate Body had recently clarified the obligations of Article 70.8 and 70.9 of the TRIPS Agreement. It had not found India's arguments convincing the first time and the Panel should be guided by its conclusions.

- The WTO dispute settlement system could not function effectively without consistent panel judgments. The United States had a strong interest in ensuring that these panel proceedings did not prejudice its rights as determined by the Appellate Body. Inconsistent interpretations of India's TRIPS obligations would also prejudice the rights of other WTO Members and make it impossible to apply the most-favoured-nation obligation in a meaningful way. Without consistent judgments, WTO Members would find little guidance in the legal interpretations developed by dispute settlement panels and the Appellate Body. The role of the dispute settlement system was greatly diminished and the system could not fulfill its purpose: to serve as a "central element in providing security and predictability to the multilateral trading system".⁸⁴

Article 3.8 of the DSU

5.5 Commenting on the approach that the Panel should take in the present dispute, the United States expressed the view that the Panel should presume that India's non-compliance with Article 70.8 and 70.9 had had an adverse impact on right holders in the European Communities, but that India was entitled to present evidence to rebut that presumption. Article 3.8 of the DSU provided that "In cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment. This means that there is normally a presumption that a breach of the rules has an adverse impact on other Members parties to that covered agreement, and in such cases, it shall be up to the Member against whom the complaint has been brought to rebut the charge". According to the analysis of the Appellate Body, India's legal regime did not comply with Article 70.8 and 70.9 of the TRIPS Agreement. This Panel should therefore follow the Appellate Body's analysis and reach the same conclusion. If the Panel reached

⁸³ DSU, Article 3.2

⁸⁴ DSU, Article 3.2 (emphasis added)

this conclusion, under Article 3.8 of the DSU, the EC was entitled to a presumption that India's breach of the TRIPS Agreement had had an adverse impact on the nationals of its member States.⁸⁵

5.6 Of course, this presumption was a rebuttable one and the Panel should consider any evidence presented by India that its failure to comply with Article 70.8 and 70.9 had not nullified or impaired benefits to the European Communities and their member States.

VI. INTERIM REVIEW

6.1 On 1 July 1998, 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 19 June 1998. The European Communities and their member States did not request a review, but submitted, in a letter dated 6 July 1997, comments on India's request for a review of the aspects in question requesting the Panel to reject India's comments. Neither party 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 those arguments it considered to be relevant.

A. ARTICLES 9.1 AND 10.4 OF THE DSU

6.2 In its review request, India claimed that the Panel had not followed the principles of treaty interpretation set out in Article 31(1) of the Vienna Convention on the Law of Treaties, i.e. the Panel had failed to interpret the DSU in accordance with the ordinary meaning to the terms of the treaty in their context and in the light of its object and purpose. This failure, according to India, significantly affected the reasoning and conclusions of the Panel.

6.3 India noted that Article 3.10 of the DSU declared the guiding provision in that "[i]t is understood that requests for conciliation and the use of dispute settlement procedures should not be intended or considered as contentious acts and that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute". It also noted that under the MFN provisions of the TRIPS Agreement, any benefit or concession made to any country would be equally extended to all the other Members. India considered that these two provisions read together in the context of dispute settlement invested the Panel with the power to examine whether the EC complaint should be taken up for examination or should be dismissed in limine. It was all the more important, in India's view, for the Panel to exercise this power because the DSB did not have discretion to make a summary examination of the complaint.

6.4 According to India, the first sentence of Article 11 of the DSU, which provided that "[t]he function of the panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements" would also suggest that the Panel should exercise such a power. In doing so, "a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case ...". The objective assessment, in India's view, included an examination whether a matter existed in substance or not. India argued that the power to make an objective assessment of the facts might not be interpreted as overriding the power of objective assessment of the matter.

⁸⁵ In a scenario involving two successive disputes concerning the same matter and legal claims, such a presumption would not necessarily exist in the later case if the earlier case concerned solely "non-violation" nullification or impairment.

6.5 India further noted that Article 3.2 of the DSU provided that "[t]he dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system". In India's view, an unmitigated right to bring successive complaints, particularly by parties who had joined as a third party in earlier similar disputes, with nothing to add, would not provide any security to the multilateral trading system and would go against its predictability.

6.6 According to India, the Panel's failure to so assess the EC complaint was inconsistent with the panel rulings in the Bananas case⁸⁶ made with reference to the power of panels to examine compliance with Article 6.2 of the DSU.

6.7 India argued that the consultations factor relied upon by the Panel in what is now paragraph 7.16 was not relevant as there was nothing to be added. India also noted that the EC had requested the Panel to "extend its findings" and not to settle the dispute. India considered that there was no possibility in the scheme of the DSU for a panel to extend the findings of an earlier dispute.

6.8 Noting the Panel's discussion in what is now paragraph 7.22, India observed that the Panel had not found itself the appropriate forum for resolving certain issues raised by India. In India's view, proper consideration of the context and the object and purpose of the DSU as mentioned in the preceding paragraphs would have led to a different conclusion.

6.9 India argued that the security and predictability of the multilateral trading system envisaged by Article 3.2 of the DSU bound the parties to the statements made by them in earlier disputes, unless the context did not permit the same. According to India, India's argument in this regard at paragraph 4.2 had not been dealt with by the Panel. The complainant's statement in earlier cases before a panel should have been taken as an admission in the present case and the EC should not have been allowed to make a volte face in the present procedures.

6.10 India considered that the acceptance by the Panel at what is now paragraph 7.15 of the complainant's right to determine whether and when to pursue a complaint under the DSU was fraught with danger and was not consistent with the spirit of Article 3.10 and 3.12 of the DSU. India also considered that acceptance of such a right would be inconsistent with the principles of the DSU relating to non-contentious acts, good faith and achievement of positive solutions to disputes and would result in harassment of the defending Member. There would also be problems of implementation of different DSU decisions given at different points in time. India felt that this should have engaged the attention of the Panel.

6.11 In India's view, there was another inconsistency in the findings of the Panel. While the trouble, expense and exposure of India to successive WTO proceedings had not influenced the Panel's findings, in what is now paragraph 7.54 the Panel was relying on the mere possibility of the challenge of India's mailbox system under the administrative instructions and the further possibility of its being struck down by a court of law in India. The finding emphasized the guarantee that the public - including interested nationals of WTO Members - be adequately informed, but denied a similar guarantee to a harassed defending party.

6.12 According to India, the Panel's findings would lead to a vacuum in the scheme of the DSU. India considered that it was an established rule of interpretation that where two views were possible, the one which promoted the scheme should be favoured. Non-examination of India's arguments caused prejudice to India's defence.

⁸⁶ India referred to paragraph 7.26 of the panel reports on European Communities - Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/R, adopted on 25 September 1997. See paragraph 4.2 above.

