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India - Patent Protection for Pharmaceutical and Agricultural Chemical Products

Report of the Panel

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I. INTRODUCTION

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

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

Terms of reference

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

Composition

Chairman: Mr. Thomas Cottier
Panelists: Mr. Douglas Chester
Mr. Yanyong Phuangrach

1.3. The Panel heard the parties to the dispute on 15 April and 13 May 1997. The Panel decided to give the parties the chance to comment, after the second session, in writing on each other's arguments related to the United States' claim based on Article 63, which claim had been made for the first time at the first session. The interim report was issued to the parties on 27 June 1997. Only India requested the Panel to review parts of the interim report and no request was received to hold an additional meeting.

II. FACTUAL ASPECTS

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

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

2.3 On 31 December 1994, the President of India promulgated the Patents (Amendment) Ordinance 1994, to amend the Patents Act 1970 to provide a means in the Act for the filing and handling of patent applications for pharmaceutical or agricultural chemical products (as required by subparagraph (a) of Article 70.8 of the TRIPS Agreement) and for the grant of exclusive marketing rights with respect

to the products that are the subject of such patent applications (as required by Article 70.9 of the Agreement).[1] This Ordinance was issued in exercise of the powers conferred upon the President by clause (1) of Article 123 of the Indian Constitution, which enables the President to legislate when Parliament (either House or both Houses) is not in session and the President "is satisfied that circumstances exist which render it necessary for him to take immediate action". The Ordinance became effective on 1 January 1995 and lapsed on 26 March 1995, since legislation of this kind ceases to apply at the expiration of six weeks from the re-assembly of Parliament.

2.4 At the time of the promulgation of the Patents (Amendment) Ordinance 1994, a Press Note was issued providing an explanation of its background and purposes. According to paragraph 4 of this Press Note, the Indian Government had set up an Expert Group which had been entrusted with the task of suggesting specific amendments necessary in Indian laws to comply with India's obligations under the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement and also to safeguard India's interests in this regard; this Expert Group had recommended a set of 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). During this period, 125 applications had been received and filed.

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

(a) Article 70.8

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

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

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

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

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

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

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

- Chapter III (Sections 6 through 11) deals with applications for patents. These provisions do not require that applications for patents must be limited to patentable subject matter. In respect of the subject matter of the claims, they only require that such applications should be for inventions.

- Inventions are defined in Section 2(1)(j) as, *inter alia*, any new and useful substance produced by manufacture, including any new and useful improvement of such a substance.

- Section 5 makes it clear that inventions claiming substances intended for use, or capable of being used, as a food, medicine or drug or relating to substances prepared or produced by chemical processes are not in themselves patentable, but methods or processes for their manufacture are. Under Section 2(1)(l)(iv) the term 'medicine or drug' includes insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants.

- Chapter IV of the Patents Act concerns the examination of applications. Section 12 requires that, when the complete specification has been filed[2] in respect of an application for a patent the application shall be referred by the Controller General of Patents, Designs and Trademarks to an examiner. The examiner shall ordinarily report

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

to the Controller within a period of 18 months on, *inter alia*, whether the application and the specification are in accordance with the requirements of the Act and whether there is any lawful ground for objecting to the grant of the patent under the Act.

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

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

(b)Article 70.9

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

III.FINDINGS AND RECOMMENDATIONS REQUESTED BY THE PARTIES

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

Article 70.8

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

(b) Article 70.8 of the TRIPS Agreement requires India to ensure that persons who filed or would have filed "mailbox"[3] applications had the "mailbox" been in place on time and maintained can file such applications and receive the filing date they would have received.

Article 63

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

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

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

Article 70.9

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

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

Article 70.8 and 70.9

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

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

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

Article 70.8

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

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

Article 63

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

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

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

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

Article 70.9

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

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

Article 70.8 and 70.9

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

IV. ARGUMENTS OF THE PARTIES

Article 70.8

(a) The United States' claim that India does not have in place a mailbox system that corresponds to the requirements of Article 70.8

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

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

- The Patents Act and the administrative practices governing patent applications permitted the filing of a patent application for a pharmaceutical or agricultural chemical product notwithstanding the fact that such products were currently not patentable. Section 6 of the Act provided for the receipt of applications for a patent for inventions. It was not a precondition of Section 6 that the application should relate to a patentable invention. The Patents Act of 1970 defined "invention" in Section 2(1)(j) and further provided in Section 3 that certain subject matters were not inventions. In Section 5, the Act recognized that there might be an invention in relation to pharmaceutical products and chemical products, but provided that such inventions were not patentable in respect of the product itself while being patentable for the methods or processes of manufacture.

- It was true that, should an application be examined under the provisions of Section 12, the examiner would be duty-bound to apply the provisions of Section 5 and at this stage raise

objections to the patentability of a pharmaceutical and agricultural chemical product. However, applications for patents for pharmaceutical and agricultural chemical products were not being referred by the Controller General of Patents, Trademarks and Designs for examination. Therefore, the question of their rejection did not arise, since that question could only arise after examination and the application of Section 5. Thus, patent applications for pharmaceutical or agricultural chemical products would not be refused and withdrawn from consideration prior to the date when such protection would become available. Once patent protection or exclusive marketing rights for pharmaceutical and agricultural chemical products must be granted in accordance with Article 70.8(c) and 70.9, a complete record going back to the date of entry into force of the WTO Agreement of all patent applications for pharmaceutical and agricultural chemical products, including the date and the sequence of the applications, would thus be available.

- Article 70.8(a) of the TRIPS Agreement created, at present, only one obligation for India in respect of pharmaceutical and agricultural chemical products, namely "to provide as from the date of entry into force of the WTO Agreement *a means* by which *applications for patents* for such inventions *can be filed*" (*emphasis added by India*). A method of filing applications for pharmaceutical and agricultural chemical products had been made available and was being used.

- WTO Members were free to determine the means by which patent applications could be filed. Article 70.8(a) required Members to provide "a means" for filing; it did not prescribe the choice of a particular method. This was explicitly recognized in Article 1.1 of the TRIPS Agreement which made clear that "Members shall be *free to determine the appropriate method* of implementing the provisions of this Agreement within their own legal *system and practice*" (*emphasis added by India*). India had initially decided to provide for a means for the filing of applications through an ordinance by the President and, when this ordinance had lapsed, through administrative action by instructing the patent offices to continue to receive applications and to store them separately for future action in accordance with Article 70.8. Both the legislative and the administrative approaches were available to India under Articles 1 and 70 of the TRIPS Agreement. It was therefore not correct for the United States to claim that India must create a mailbox *system* in its *law* for the filing of patent applications (*emphasis by India*). WTO Members were free to determine the means by which patent applications could be filed and India was free to choose an administrative method pending the change in legislation.

- The means currently provided by India was capable of attaining the objectives of Article 70.8. The main rationale of the requirement of subparagraph (a) of Article 70.8 was to ensure that the WTO Member, when it eventually granted patents for pharmaceutical and agricultural chemical products, was able to assign a filing date to the patent for the purpose of determining the remaining patent term. Any method of filing, registration and storage of applications that enabled the Member to assign a filing date to patent applications must, therefore, be regarded as a proper means for filing within the meaning of Article 70.8.

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

[5]The numbers are reflected in paragraph 2.11 above

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

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

- As a result of the rejection by Parliament of the Patents (Amendment) Bill 1995, Sections 5, 12 and 15 of the Patents Act 1970 remained in force and continued to require that applications drawn to pharmaceutical and agricultural chemical products be rejected. In this case, Parliament must take action to modify this statutory system before an administrative system of the type described by India could have legal effect.