6.13 The Panel carefully examined these comments by India, but was not convinced that it should modify its findings regarding Articles 9.1 and 10.4 of the DSU. The Panel noted that India's arguments reflected in paragraphs 6.2 to 6.6 above were essentially a repetition of the arguments that had been reflected in paragraph 4.2 of the report. The Panel's view in this regard was clearly stated in what is now paragraph 7.23. In the Panel's view, India's criticism, as reflected in paragraphs 6.7 and 6.8 above, of what is now paragraph 7.16 was unwarranted because the Panel was not "relying on" the consultations factor. The Panel's view remained unchanged: it was not feasible to establish a single panel to hear the complaints of the United States and the EC in this instance. Nor did the Panel simply "extend its findings" in the prior case.⁸⁷ Regarding India's argument about a *volte face* by the EC (see paragraph 6.9 above), the Panel took the view that statements made by the EC in another context – that is to say, not the context of the present dispute including, in the present situation, statements made in the context of dispute WT/DS50 - were outside the purview of its examination of the matter referred to it; it did not consider the statements made by the EC in this case contradictory. The Panel took note of India's comments reflected in paragraphs 6.8 and 6.10 above, but did not consider it necessary to amend its reasoning in what are now paragraphs 7.15 and 7.22 below. Regarding India's charge of inconsistency within the findings (see paragraph 6.11 above), the Panel failed to understand the basis of comparison, as suggested by India, between the procedural aspects of the DSU and the substantive obligations under the TRIPS Agreement. Finally, the Panel did not consider that its findings in this particular case would lead to a vacuum in the scheme of the DSU.

6.14 Accordingly, the Panel did not introduce any changes to its findings regarding Articles 9.1 and 10.4 of the DSU.

B. ARTICLE 70.8(a) AND 70.9 OF THE TRIPS AGREEMENT

6.15 India noted that, in what is now paragraph 7.30, the Panel concluded that it was not legally bound by the conclusions of the Panel in dispute WT/DS50 as modified by the Appellate Body report, but that in what are now paragraphs 7.55 and 7.73 the Panel refused to review questions relating to the manner in which the Appellate Body had reached its conclusions. In India's view, the two positions were mutually inconsistent. India considered that once the Panel held that it was not legally bound by the conclusions arrived at by an earlier panel or Appellate Body report, it followed that it was legally competent to review their conclusions as well as reasons. The absence of power to review conclusions reached earlier was different from the absence of material to review the process of arriving at such conclusions. In India's view, the self-imposed limitation by the Panel in not reviewing the manner in which the Panel or the Appellate Body in dispute WT/DS50 had reached their conclusions was not warranted.

6.16 In the Panel's view, however, India's comments above failed to take account of the remainder of what are now paragraph 7.30, where the Panel stated:

"However, in the course of "normal dispute settlement procedures" required under Article 10.4 of the DSU, we will take into account the conclusions and reasoning in the Panel and Appellate Body reports in WT/DS50. Moreover, in our examination, we believe that we should give significant weight to both Article 3.2 of the DSU, which stresses the rôle of the WTO dispute settlement system in providing security and predictability to the multilateral trading system, and to the need to avoid inconsistent rulings (which concern has been referred to by both parties). In our view, these considerations form the basis of

⁸⁷ See also section B below.

the requirement of the referral to the 'original panel' wherever possible under Article 10.4 of the DSU.";

and paragraph 7.33, where the Panel stated:

"We note that India has not introduced any changes to its patent régime since the adoption of the Panel and Appellate Body reports in dispute WT/DS50. However, we also note that the Appellate Body modified the reasoning in the Panel report in dispute WT/DS50 and that India has provided certain additional information regarding its mailbox system to us. In the following analysis, we will take account of these new elements as necessary."

Moreover, the paragraphs to which India had referred, i.e. what are now paragraphs 7.55 and 7.73, not only stated that the Panel was of the view that it was not for it to review questions regarding how the Appellate Body had arrived at its conclusions, but also that the Panel did "not consider it necessary in the light of the foregoing".

C. ARTICLE 70.8(a) OF THE TRIPS AGREEMENT

6.17 India argued that the finding at what is now paragraph 7.51 was not substantiated by its reasoning. According to India, the basis for the Panel's assumption was that, had the administrative instructions been effective, there would have been no need to recommend the amendment of the Indian Patents Act. In other words, India suggested that the Panel believed that statutory actions could only "create" law. However, according to India, many statutory provisions were of a declaratory or clarificatory nature: they declared in a statutory form what the law otherwise was. Since the Panel had not examined whether the amendments to the Patents Act fell in the category of clarification provisions, in India's view, what is now paragraph 7.51 should be deleted from the final report.

6.18 The Panel examined the point made by India, but saw no reason to delete what is now paragraph 7.51. The paragraph was stating a fact by reiterating the content of paragraph 2.3 above. For clarification, it decided to add a footnote to paragraph 7.51 which refers back to the language of paragraph 2.3.

6.19 In the interim report, the fourth sentence of the paragraph corresponding to what is now paragraph 7.54 read as follows: "In any event, India itself admits that once an exclusive marketing right is granted to a mailbox applicant, the competitor would be able to demonstrate actual damage, which constitutes proper cause of action". India claimed that this sentence did not put India's argument in the proper context. India's reply to the Panel cited in footnote 59 referred to the time when a mailbox application would result in the grant of a patent or exclusive marketing right. According to India, nowhere had India made the admission attributed to it.

6.20 The Panel had some difficulty in addressing the point raised by India because the sentence to which India was referring was clearly limited to the situation when an exclusive marketing right had been granted; there was no suggestion that India had made a statement in regard to any earlier date. Nonetheless, given the need to avoid any risk of misrepresentation, the Panel decided to modify what is now paragraph 7.54 as follows. In the sentence referred to in the previous paragraph, the phrase "India itself admits that" was deleted and the word "would" was changed to "might". The Panel also decided that it would be a helpful clarification to add two new sentences, reading: "As pointed out in paragraph 7.67 and following below, since it is impossible to indicate the exact time on which a product may meet the terms of Article 70.9, WTO Members concerned are required to reckon with the possibility that this moment may arise at any time subsequent to the

date of entry into force of the WTO Agreement. By the same token, the possibility of a dispute over a relevant filing date in the context of a court procedure regarding the grant of an exclusive marketing right must also be reckoned with at any point in time after 1 January 1995."

6.21 India observed that the Panel noted that applications had been received by the Patent Office and stored for future action (paragraph 7.56); that to date neither the system established by the administrative instructions nor any individual mailbox applications had been challenged before a court (paragraph 7.54); and that economic operators in this area were usually well informed about the systems for the protection of their rights (paragraph 7.56). However, no inference had been drawn that India had provided a "means" by which applications for patents of inventions could be filed. On the contrary, the Panel had come to the conclusion that "there must be a guarantee that the public - including interested nationals of other WTO Members - is adequately informed" (paragraph 7.56).

6.22 In India's view, this added something more to the text of Article 70.8(a) than could be done through interpretation. According to India, the drafters of the TRIPS Agreement had been consciously silent on the nature, method or sweep of the "means". India considered that the Panel put an additional obligation by reading a guarantee in the obligation under Article 70.8(a). The conclusion at what is now paragraph 9.1 was, therefore, not in consonance with the provisions of Article 70.8(a).

6.23 The Panel did not agree with India and recalled that the relevance of the unwritten, unpublished nature of the administrative instructions had already been discussed by the Panel in the previous case and had also been addressed by the Appellate Body. In what are now paragraphs 7.56 to 7.58, the Panel reiterated the essence of the reasoning in question while adding its views on India's argument that the present system ensured the retention of the necessary facts to determine novelty and priority for the purposes of decisions on the future grant of patent rights pursuant to Article 70.8(b) and (c). In any event, the Panel's reasoning which led to its conclusion at what is now paragraph 9.1 was not limited to paragraph 7.56. However, for clarification, the Panel decided to change the last sentence of what is now paragraph 7.56, so that it would read: "While Article 70.8 does not explicitly provide for a publication obligation, doubts have to remain as to whether an unwritten and unpublished system for permitting the filing of applications by nationals of other WTO Members could be construed as a 'means' which adequately responds to the requirements of Article 70.8." However, the Panel did not feel it necessary to make a specific finding on the point.