- India's claim that the Patents Act 1970 permitted it to grant special treatment to applications drawn to pharmaceutical and agricultural chemical products because such applications allegedly were different from applications drawn to other types of unpatentable subject matter listed in Section 3 of the Patents Act had no legal or regulatory basis. The process for review of applications that dealt with subject matter listed in Sections 3 and 5 was identical to the review of any other type of subject matter - once filed with the Patent Office, these applications were to be forwarded to examiners for a review of patentability. Section 15 of the Patents Act stated that an examiner shall identify unpatentable subject matter, regardless of whether it fell within the subject matter listed in Sections 3 and 5. In any event, this alleged distinction between applications drawn to different types of unpatentable subject matter was irrelevant. The matters before this Panel related only to the fact that Sections 5, 12 and 15 of the Patents Act required the Controller to forward applications drawn to pharmaceutical and agricultural chemical products to examiners and ultimately reject them for being drawn to unpatentable subject matter. Therefore, Indian law did not permit the Indian Patent Office to treat, on an *ad hoc* basis, one set of applications any differently; once filed with the Patent Office, applications must be forwarded to the examiners for a review of patentability. India's attempt to claim that it was able to do so was contrary to the law, and any patents granted on applications filed under this informal, unrecognized system might be subject to legal challenge

based on a claim that they were filed and processed in a manner inconsistent with the current law. In such a case, a court might find that the system for handling the applications was *ultra vires* and applications filed under that system could not result in the grant of a valid patent. A group of 11 patent experts convened by the Indian Government in 1994 to discuss whether India's laws must be amended to implement Article 70.8 and 70.9 had known this. They specifically had considered the option of implementing the mailbox system administratively and rejected it, finding it far too likely to invite legal challenges to any applications filed under such a system. They had concluded that amendments to the Patents Act to disable the automatic process for forwarding applications to examiners and ultimately rejecting those drawn to pharmaceutical and agricultural chemical inventions were necessary to establish a mailbox system in accordance with Article 70.8.

- India's claim that it had a mailbox system in place was called into question by the fact that it had never notified such a system to the Council for TRIPS, as required by the TRIPS Agreement. The only notification India had made to the Council for TRIPS was the notification setting forth the text of the Patents (Amendment) Ordinance 1994. This notification made it clear to all governments and potential applicants that the system established by the Ordinance created the basis for accepting mailbox applications. In other words, without this system mailbox applications would not be processed or have the legal status required by the TRIPS Agreement. India had never sent a follow-up notification to the Council for TRIPS stating that, notwithstanding the clear requirements of its law, applications for unpatentable subject matter would not be refused and would receive the status required by the TRIPS Agreement.

- India's claim that it had implemented a mailbox system was inconsistent with its obligations under Article 63 of the TRIPS Agreement to publish or make publicly available the specific terms and provisions of its system "*in such manner as to enable governments and right holders to become acquainted with them*" (*emphasis by the United States*). This claim had been made for the first time on 8 April 1997 in a confidential document that would not be circulated to WTO Members, let alone to the public. The private sector had no idea of the existence of this system and those people who, despite all indications to the contrary, had invested time and money in filing applications claiming pharmaceutical and agricultural chemical inventions, had no idea of the legal status of their applications. This could not under any criteria be considered an acceptable implementation of India’s Article 70.8 obligation, particularly in light of the transparency obligations in the TRIPS Agreement, and should create a presumption that it did not have a legally valid system in place. Article 70.8 was clear in its requirement that an open and known process be developed for accepting applications for pharmaceutical and agricultural chemical product patents and granting those applications the proper legal status. The first element of this obligation was the establishment of a system that people knew about and knew how to use. A mailbox system that was unknown to the world was useless.

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

- The principal purpose of the requirement to establish a mailbox system was to ensure that applications that were filed in the transitional period would not lose their novelty and, consequently, to allow mailbox applicants to preserve their ability to obtain patent protection for pharmaceutical and agricultural chemical products in a Member taking advantage of some or all of the transitional period. The benefit provided by the system was such that, when patent protection for pharmaceutical and agricultural chemical products was established, such protection would also be available to persons who had filed applications during the transitional

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

- The mailbox system, therefore, had a rationale common to many other WTO obligations, "namely to protect expectations of the contracting parties as to the competitive relationship between their products and those of other contracting parties"[6]. The *Superfund* report had established clearly the importance of "creat[ing] the predictability needed to plan future trade"[7]. Applicants must be able to anchor, during the transitional period, their right to receive a patent at the end of the transitional period so that they could plan their business operations accordingly (e.g., where to invest, where to move operations, whom to hire, which distribution networks to establish, etc.). As regards how applicants could make informed business decisions based on the right to seek a patent in the future, it should be borne in mind that, if the particular application proved unpatentable in other WTO Members during the transitional period, then this right might not be of much value, but that, on the contrary, if an application proved to be patentable everywhere else, then it would presumably be patentable in India at the end of the transitional period; thus, the current right to seek patent protection based on the appropriate filing date was of great strategic and commercial value to applicants. Article 70.8 established the expectation that through the grant of this legal status to their applications, applicants would be able to establish their competitive position in the country at issue and factor this competitive position into their business plans.