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 of 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".⁸⁸ Only "claims for the methods or processes of manufacture shall be patentable" in respect of those substances.⁸⁹ Thus, India

⁸⁸ 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 3 of this report).

⁸⁹ See paragraph 2.9 above and Annex 3 of this report.

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 the transition provisions of Articles 65.4 and 70.8 of the TRIPS Agreement and to certain exceptions not applicable in this case.

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, pursuant to the recommendation by a group of patent experts. 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.⁹⁰ 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.

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 1995.⁹¹ 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.

7.4 Since the lapse of the Patents Ordinance, India has continued receiving patent applications for pharmaceutical or agricultural chemical products through unpublished "administrative instructions". Between 1 January 1995 and 31 January 1998, a total of 2,212 applications for pharmaceutical and agricultural chemical products have been received.⁹² 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.

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" 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.⁹³

⁹⁰ Section 12 sets out the procedure for the reference of patent applications by the Controller to examiners (see Annex 3 of this report).

⁹¹ See paragraph 2.2 above.

⁹² See paragraph 2.10 above.

⁹³ One EC pharmaceutical company has applied for marketing approval for a product regarding which a mailbox application has been filed (see Annex 4 of this report).

7.6 On 20 November 1996, the Dispute Settlement Body (DSB) established a panel to examine this matter at the request of the United States (WT/DS50). The European Communities and their member States (hereinafter collectively referred to as the "EC") participated in the panel process as an interested third party. The report of the Panel, which found that India violated the provisions of Article 70.8(a) and Article 70.9 of the TRIPS Agreement, was circulated to WTO Members on 5 September 1997. India appealed from certain issues of law and legal interpretations in the Panel report. The report of the Appellate Body, which modified the reasoning of the Panel but essentially upheld the conclusions of the Panel report in respect of Article 70.8(a) and Article 70.9, was circulated to WTO Members on 19 December 1997. The Appellate Body report and the Panel report, as modified by the Appellate Body, were adopted by the DSB on 16 January 1998. At the DSB meeting of 22 April 1998, the United States and India announced that they had agreed on an implementation period of 15 months.

Claims of the Complainant

7.7 The EC claims - largely relying on the conclusions of the Panel and the Appellate Body in dispute WT/DS50 - that: (a) India has not complied with its obligations under Article 70.8 of the TRIPS Agreement 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 period provided for in Article 65 of the TRIPS Agreement; (b) India has not complied with its obligations under Article 70.9 of the TRIPS Agreement; and (c) India thereby nullifies or impairs benefits accruing directly or indirectly to the EC under the TRIPS Agreement.

Claims of the Respondent

7.8 India claims that the EC's complaint in this case should be dismissed as inconsistent with the rules of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) on multiple complaints, in particular Articles 9.1 and 10.4, because the EC did not join the United States' complaint in the previous case. In the alternative, India claims that: (i) the mailbox system currently in force in India is consistent with Article 70.8(a) of the TRIPS Agreement; and (ii) India has not acted inconsistently with Article 70.9 of the TRIPS Agreement because it is not obligated to establish a system for the grant of exclusive marketing rights before all the conditions for the grant of the rights have been met in respect of a specific product.

B. PROCEDURAL ISSUES

Introduction

7.9 India has requested the Panel to dismiss the EC's complaint as inadmissible on procedural grounds. India argues that since it was "feasible" for the EC to have brought its complaint simultaneously with the United States' complaint (WT/DS50), the EC was required to do so. In India's view, the principle of stare decisis does not apply to the interpretations of a panel or the Appellate Body.⁹⁴ As a result, it argues that, in the absence of a specific rule to the contrary, successive multiple complaints by different Members on the same matter would have to be examined as separate new cases. The resulting danger of contradictory decisions and the waste of resources, according to India, would be tremendous. Furthermore, India argues that such complaints amount to unwarranted harassment. In India's view, these shortcomings can be avoided

⁹⁴ See also section C below.

by strict interpretation of Articles 9.1 and 10.4 of the DSU, which require multiple complainants to submit their case to the same panel "whenever feasible" or "wherever possible".

7.10 The EC disagrees with India on the interpretation of Articles 9.1 and 10.4 of the DSU. The EC argues that neither Article 9 nor Article 10 impose any obligation on WTO Members to make a complaint at a given point in time. In support of its argument, the EC cites Article 3.7 of the DSU, which provides that Members shall, before bringing a case, exercise their judgement as to whether action under the DSU would be fruitful.

Article 9 of the DSU

7.11 Article 9 of the DSU, which sets out the procedure for multiple complaints, provides as follows:

"1. Where more than one Member requests the establishment of a panel related to the same matter, a single panel may be established to examine these complaints taking into account the rights of all Members concerned. A single panel should be established to examine such complaints whenever feasible.

"2. The single panel shall organize its examination and present its findings to the DSB in such a manner that the rights which the parties to the dispute would have enjoyed had separate panels examined the complaints are in no way impaired. If one of the parties to the dispute so requests, the panel shall submit separate reports on the dispute concerned. The written submissions by each of the complainants shall be made available to the other complainants, and each complainant shall have the right to be present when any one of the other complainants presents its views to the panel.

"3. 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."

7.12 India argues that Article 9.1 does not make clear to whom it is addressed because of its use of the passive voice. However, according to India, in view of its object and purpose, the duty to submit multiple complaints to a single panel whenever feasible is a duty falling on both the WTO and its membership. India claims that the EC's complaint should be dismissed because the EC did not perform this duty.

7.13 In order to assess India's argument, we need to consider: (i) the nature of the requirement contained in Article 9.1; (ii) the rights generally of Members under the DSU; and (iii) whether it was feasible to establish a single panel in this particular case.

7.14 Given their ordinary meaning, the terms of Article 9.1 are directory or recommendatory, not mandatory. They direct that a single panel should (not "shall") be established, and that direction is limited to cases where it is feasible. We disagree with India that the addressee of Article 9.1 is not clear. Article 9.1 is clearly a code of conduct for the DSB because its provisions pertain to the establishment of a panel, the authority for which is exclusively reserved for the DSB. As such, Article 9.1 should not affect substantive and procedural rights and obligations of individual Members under the DSU.

7.15 Indeed, the text of Article 9.1, as well as the text of Article 9.2, which is part of the context of Article 9.1, make it clear that Article 9 is not intended to limit the rights of WTO Members. In our view, one of those rights is the freedom to determine whether and when to pursue a complaint under the DSU. According to Article 3.7 of the DSU, "[t]he aim of dispute settlement mechanism is to secure a positive solution to a dispute. A solution mutually acceptable to the parties to a dispute and consistent with the covered agreements is clearly to be preferred". It would be inconsistent with this aim of the dispute settlement mechanism to attempt to force Members to take decisions earlier than they wish on whether to request a panel in a dispute, or to continue consultations aimed at securing a mutually acceptable solution.

7.16 As to feasibility, it is not disputed by the parties that the complaints by the United States (WT/DS50) and the EC (WT/DS79) relate to the same matter, i.e. India's compliance with Article 70.8 and 70.9 of the TRIPS Agreement. Was it then "feasible" for the DSB to establish a single panel at the time of the United States' panel request in November 1996? The answer is no, because at that time the EC had not requested the establishment of a panel. Indeed, the EC was not even entitled to make such a request as it was not until 28 April 1997 that the EC requested consultations with India on this matter.

7.17 Accordingly, we find no violation of Article 9.1 of the DSU.

Article 10 of the DSU

7.18 We now turn to the examination of whether the EC's complaint in the present case is permissible under Article 10 of the DSU, which provides:

"1. The interests of the parties to a dispute and those of other Members under a covered agreement at issue in the dispute shall be fully taken into account during the panel process.

"2. Any Member having a substantial interest in a matter before a panel and having notified its interest to the DSB (referred to in this Understanding as a "third party") shall have an opportunity to be heard by the panel and to make written submissions to the panel. These submissions shall also be given to the parties to the dispute and shall be reflected in the panel report.

"3. Third parties shall receive the submissions of the parties to the dispute to the first meeting of the panel.

"4. If a third party considers that a measure already the subject of a panel proceeding nullifies or impairs benefits accruing to it under any covered agreement, that Member may have recourse to normal dispute settlement procedures under this Understanding. Such a dispute shall be referred to the original panel wherever possible."

7.19 India claims that since the EC was a third party in the previous case, and since it was "possible" to do so, it was required to submit its complaint to the Panel which examined the United States' claims on this matter (WT/DS50) under Article 10.4 of the DSU. As the EC did not meet this requirement, India requests that the Panel declare the EC's complaint as inadmissible.

7.20 India's claim that the EC did not meet the requirement of Article 10.4 can only be understood in the light of India's view that the term "original panel" is limited to a panel which has not yet issued its final report. We do not see that this limitation flows from the ordinary meaning of

the text. We also note that, the phrase "original panel" is used elsewhere in the DSU (Article 21.5 and Article 22.6), where it is clear that the reference is to a panel the final report of which has already been issued and adopted. The text of Article 10.4, read in this context, does not support the Indian view.

7.21 Thus, in our view, the terms of Article 10.4 have been complied with in the present case. The EC, which was a third party in the proceeding initiated by the United States in respect of the same Indian measures, decided to have recourse to a panel under the DSU. This is precisely what Article 10.4 permits. The two members of the Panel in WT/DS50 were reappointed, while the Panel chairman, who was no longer available, was replaced.⁹⁵ We therefore find that India's claim regarding a violation of Article 10.4 lacks both factual and legal basis.

Conclusion

7.22 We note that India's rationale behind its restrictive reading of Articles 9.1 and 10.4 is that an unmitigated right to bring successive complaints by different parties based on the same facts and legal claims would entail serious risks for the multilateral trade order because of the possibility of inconsistent rulings, as well as problems of waste of resources and unwarranted harassment. While we recognize that these are serious concerns, this Panel is not an appropriate forum to address these issues.

7.23 According to Article 11 of the DSU, the Panel's role is to "make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability and conformity with the relevant covered agreements". Furthermore, under Article 3.2 of the DSU, the purpose of the panel process is to "clarify the existing provisions of [covered] agreements in accordance with customary rules of interpretation of public international law". The same paragraph goes on to state that "Recommendation and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements", and Article 19.2 also states that "... in their findings and recommendations, the panel and the Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements".⁹⁶ Thus, the Panel is required to base its findings on the language of the DSU. We simply cannot make a ruling *ex aequo et bono* to address a systemic concern divorced from explicit language of the DSU.

7.24 For the reasons stated above, the Panel rejects India's request for dismissal of the EC's complaint.

C. THE EXTENT OF THE BINDING NATURE OF PRECEDENTS

7.25 Before we move on to the examination of substantive aspects of this dispute, however, we need to address the question of whether, and if so, to what extent we are bound by the reports by the Panel and the Appellate Body regarding the same subject-matter in the dispute between the United States and India (WT/DS50). This question is relevant because the EC, on the one hand, is asking the Panel to "extend" to it the findings in the earlier dispute and India, on the other hand, argues that it is entitled to "normal dispute settlement procedures" under Article 10.4 of the DSU.

⁹⁵ See paragraph 1.2 above.

⁹⁶ The DSU is not included in the definition of the "covered agreements" under Article 1.1, first sentence. However, the second sentence of Article 1.1 makes it clear that the rules and procedures of the DSU are applicable to disputes concerning Member's rights and obligations under the DSU.

7.26 A number of GATT panels have examined complaints by different contracting parties involving the same or similar measures of a responding party. For instance, both the 1983 panel report on Spring Assemblies (complaint by Canada)⁹⁷ and the 1989 panel report on Section 337 (complaint by the EC)⁹⁸ concerned the application of Section 337 of the Tariff Act by the United States. The 1980 panel report on Apples (complaint by Chile)⁹⁹ and the 1989 panel reports on Dessert Apples (complaints by Chile and the United States)¹⁰⁰ essentially dealt with the same measure taken by the EEC.¹⁰¹ The 1988 panel report on Canadian Liquor Boards (complaint by the EC)¹⁰² and the 1992 panel report on the same subject-matter (complaint by the United States)¹⁰³ were indeed examined by the same panelists. The unadopted panel reports on Tuna¹⁰⁴ addressed the same legislation - the Marine Mammal Protection Act - of the United States.

7.27 The issue of whether adopted panel reports are *stare decisis*, i.e. binding precedents, has not been directly addressed in any of these cases. The following passage from the second Tuna report is the only instance where a discussion of *stare decisis* occurs in GATT panel reports:

"In the view of the EEC and the Netherlands, the United States interpretation of the term 'necessary' as meaning 'needed' amounted to a rejection of adopted panel reports, which constituted agreed interpretations of the General Agreement. The EEC recognized that there was no *stare decisis* in the GATT, if only because there was no hierarchy between courts or arbitral bodies in the GATT. This was also the case for most international courts or tribunals. Nevertheless, such international courts and tribunals were always very careful about maintaining their own precedents and a certain coherence in their decisions. The GATT required such coherence in panel interpretations in order to provide stability within the international trading system".¹⁰⁵

⁹⁷ Panel report on United States - Imports of Certain Automotive Spring Assemblies, adopted on 26 May 1983, BISD 30S/107. It should be noted that this report was adopted "on the understanding that this shall not foreclose future examination of the use of Section 337 to deal with patent infringement cases from the point of view of consistency with Articles III and XX of the General Agreement" (C/M/168).

⁹⁸ Panel report on United States - Section 337 of the Tariff Act of 1930, adopted on 7 November 1989, BISD 36S/345

⁹⁹ Panel report on EEC - Restrictions on Imports of Apples from Chile, adopted on 10 November 1980, BISD 27S/98

¹⁰⁰ Panel reports on EEC - Restrictions on Imports of Dessert Apples, Complaint by Chile, adopted on 22 June 1989, BISD 36S/93; EEC - Restrictions on Imports of Apples, Complaint by the United States, adopted on 22 June 1989, BISD 36S/135

¹⁰¹ There is another panel report dealing with the same subject-matter between the EEC and Chile. DS39/R, circulated on 20 June 1994. This is a short report describing that the issue was settled bilaterally.

¹⁰² Panel report on Import, Distribution and Sale of Alcoholic Drinks by Canadian Provincial Marketing Agencies, adopted on 22 March 1988, BISD 35S/37

¹⁰³ Panel report on Canada - Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies, adopted on 18 February 1992, BISD 39S/27

¹⁰⁴ Panel reports on United States - Restrictions on Imports of Tuna, Complaint by Mexico, DS21/R, circulated on 3 September 1991; United States - Restrictions on Imports of Tuna, Complaints by the EEC and the Netherlands, DS29/R, circulated on 19 June 1994

¹⁰⁵ Document DS29/R, *op. cit.*, paragraph 3.74

It should be noted that in the Tuna case, the EEC did not rely on the notion of stare decisis and rather advocated a softer approach of "coherence". It should also be noted that this argument was about the interpretation of Article XX in general and that the EEC did not ask the panel simply to extend the findings of the earlier Tuna panel.