- Despite India's claim that it had decided for the moment not to enforce the mandatory provisions of Sections 5, 12 and 15 of the Patents Act 1970 (which claim was unknown to other governments and the public), that "measure continues to be mandatory legislation which may influence the decisions of economic operators"[8]. The economic operators in the present case - potential patent applicants - had no confidence that a valid mailbox system had been established, and thus would not file mailbox-eligible applications in India. To paraphrase the *Beer II* panel, a non-enforcement of a mandatory law that violated a WTO obligation did not ensure that the obligation was not being broken.[9] Here, Sections 5, 12 and 15 mandated that applications for pharmaceutical and agricultural chemical product patents be forwarded to examiners, determined to be drawn to unpatentable subject matter, and rejected. Because India had failed to establish a fully functional mailbox system that granted mailbox applications the legal status required by the TRIPS Agreement as of their priority filing date,

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

[7]*Id.*

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

[9]*Id.*

large numbers of applications that would have been filed were currently being withheld until India established such a system. Although India would not be obligated to grant patents on such applications meeting the criteria for patentability set out in Article 27 of the TRIPS Agreement as of their appropriate filing date until the end of the transitional period, it would not be sufficient that the legal changes necessary to provide an assurance of patentability were made at the end of the transitional period. Applicants must be given the legal assurance of a current right to the conditional future benefit that they would be able to seek patent protection on the basis of those criteria as of 1 January 1995, allowing them to plan their business operations accordingly as of that time. If a valid mailbox system were established today and an applicant who would have filed in July 1995 did so tomorrow and was assigned its July 1995 filing date, that applicant would be granted the right it must have under the TRIPS Agreement, but would have lost almost two years of shaping its business plan with the knowledge that it had an application with the legal status required by Article 70.8.

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

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

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

- Under India’s legal system there was more than one method by which it could satisfy its obligations under Article 70.8 of the TRIPS Agreement. This could be done by statute, subordinate legislation, such as rules or regulations, and even by administrative instructions and practice. Initially, India had chosen the legislative route to provide a means for receiving applications for pharmaceutical and agricultural chemical products and according priority to them. At present, India administratively continued to receive applications for pharmaceutical and agricultural chemical products and was deferring their examination. Such an administrative decision was permissible under Article 73(1)(a) of the Indian Constitution which provided that "the executive power of the Union shall extend to the matters to which Parliament has the power to make law". Under this constitutional provision, the Executive could act administratively in cases in which Parliament had legislative competence. In the case of providing the necessary "means" under Article 70.8 of the TRIPS Agreement, the relevant legislative power would be Entry 49 of List I or List III of the Seventh Schedule to the Constitution which read "Patents, inventions and designs; copyright; trade marks and merchandise marks". In this connection, two Supreme Court opinions showed that administrative action was an available method for the Executive, namely *J.R. Raghupathy vs State of Andra Pradesh* and *Union of India vs H.R. Patankar and Others*.[11]

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

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

- Advancing evidence of the decision not to take up the applications for examination until 1 January 2005, India referred to a question that had been asked in Parliament about the action taken or proposed to be taken in respect of applications for pharmaceutical and agricultural chemical products (Unstarred Question No. 2601 asked by a Member of Parliament (Lok Sabha)) and the reply given by the Government in Parliament on 2 August 1996 that "the applications for patent will be taken up for examination after 1 January 2005 as per the WTO Agreement which had come into force on 1 January 1995".[12]

- There was no requirement that Parliament should recognize an administrative practice unless explicitly required by the Constitution or statute.

- With regard to the claim of the United States with respect to Article 123 of the Constitution, India stated that Article 123 was intended to enable legislation even when Parliament (either House or both Houses) was not in session. Therefore, the determination that the President was required to make under Article 123 was that it was necessary *to take immediate action* to promulgate an Ordinance despite Parliament not being in session and not that legislation was the only means of satisfying a particular obligation (*emphasis by India*).