7.28 Turning to the issue of how adopted panel reports should be treated in the absence of stare decisis, we note that the Appellate Body discussed the effect of adopted panel reports in its report on the Japan - Liquor case as follows:

"Adopted panel reports are an important part of the GATT acquis. They are often considered by subsequent panels. They create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute. However, they are not binding, except with respect to resolving the particular dispute between the parties to that dispute".¹⁰⁶

7.29 This approach follows GATT practice, as explained in the above-mentioned 1989 Apples report, which stated:

"The Panel first examined the EEC's system of restrictive licensing applied to imports of apples from April through August 1988 under Article XI, as consistency with this Article was the primary determinant of the conformity of the EEC's system with the General Agreement, before proceeding to consider the measures under Articles XIII and X and Part IV of the Agreement. In considering the facts and arguments relating to Article XI in particular, the Panel took note of the fact that a previous Panel, in 1980¹⁰⁷, had reported on a complaint involving the same product and the same parties as the present matter and a similar set of GATT issues. The Panel noted carefully the arguments of the parties concerning the precedent value of this Panel's and other previous panels' recommendations, and the arguments on the legitimate expectations of contracting parties arising out of the adoption of panel reports. The Panel construed its terms of reference to mean that it was authorized to examine the matter referred to it by Chile in the light of all relevant provisions of the General Agreement and those related to its interpretation and implementation. It would take into account the 1980 Panel report and the legitimate expectations created by the adoption of this report, but also other GATT practices and panel reports adopted by the CONTRACTING PARTIES and the particular circumstances of this complaint. The Panel, therefore, did not feel it was legally bound by all the details and legal reasoning of the 1980 Panel report. ..." ¹⁰⁸

7.30 It can thus be concluded that panels are not bound by previous decisions of panels or the Appellate Body even if the subject-matter is the same. In examining dispute WT/DS79 we are not legally bound by the conclusions of the Panel in dispute WT/DS50 as modified by the Appellate

¹⁰⁶ Ibid. (Appellate Body report), page 14. The footnote to the cited passage states: "It is worth noting that the Statute of the International Court of Justice has an explicit provision, Article 59, to the same effect. This has not inhibited the development by that Court (and its predecessor) of a body of case law in which considerable reliance on the value of previous decisions is readily discernible."

¹⁰⁷ The footnote to this sentence refers to BISD 27S/98-117.

¹⁰⁸ Panel report on Dessert Apples (complaint by Chile), op. cit., paragraph 12.1. The parallel report addressing the United States' complaint, op. cit., contains almost identical paragraphs at paragraph 5.1.

Body report. However, in the course of "normal dispute settlement procedures" required under Article 10.4 of the DSU, we will take into account the conclusions and reasoning in the Panel and Appellate Body reports in WT/DS50. Moreover, in our examination, we believe that we should give significant weight to both Article 3.2 of the DSU, which stresses the role of the WTO dispute settlement system in providing security and predictability to the multilateral trading system, and to the need to avoid inconsistent rulings (which concern has been referred to by both parties).¹⁰⁹ In our view, these considerations form the basis of the requirement of the referral to the "original panel" wherever possible under Article 10.4 of the DSU.

D. ARTICLE 70.8(a) OF THE TRIPS AGREEMENT

Introduction

7.31 We now turn to the examination of the EC's 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 EC claims, largely relying on the results of the previous case (dispute WT/DS50), that India has failed to fulfil its obligation under this paragraph by not establishing a valid system for receiving "mailbox" applications. In particular, it notes that there has been no legislative change in the Indian patent system after the adoption of the Panel and the Appellate Body reports in dispute WT/DS50, in which it was found that India had failed to fulfil such obligation.

7.32 Initially, we note that the only obligation India currently assumes under Article 70.8 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 us is whether India has taken the action necessary to implement its obligations under subparagraph (a) of Article 70.8.

¹⁰⁹ See paragraphs 4.2, fifth indent and 4.8 above.

7.33 In this regard, we recall that the Panel in dispute WT/DS50 reached the conclusion that India had failed to take the action necessary to implement its obligations under Article 70.8(a), which had been upheld by the Appellate Body. We note that India has not introduced any changes to its patent regime since the adoption of the Panel and the Appellate Body reports in dispute WT/DS50. However, we also note that the Appellate Body modified the reasoning in the Panel report in dispute WT/DS50 and that India has provided certain additional information regarding its mailbox system to us. In the following analysis, we will take account of these new elements as necessary.

Nature of the Obligations

7.34 We recall that the Panel report in dispute WT/DS50 first described the nature of obligations at issue under Article 70.8(a). The EC, by requesting the Panel to extend the finding in that report as modified by the Appellate Body, implicitly accepts the analysis set out in the following six paragraphs. India does not contest this part of the finding in the previous case, either.

7.35 Subparagraph (a) of Article 70.8, like all other provisions of the covered agreements, must be interpreted in good faith in the 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 1969 Vienna Convention on the Law of Treaties (hereinafter referred to as the "Vienna Convention").

7.36 Subparagraph (a) starts with the phrase "notwithstanding the provisions of Part VI". This indicates that the transitional arrangements contained in Part VI of the TRIPS Agreement are not applicable. Thus, a Member not making available as of 1 January 1995 patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27 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.

7.37 We thus need to analyse the context of this subparagraph. The means for filing is necessary because, under subparagraphs (b) and (c) of Article 70.8, a Member which does not make patents available as of 1 January 1995 for pharmaceutical and agricultural chemical products must, after the expiry of the transitional period, apply the criteria for patentability as laid down in the TRIPS Agreement to the applications so filed and must accord patent protection for those products that meet these 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.

7.38 Furthermore, the object and purpose of the TRIPS Agreement must be taken into account in our analysis. Article 27 of the TRIPS Agreement 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 patent protection in areas of technology to which such protection would otherwise have to be extended in its territory on 1 January 2000 under the general transition rule. Thus, in such areas of technology, developing countries meeting these conditions 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 commensurate with Article 27 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.

7.39 In order to achieve the object and purpose of the TRIPS Agreement, as expressed in 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 after the expiry of the transitional period. Once these inventions can be protected by product patents, Article 27 requires such patents to be available for 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, a filing must entitle the applicant to claim priority, if available, 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.

7.40 The findings above can be confirmed by the negotiating history of the TRIPS Agreement.¹¹⁰ 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 concerning 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" for filing mailbox

¹¹⁰ 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.

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.

Mechanism for Implementing the Obligations

7.41 As noted in the previous case, pursuant to Article 1.1 of the TRIPS Agreement, it is up to India to decide how to implement its obligations under Article 70.8.¹¹¹ After examining the consistency of the administrative instructions at issue with the Patents Act, the Panel in dispute WT/DS50 reached the conclusion that the means chosen by India to implement its obligations under Article 70.8(a), i.e. administrative instructions regarding the continued receipt of mailbox applications, does not provide a sound legal basis for preserving the novelty and priority as required under Article 70.8(a). The Appellate Body upheld this conclusion in stating that "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".¹¹² However, on the basis of additional information and arguments provided to us, India essentially requests us to reverse the finding in the previous case and to find that there is a sound legal basis in the current system.

7.42 The Panel report in dispute WT/DS50 follows the approach to the burden of proof established by the Appellate Body in the Shirts and Blouses case.¹¹³ India claims that this approach violates established principles governing the burden and standard of proof.¹¹⁴ We note, however, that the correctness of this approach was affirmed by the Appellate Body.¹¹⁵ We will follow the same approach in the present case. It is our view that the EC has, on the basis of its reference to the finding in the previous case - upheld by the Appellate Body - that India was in violation of its obligations, established a prima facie case of violation with respect to Article 70.8(a). Now the onus shifts to India to bring forward evidence and arguments to disprove the claim by the EC.

7.43 In dispute WT/DS50, the Panel found that India's current system based on administrative instructions does not provide 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, because it creates a certain degree of legal insecurity in that it requires Indian officials to ignore certain mandatory provisions of the Patents Act.¹¹⁶

7.44 The Panel noted that under Section 12(1) of the Patents Act, when the complete specification has been filed in respect of a patent application, the Controller must refer the matter to an examiner and that Section 12(2) obliges the examiner ordinarily to complete examination within 18 months of the date of reference by the Controller. The Panel also noted that under

¹¹¹ Document WT/DS50/R, paragraph 7.33

¹¹² Document WT/DS50/AB/R, paragraph 70

¹¹³ Appellate Body report on Measure Affecting Imports of Woven Wool Shirts and Blouses from India, adopted on 23 May 1997, WT/DS33/AB/R, page 16

¹¹⁴ See paragraph 4.12 above.

¹¹⁵ Document WT/DS50/AB/R, paragraph 74

¹¹⁶ Document WT/DS50/R, paragraph 7.35

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.

7.45 In its examination of the Panel's finding, the Appellate Body stated:

"[L]ike the Panel, we are not persuaded that India's 'administrative instructions' would prevail over the contradictory mandatory provisions of the Patents Act.¹¹⁷ We note also that, in issuing these 'administrative instructions', the Government of India did not avail itself of the provisions of section 159 of the Patents Act, which allows the Central Government 'to make rules for carrying out the provisions of [the] Act' or section 160 of the Patents Act, which requires that such rules be laid before each House of the Indian Parliament. We are told by India that such rulemaking was not required for the 'administrative instructions' at issue here. But this, too, seems to be inconsistent with the mandatory provisions of the Patents Act."¹¹⁸

7.46 India now argues that this reading of the Patents Act was incorrect. According to India, there is no conflict between the administrative instructions giving effect to a "mailbox" mechanism and the Patents Act; Article 73 of the Indian Constitution defining the extent of executive power provides a sound legal basis for these instructions. India argues this on the basis that, while Section 12(1) of the Patents Act requires the Controller to refer patent applications to an examiner, it does not specify the time-frame within which the Controller must do so. Moreover, India draws attention to a principle of statutory interpretation in Indian law to the effect that, even where a statutory provision specifies a time for performing a statutory duty, the time specified is only directory and not mandatory. It also argues that a principle of statutory interpretation in Indian domestic law that a statutory provision must be interpreted consistently with India's existing international obligations further justifies the Controller using discretion on matters of timing in order to give effect to mailbox obligations.

7.47 In this regard, we note that arguments relating generally to administrative discretion were made by India also in dispute WT/DS50. Indeed, the arguments on such discretion and on international law now made by India are not based on new developments in the Indian legal system. However, we will examine India's claim in more detail in view of the additional information provided by India and India's further elaboration of its arguments.

7.48 In regard to the time-frame under Section 12(1) of the Patents Act for the Controller to refer applications to an examiner, we note that the relevant part of the text of Section 12(1) reads: "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 ...". We are not persuaded that this text gives complete discretion to the Controller regarding the timing of the referral. Indeed, on its face it specifies a time for referral, i.e. "[w]hen the complete specification has been filed".

7.49 In regard to the times specified for performing a statutory duty, while we accept that they may be only directory and not mandatory in nature, we are not persuaded that such discretion would go beyond what is necessary for administrative purposes and extend to actions that, on the face of it, would defeat a basic feature of a statute, namely, in this case, the non-patentability of inventions of pharmaceutical and agricultural chemical products (Section 5). The directory nature of a time-bound

¹¹⁷ Ibid., paragraph 7.37

¹¹⁸ Document WT/DS50/AB/R, paragraph 69

provision does not necessarily provide a legal basis for positive actions not stipulated in a statute.¹¹⁹ With regard to the principle of interpretation in accordance with international obligations, we note that India makes it clear that this would only be possible where legislation is capable of more than one meaning and one of those meanings is consonant with the treaty obligation in question. This does not appear to be the case in this instance; the terms of Sections 12(1), 12(2) and 15(2) of the Patents Act do not appear to be capable of more than one meaning. We also note in this connection that according to India international treaty obligations are not self-executing in India's domestic legal order.¹²⁰ For the reasons indicated above we are not persuaded, notwithstanding the new arguments advanced by India, that the administrative instructions at issue for giving effect to the obligations of Article 70.8(a) of the TRIPS Agreement are not in conflict with provisions of the Patents Act.

7.50 Given this, we are also not persuaded that Article 73 of the Indian Constitution provides a sound legal basis for these administrative instructions. We note that India's argument that Article 73 of the Constitution can provide a sound legal basis is predicated on the "statutory silence" of the Patents Act in specifying the timing of referrals of applications for examination.¹²¹ However, for the reasons outlined in paragraphs 7.44, 7.45, 7.48 and 7.49 above, we cannot see how the Act can be construed as silent on this point. We also note that, according to a well-established principle of Indian administrative law, administrative instructions "cannot be issued on any matter which is the subject of legislation" and that, while the necessary administrative information can be issued "wherever there is no statutory provision or where there are gaps in any enactment", "the only rider on the authority to issue such administrative instructions is that there should be no statutory provision either expressly or by necessary implication to the contrary".¹²² Since the Patents Act does contain statutory provisions regarding the examination and rejection of patent applications for pharmaceutical and agricultural chemical products, we fail to see how Article 73 of the Constitution could provide a legal basis for the administrative instructions at issue in the present case.¹²³

7.51 We further note that these arguments submitted by India to us reach a conclusion which is different from that reached by patent experts when they recommended the amendment of the Patents Act in late 1994, a course of action then attempted by India.¹²⁴

7.52 The possibility of a challenge was another issue noted in dispute WT/DS50. The Panel report in that case points out that 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

¹¹⁹ Black's Law Dictionary (Sixth Edition) defines a directory provision as "[a] provision in a statute, rule of procedure, or the like, which is a mere direction or instruction of no obligatory force, and involving no invalidating consequence for its disregard, as opposed to an imperative or mandatory provision, which must be followed". It further states: "The general rule is that the prescriptions of a statute relating to the performance of a public duty are so far directory that, though neglect of them may be punishable, yet it does not affect the validity of acts done under them, as in the case of a statute requiring an officer to prepare and deliver a document to another officer on or before a certain day". Even if Section 12(1) of the Patents Act can be regarded as a directory provision, it does not follow that the Controller's positive actions are necessarily legal.

¹²⁰ See paragraph 2.1 above.

¹²¹ See paragraph 4.16 above.

¹²² See paragraphs 2.1 and 4.17, footnote 58 above.

¹²³ Moreover, if there were deemed to be such a gap, the Patents Act provides the means to fill it through its Section 159. Yet, as noted by the Appellate Body, India did not avail itself of this provision (see paragraph 7.45 above).

¹²⁴ See the text of paragraph 2.3 above.

rejection of a patent claim; 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.¹²⁵ The Appellate Body reached the same conclusion: "[W]e are not persuaded that India's 'administrative instructions' would survive a legal challenge under the Patents Act."¹²⁶

7.53 India now argues that an Indian court will never examine a request by a competitor to force the Controller to refer a mailbox application to an examiner for examination because basic principles of standing and ripeness dictate the rejection of challenges to contingent, future rights such as are represented by mailbox applications.