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

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

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

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

4.9 India further argued that whether the means of filing provided by India conformed to the requirements set out in Article 70.8 should be considered in accordance with the principle set out in Article 31 of the Vienna Convention on the Law of Treaties that a treaty shall be interpreted in

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

accordance with "the ordinary meaning to be given to the *terms* of the treaty in their *context* and in the light of its *object and purpose*" (*emphasis added by India*). In this connection, India noted that the Appellate Body had, consistently with Article 3 of the DSU, determined the meaning of the terms of the WTO agreements on the basis of the principles of interpretation of the said Vienna Convention.

The terms of the TRIPS Agreement

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

Context

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

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

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

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

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

Object and purpose

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

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

- The only evidence that India could muster to show that it had made a public decision to establish an administrative mailbox system was a question and answer in the Lok Sabha that apparently had taken place on 2 August 1996. However, it was interesting to note that the answer to the question: (a) did not state that the applications that had been filed had been granted the proper legal status; (b) had apparently never been made known to the public (let alone notified to other WTO Members through the Council for TRIPS); and (c) was of no apparent legal effect.

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

4.11 The United States also responded that India could not persuasively claim that individual companies had access to the necessary information. India apparently acknowledged that a mailbox

[13]Paragraph 4 of the opinion

[14]Paragraphs 18 and 30 of the opinion

[15]Paragraph 29 of the opinion

system that was totally unknown to the public was of no value, but claimed that "it is sufficient that individual companies that wish to submit an application can obtain the necessary information from the relevant authorities". Even if India's assertion of what constituted fulfilment of WTO obligations were correct (which it was not), India had not even met this low standard. India repeatedly had made clear to WTO Members, its own nationals, and the rest of the world that it would not have a valid mailbox system in place until it had amended its patent law. The United States Government had attempted for over two years to clarify the situation and had been either ignored or led to believe that India did not have a valid mailbox system in place. There was no reason to expect individual companies to receive any better treatment or information than the United States Government. Individual companies that had filed or would have filed pharmaceutical and agricultural chemical product patent applications in India continued to believe that India did not have a TRIPS-consistent mailbox system in place.[16]

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

- The written answer from the Government to Unstarred Question No. 2601 in the Lok Sabha on 2 August 1996 put beyond any doubt that the applications received had a proper legal status. The Government had stated in this written answer that until 15 July 1996 as many as 893 applications had been received from Indian as well as foreign companies in the fields of drugs and medicine. It had further been stated that these applications would be taken up for examination after 1 January 2005 as per the WTO Agreement which had come into force on 1 January 1995. It was to be borne in mind that the Indian legal system was based upon common law systems and that any statement, more particularly written statement, made in any House of the central legislature, by the Minister who was an authorized functionary of the Government, put that Government under the obligation of the common law doctrine of "estoppel", in the sense that the Government at no stage could perform any act in contravention of the position already taken under that statement.

- As regards the United States' assertion that the answer to Unstarred Question No. 2601 had apparently never been made known to the public, all answers to questions put by Members of Parliament were given in writing and were laid on the table of the relevant House and circulated amongst all Members of that House. The national and international electronic, print and other media had open access to the answers given in the House and widely reported them. Questions and answers given were reported in the Reporters published by the secretariat of the respective House and formed a permanent printed record which was accessible to the public.

- Regarding the United States' assertions based on the two Indian Supreme Court opinions, India stated that it was a settled proposition in Indian law that the executive power of the central government under Article 73 was co-extensive with the legislative power of the Parliament. In other words, it extended over the whole of the territory of India with respect to the matters enumerated in List I (including Entry 49 "Patents, inventions and designs; copyright, trademarks and merchandise marks") and List III of the Seventh Schedule to the Indian Constitution. In *J.R. Raghupathy vs State of Andra Pradesh*, the Supreme Court had stated that the executive powers of the Union under Article 73 were much wider than the