7.54 We are not persuaded by this argument. India's argument is based on the assumption that a competitor can never demonstrate actual damage caused by the existence of a mailbox application prior to the grant of an exclusive marketing right or a patent. This would appear to assume that investment decisions of a competitor in the production of the product in question cannot be influenced by the prospect of the product being protected by an exclusive marketing right or a patent in the future. In any event, once an exclusive marketing right is granted to a mailbox applicant, the competitor might be able to demonstrate actual damage, which constitutes proper cause of action.¹²⁷ Moreover, as the EC points out, a dispute over a relevant filing date could arise even during the transition period in the context of a court procedure regarding the granting of an exclusive marketing right under Article 70.9 of the TRIPS Agreement.¹²⁸ We note the point made by India that, to date, neither the system established by the administrative instructions nor any individual mailbox application has been challenged before a court, but do not consider that this is decisive in establishing whether they are challengeable. As pointed out in paragraph 7.67 and following below, since it is impossible to indicate the exact time on which a product may meet the terms of Article 70.9, WTO Members concerned are required to reckon with the possibility that this moment may arise at any time subsequent to the date of entry into force of the WTO Agreement. By the same token, the possibility of a dispute over a relevant filing date in the context of a court procedure regarding the grant of an exclusive marketing right must also be reckoned with at any point in time after 1 January 1995.

7.55 Finally, we take note of India's arguments concerning what it views as contradictory rulings by the Appellate Body in respect of its examination of the findings of the Panel in dispute WT/DS50 in respect of Article 70.8(a), and, in particular, those relating to interpretation of municipal law, reasonable doubt and burden of proof. In our view, it is not for us to review questions regarding how the Appellate Body arrived at its conclusions nor do we consider it necessary in the light of the foregoing. The ultimate conclusion of the Appellate Body in the previous case was quite clear: "[W]e 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 [W]e 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."¹²⁹

¹²⁵ Document WT/DS50/R, paragraph 7.37

¹²⁶ Document WT/DS50/AB/R, paragraph 70

¹²⁷ See footnote 59 above.

¹²⁸ See paragraph 4.19 above.

¹²⁹ Document WT/DS50/AB/R, paragraphs 70 and 71

7.56 It is also recalled that the administrative instructions relied upon by India in the present case are unwritten and unpublished.¹³⁰ Moreover, as noted in the previous case, the mere existence of a possibility for making mailbox applications is hardly sufficient as the legal basis, 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.¹³¹ This holds true even if some mailbox applications have been received by the Patent Office and stored for future action. While Article 70.8 does not explicitly provide for a publication obligation, doubts have to remain as to whether an unwritten and unpublished system for permitting the filing of applications by nationals of other WTO Members could be construed as a 'means' which adequately responds to the requirements of Article 70.8.

7.57 India claims that the public was informed through unstarred question No. 2601 at Lok Sabha (attached to this report as Annex 2). However, the Indian government's answer to this question in Parliament only indicates that the Patent Offices had received a certain number of mailbox applications and that they would be taken up for examination after 1 January 2005. There is no mention of administrative instructions. Nor is there any explanation regarding how the novelty and priority are going to be preserved. This answer alone hardly provides a sound legal basis for the purposes of Article 70.8(a).

7.58 We note the point made by India that the present system ensures the retention of the necessary facts to determine novelty and priority for the purposes of decisions on the future grant of patent rights pursuant to Article 70.8(b) and (c). Even if we were persuaded that this was the case despite the unpublished nature of the system, we do not believe that this would alter our concerns regarding the soundness of the legal basis for the system under the law as it presently stands.

Conclusion

7.59 For the reasons outlined above, we do not consider that India has successfully rebutted the prima facie case of violation of Article 70.8(a) that has been established by the EC in the present case. In conclusion, we find that India has failed to take the action necessary to implement its obligations under subparagraph (a) of Article 70.8.

E. ARTICLE 70.9 OF THE TRIPS AGREEMENT

Introduction

7.60 We now turn to our examination of the EC's 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

¹³⁰ It should be noted that we are not discussing the issue as part of India's transparency obligations under Article 63 of the TRIPS Agreement, which is outside the terms of reference of this Panel.

¹³¹ Document WT/DS50/R, paragraph 7.42

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. The situation has remained unchanged since the adoption of the Panel and Appellate Body reports in dispute WT/DS50. 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.

7.61 The EC 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 us is that of timing: as of when should there be a mechanism ready for the grant of exclusive marketing rights?

7.62 We note that, in dispute WT/DS50, both the Panel and the Appellate Body found that India has an obligation to implement the provisions of Article 70.9 effective as from the date of the entry into force of the WTO Agreement, that is, 1 January 1995. Thus, the Appellate Body held that "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".

7.63 We further note that, regarding Article 70.9, India has not brought forward any new factual information. It criticizes the Panel and the Appellate Body reports, pointing out certain perceived logical inconsistencies.

Textual Analysis

7.64 Following the rules under Article 31 of the Vienna Convention, the starting point of our analysis on the question of timing should be the wording of Article 70.9. 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 that 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.

7.65 India essentially repeats its arguments in the previous case 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 27.¹³² We disagree. The Panel report in dispute WT/DS50 points out that

¹³² See paragraph 4.22 above.

the term "right" connotes an entitlement to which a person has a just claim and that, as such, it implies general, non-discretionary availability in the case of those eligible to exercise it. It was held that an exclusive marketing right could not be "granted" in a specific case unless it was "available" in the first place.¹³³ The Panel's view was upheld by the Appellate Body, and we do not see any reason to adopt a different position in the present case. In this connection, we would also note that India considers that exclusive marketing rights are to be granted in response to requests from those who are eligible. In our view, a request-based system of rights cannot operate effectively unless there is a mechanism in place that establishes general availability and enables such requests to be made.

Contextual Analysis

7.66 India argues that the Panel in dispute WT/DS50 did not examine the context of Article 70.9 fully. To support its argument, India cites provisions of Articles 42 to 48 of the TRIPS Agreement, for instance, where the judicial authorities of Members "shall have authority" to order certain actions and contrasts this wording with that of Article 70.9, which provides that marketing rights "shall be granted" when certain conditions are met. We do not share India's view that it can be deduced from the use of these words in those Articles that a system of general availability is not called for under Article 70.9. To infer this, one would have to hold that the omission of the words "shall have the authority" in Articles 42-48 (so that a court was required to act in a certain way when prescribed conditions were met, rather than merely having the authority to do so) would mean that a Member would not be expected to give its judicial authorities in advance the authority to act in this way, for example to award an injunction, but could legislate to this effect when a specific occasion arose. Such an inference would obviously be absurd. Rather the function of the words "shall have the authority" is to address the issue of judicial discretion, not that of general availability.

Object and Purpose

7.67 Based on textual and contextual analysis, the Panel report in dispute WT/DS50 reaches 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. This conclusion was affirmed by the Appellate Body.

7.68 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. 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.

¹³³ See footnote 112 to document WT/DS50/R.

As pointed out in the previous case, 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 EC, there is at least one pharmaceutical company based in the EC that has applied for marketing approval in India for a product regarding which a mailbox application has been filed.¹³⁴

7.69 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.¹³⁵

7.70 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. 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.