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

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

prerogative powers in England. The provisions of Article 73 of the Constitution as interpreted in *Union of India vs H.R. Patankar and Others* and *J.R Raghupathy vs State of Andra Pradesh* were in the nature of support mechanisms for the legislative provisions in the Patents Act 1970 which formed the basis for the current filing system. The United States had quoted the *J.R.Raghupathy* opinion out of context. The essence of the Supreme Court opinion was that if there were certain deviations from the guidelines set for in-house management of the government departments, the courts did not need to interfere. However, where administrative instructions impinged upon the rights of persons, there was no way out and the courts were bound to come into active play. The explicit position taken by the Supreme Court in *Union of India vs H.R. Patankar* made it clear that even if there were any statutory rules, but they were silent on any particular subject, the Government was competent to fill in the lacunae in the statutory rules.

(b) The United States' claim that Article 70.8 of the TRIPS Agreement requires India to ensure that persons who filed or would have filed mailbox applications had the mailbox been in place on time and maintained can file such applications and receive the filing date they would have received

4.13 The **United States** argued that the number of applications filed in India for pharmaceutical and agricultural chemical products was far less than that which would have been filed had a valid system been in place. Any applications filed subsequent to the expiration of the Patents (Amendment) Ordinance 1994 had been filed by companies willing to take the risk that they would have the legal status required by the TRIPS Agreement. Many other applicants who would have filed had a system been in place had not filed. Under a mailbox system that had been established by 1 January 1995 and subsequently maintained in accordance with Article 70.8 of the TRIPS Agreement, ensuring that applications were assigned their effective filing date was relatively straightforward: applications were simply assigned an effective filing date of either (a) the date they had been filed with the Member, or (b) where that Member granted priority filing benefits, the priority filing date. Where, as in the case of India, a Member had failed to establish a mailbox system by 1 January 1995 and subsequently maintain it, additional steps might be necessary to ensure that applicants were assigned an effective filing date that reflected the filing date they would have received had a mailbox application system been in place.

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

4.15 The **United States** rebutted that it was not seeking a specific remedy in this matter, but a determination by this Panel that India had failed to fulfil the Article 70.8 obligation to ensure that transitional period applicants would be able to obtain patent protection when it became available in India for pharmaceutical and agricultural chemical products, and to establish a means to ensure that applications that were filed in this transitional period would not lose their novelty. Although the number of these applicants was irrelevant since, in light of India's clear violation of the mailbox provisions of the TRIPS Agreement, a showing of actual damage was not a prerequisite to a finding that India's failure to establish a TRIPS-consistent mailbox system was nullifying or impairing benefits under the TRIPS Agreement[18], evidence of the fact that additional applications would have been filed had a legally valid mailbox system been in place on time could be found in the letter from Dr. Harvey E. Bale, Jr.[19,20]

Article 63

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

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

(a)Procedural grounds

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

- The Panel's terms of reference did not cover the United States' Article 63 claim. According to Article 7.1 of the DSU, the mandate of the Panel was to examine the matter referred to the DSB in the document in which the United States had requested the establishment of a panel in accordance with Article 6 of the DSU, i.e. document WT/DS50/4. Neither that request nor, earlier, the United States' request for consultations had raised the issue of transparency or compliance with Article 63 of the TRIPS Agreement. In these requests, the United States had summarized the issues as follows: "The legal regime in India currently does not make patent protection available for inventions as specified in Article 27 of the TRIPS Agreement or provide systems that conform to obligations of the TRIPS Agreement regarding the acceptance of applications and the grant of exclusive marketing rights. As a result, India's legal regime appears to be inconsistent with the obligations of the TRIPS Agreement, including but not necessarily limited to Articles 27, 65 and 70".

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

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

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

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

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

- Under the unusual and unfortunate circumstances of this case - where India had indicated publicly and during consultations that it had no mailbox system in place and refused to answer United States' questions regarding whether such a system existed - it would be appropriate for the Panel to provide the United States with an opportunity to identify specific legal claims regarding transparency during the first substantive meeting. The only reason that Article 63 had not been explicitly referenced previously was that India had maintained for two years that it had no mailbox system in place and first claimed that it had a mailbox system in place in its first written submission to the Panel.