7.71 India argues that this interpretation entails the absurd consequence that the transitional arrangements would allow developing countries to postpone legislative changes in all fields of technology except in the most sensitive ones, i.e. pharmaceutical and agricultural chemical products. India's view is that such a consequence cannot be justified in view of the object and purpose of the transitional arrangements in the TRIPS Agreement. In this regard, we recall that we have analysed the object and purpose of the transitional arrangements regarding pharmaceutical and agricultural chemical products in paragraphs 7.38 and 7.39 above. Article 70.9 is, as was the case with Article 70.8(a), a special obligation imposed on those Members benefitting from the transitional arrangements. We note further that India did in fact implement this special obligation through legislative action, when it promulgated in December 1994 the Patents (Amendment) Ordinance, setting out details for the grant of exclusive marketing rights.

7.72 The observation above can be confirmed by the drafting history of the TRIPS Agreement. Exclusive marketing rights were a quid pro quo for the delay of the availability of product patents for pharmaceutical and agricultural chemical products until 1 January 2005, based on a careful balancing of obligations between interested parties during the Uruguay Round negotiations. We therefore disagree with India that the object and purpose of Article 70.9 would not support the conclusion reached above.

7.73 Finally, we take note of India's arguments concerning what it views as contradictory rulings by the Appellate Body in respect of its examination of the Panel's findings in the previous case in respect of Article 70.9, in particular regarding the concept of legitimate expectations. As indicated in paragraph 7.55 above, it is not, in our view, for us to review questions regarding how the Appellate Body reached its conclusions, nor do we consider it necessary in the light of the foregoing. Rather, we confine ourselves to noting that the Appellate Body did not question the legal reasoning and findings of the Panel in the previous case in regard to Article 70.9 and came to a clear conclusion:

¹³⁴ See paragraph 4.25 above and Annex 4 of this report.

¹³⁵ Article 26 of the Vienna Convention states: "Every treaty in force is binding upon the parties to it and must be performed by them in good faith".

"... 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".

Conclusion

7.74 In conclusion, we find that India has failed to implement its obligations under Article 70.9 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.

F. NULLIFICATION OR IMPAIRMENT

7.75 Pursuant to Article 3.8 of the DSU, the findings in sections D and E above also constitute a case of prima facie nullification or impairment of benefits accruing to the EC under the TRIPS Agreement, which India has not rebutted.

VIII. CONCLUDING REMARKS

8.1 Since the matter has been addressed by India in its arguments and caused some confusion in the previous case, we would like to underline that the Panel's findings do not in any way foreshorten the transition period of until, at the latest, 1 January 2005 that India has for meeting its obligations under Articles 65.4 and 70.8(b) and (c). Rather the Panel's findings only relate to the legal basis required to give effect to the provisions of Article 70.8(a) and 70.9, which concern action to be taken during the transition period. As mentioned earlier, to come to any other conclusion would upset the delicate balance found in the Uruguay Round negotiations between these two sets of provisions.

IX. CONCLUSIONS

9.1 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) because it has failed to establish a sound legal basis for adequately preserving 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 TRIPS Agreement; 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.

9.2 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.

ANNEX 1

WORLD TRADE
ORGANIZATION

WT/DS79/2
15 September 1997

(97-3734)

Original: English

INDIA - PATENT PROTECTION FOR PHARMACEUTICAL
AND AGRICULTURAL CHEMICAL PRODUCTS

Request for the Establishment of a Panel by the EC

The following communication, dated 9 September 1997, from the Permanent Delegation of the European Commission to the Chairman of the Dispute Settlement Body is circulated at the request of that delegation.

My authorities have asked me to submit the following request on behalf of the European Communities and their Member States for consideration at the next meeting of the Dispute Settlement Body.

The Agreement on Trade-Related Aspects of Intellectual Property Rights contained in Annex 1C to the Agreement Establishing the World Trade Organization (hereafter the "TRIPS Agreement") obliges all Members of the World Trade Organization (hereafter the "WTO") to grant patents for the subject matter specified in Article 27 of the TRIPS Agreement. Article 70.8 of the TRIPS Agreement provides that where a Member makes use of the transitional provisions contained in the TRIPS Agreement and does not make patent protection available for pharmaceutical and agricultural chemical inventions as of the date of entry into force of the WTO Agreement for it, that Member must implement measures to permit parties to file patent applications concerning such inventions on or after that date (hereafter referred to as the "interim filing procedure"). When product patent protection is established, these applications must be examined according to the criteria for patentability set forth in the Agreement, based on the earliest effective filing date claimed for the application. Patents granted on the basis of such applications must enjoy the term and rights provided for under the TRIPS Agreement. Article 70.9 of the TRIPS Agreement further requires that Members subject to the obligations under Article 70.8 of the TRIPS Agreement provide exclusive marketing rights to those parties that have filed an application under the interim filing procedure, insofar as the product covered by the invention has been granted marketing approval in the Member providing protection and another Member, and a patent has been granted on the invention in another Member.

The legal regime currently in force in India does not make patent protection available for inventions concerning pharmaceutical and agricultural chemical products as provided in Article 27 of the TRIPS Agreement, nor does it provide rules that conform to obligations of the TRIPS Agreement regarding the acceptance of applications and the grant of exclusive marketing rights. As a consequence, India's legal regime appears to be inconsistent with its obligations under the TRIPS agreement, including but not limited to Articles 27, 65 and 70 of the TRIPS Agreement.

In a communication dated 28 April 1997 (WT/DS79/1), the European Communities and their Member States requested consultations with India pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereafter the "DSU") contained in Annex 2 of the WTO Agreement and Article 64 of the TRIPS Agreement in conjunction with Article XXII of the General Agreement on Tariffs and Trade 1994. Consultations were held on 14 May 1997, but did not result in a satisfactory solution of the dispute.

Accordingly, the European Communities and their Member States request the establishment of a panel to examine the matter in the light of the relevant provisions of the TRIPS Agreement and to find that India fails to conform to the obligations contained in Article 27, 65 and 70 of the TRIPS Agreement and thereby nullifies or impairs benefits accruing directly or indirectly to the European Communities and their Member States under the TRIPS Agreement.

The European Communities and their Member States ask that this request be placed on the agenda of the meeting of the Dispute Settlement Body scheduled to be held on 25 September 1997, and that the panel be established with standard terms of reference as provided for in Article 7 of the DSU.

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

INDIA

The Patents Act, 1970¹³⁶
(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 -

¹³⁶ 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 make 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 sub-section (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 4

GlaxoWellcome Fax

Global Intellectual Property

To: Mr. Bernhard Janssen
European Commission

Fax No.00 41 22 734 22 36

From: Dr. Alan Hesketh

Date: 28 April 1998

Ref: AH/KEE

Direct tel: 0181 966 86 40

Total pages: 1 (incl. cover sheet)

Direct fax: 0181 966 57 37

Dear Mr. Janssen,

INDIA

Although I have not had replies from all companies, I can provide some positive information. There are two companies that are likely to file applications for marketing exclusivity during 1999.

One is a Swiss Company which is likely to have two cases relating to formulations during 1999.

The second company is my own company, Glaxo Wellcome. We have a product called valaciclovir for which we have patents on a tablet formulation and a crystalline form. These applications have been filed in the mail box procedure. A marketing approval application has been filed in India and we expect launch to occur in early 1999. We will therefore be making an application for marketing exclusivity before that time.

This is certainly not a comprehensive list, but I hope it provides some evidence that the marketing exclusivity provisions will need to be in place in India this year.

Regards.

Yours sincerely,

Dr. Alan Hesketh
Manager, Global Intellectual Property

Glaxo Wellcome plc

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