- The basis for the ruling of the *Bananas* Panel was that panel procedures should not operate so as to permit surprise and prejudice of a party's interests. That concept was applicable here, where the interests of the United States would be unfairly disadvantaged if the Panel did not consider, in the alternative, its Article 63 claim.

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

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

[22]*Banana* Panel Report at para. 7.30

(ii) India could not realistically claim surprise, particularly because its own actions had delayed full consideration of this issue. The panel on *Brazil - Measures Affecting Desiccated Coconut* had noted regarding Brazil's refusal to consult that such a refusal was "a matter which this Panel views with the utmost seriousness. Compliance with the fundamental obligation of WTO Members to enter into consultations where a request is made under the DSU is vital to the operation of the dispute settlement system..... pursuant to Article 4.6 of the DSU, consultations are 'without prejudice to the rights of any Member in any further proceedings'. In our view, these provisions make clear that Members' duty to consult is absolute, and is not susceptible to the prior imposition of any terms and conditions by a Member".[23] It was no less serious a matter when a Member refused in consultations to provide information of which it was aware, or gave misleading information in consultations. The Panel could and must respond to this situation through a simple application of the concept of estoppel: where a party had actively refused to respond concerning information within its exclusive control, or had given misleading information in consultations, that party should be held to its earlier representations and estopped from contradicting them at a later stage in the proceeding. At the very least, the other party should be able to present arguments on that information in the ongoing proceeding. Any contrary result would act as an incentive for parties to be as uninformative as possible in consultations and would lead to a breakdown in the WTO dispute settlement process.

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

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

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

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

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

[23]WT/DS22/R, para. 287

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

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

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

The extremely tight timetables for panel work set out in the DSU entailed the need for complainants to carefully prepare their case in advance of the proceedings and incorporate in their first submission all their factual and legal claims. According to paragraph 12 of the Working Procedures annexed to the DSU, five to eight weeks normally lapsed between the receipt of the first written submission of the complainant and the receipt of the written rebuttals. Thus, while the complainant could prepare its case without any time constraint, the respondent normally had only five to eight weeks to prepare its rebuttal, which created a significant imbalance between complainants and respondents. According to the Working Procedures, only two to three weeks normally lapsed between the first meeting of the Panel and the receipt of the written rebuttals. If the complainant were permitted to make new claims at the time of the first substantive meeting, the time available to prepare the rebuttal would therefore be reduced by more than half and the existing imbalance would be exacerbated to the point of effectively curtailing the respondent's right to be given sufficient time for the preparation of its rebuttal - a right which Article 12.10 of the DSU specifically accorded to developing countries.

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

[24]Paragraph 7.57 of the report

- The United States had no information as to what might be in an Indian staffer's notes from the consultations held with India, but could state, as it had throughout this proceeding, that until India's first written submission to the Panel, the Indian Government had never stated that it had established a valid mailbox system. Had the Indian Government made this assertion earlier, the United States would necessarily have included a reference to Article 63 of the TRIPS Agreement in its panel request. In light of this surprise, equity demanded that the Panel be able to take up the transparency issue, in the alternative.

- India had been given three opportunities to respond to the United States' alternative transparency claim under TRIPS Article 63[25], and its last written submission on this issue had been submitted seven weeks after the first substantive meeting of the Panel with the parties. India had therefore had a reasonable opportunity to respond to this issue. Furthermore, India could not claim prejudice to third parties as a basis for refusing a claim under Article 63. Article 10.3 of the DSU stated that "[t]hird parties shall receive the submissions of the parties to the dispute to the first meeting of the Panel". The rules of the DSU provided for third parties no more than the opportunity to present views to a panel. Dispute settlement was conducted first and foremost for the benefit of the parties to the dispute, not for the benefit of third parties or possible third parties.

(b) *Substantive grounds*

4.22 **India** also disputed the United States' claims regarding the transparency obligations under Article 63 on the basis of substantive grounds. It recalled the arguments summarised in paragraph 4.7 and 4.12 above and put forward the following additional arguments:

- Article 63 applied to developing countries only as of 1 January 2000. According to Article 65.2 of the TRIPS Agreement, developing countries were entitled to delay up to 1 January 2000 the date of application of the TRIPS Agreement except for its Articles 3, 4 and 5. Consequently, the provisions of Article 63 established obligations applicable to India only as of 1 January 2000. It was true that the minutes of meetings of the Council for TRIPS made reference to a "Working Hypothesis" according to which national laws and regulations would be notified as of the time that the corresponding substantive obligation applied[26], but this "Working Hypothesis" did not reflect a common understanding among Members on their obligations under the TRIPS Agreement. It had been elaborated because the differences of interpretation among Members on the scope of the transparency obligations during the transitional period could not be overcome. At the meeting of the Council for TRIPS of 21 September 1995, the Chairman had noted the existence of the "Working Hypothesis" but then correctly had stated that the "basic differences of interpretation had remained".[27] An informal arrangement of this type did not establish obligations binding under international law and could therefore not modify rights or obligations under a WTO agreement. The legal situation under Article 63 had not been changed as a result of the elaboration of the "Working Hypothesis".

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

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

[27]*Id.*

- As regards paragraph 1 of Article 63, which was the only paragraph the United States had referred to at the first substantive meeting of the Panel with the parties while not having specified any paragraph in its written submission, India took the view that the law on which India had based its means of filing had been published. This means of filing had been established on the basis of the Patents Act 1970 which, like all other acts of Parliament, had been published in the Gazette of India. According to Article 63.1, only "laws and regulations, and final judicial decisions and administrative rulings of general application" had to be published. The decision of India to continue to receive applications for pharmaceutical and agricultural chemical product patents under the Patents Act was an administrative measure of a kind that did not need to be published under Article 63.1. Under that provision, only the law on which this measure was based was subject to the publication requirement.

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

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

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

Article 70.9

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

[28]Paragraph 2.1 of document IP/C/2

[29]*Id*. at paragraph 2.2

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

(a) Timing

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

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

The terms of the TRIPS Agreement

- According to Article 70.9, exclusive marketing rights must be granted by India to a pharmaceutical or agricultural chemical product for which a patent application had been made only *after* the product met the following conditions:

  (a) A patent *application* had been filed in respect of that product in another Member of the WTO *after 1 January 1995*.

  (b) The other Member of the WTO had *granted the patent*.

  (c) The *other Member had approved the marketing* of the product.

  (d) *India had approved the marketing* of the product.

(*emphases above by India*)

- The last step in the procedures prior to eligibility - marketing approval in the Member not according patentability - was a step controlled by the Member that must subsequently grant exclusive marketing rights or patentability. It was consequently not an abstract category of products that was eligible for exclusive marketing rights under Article 70.9; the individual products that were eligible would be known before the duty to accord exclusive marketing rights arose. Article 70.9 was a transitional provision the application of which was triggered by specified future events.[31]

[30]See paragraph 4.9 above

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

- The United States had not presented evidence showing that all the above-mentioned events had occurred with respect to a particular pharmaceutical or agricultural chemical product. The principal products covered by Article 70 were drugs and medicines. It took considerable time to obtain a patent for such products and then to obtain the marketing approval first in the country of origin and then in the country in which exclusive marketing rights were sought under Article 70.9. So far, no request for exclusive marketing rights had been received by the Government of India. There was, therefore, no question of India having denied exclusive marketing rights to any product entitled to such rights under Article 70.9 of the TRIPS Agreement.

- According to the text of Article 70.9, an exclusive marketing right must be granted for a pharmaceutical or agricultural chemical product only "until a product patent is granted or rejected in that Member". The terms of Article 70.9 thus explicitly accorded developing country Members the right to choose between the grant of patentability and the grant of exclusive marketing rights with respect to each pharmaceutical or agricultural chemical product for which a patent application had been made. It would be logically inconsistent with this right to opt out of the obligation to grant exclusive marketing rights if Article 70.9 were interpreted to oblige Members to provide in their legislation for the general availability of exclusive marketing rights as from 1 January 1995.

Context

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

Object and purpose

- Article 70.9 formed part of the transitional arrangements for developing countries and its object and purpose could therefore only be ascertained in the light of these arrangements.[32] According to Article 70.9, an exclusive marketing right had to be granted only for a maximum period of five years. This five-year period corresponded to the five-year period by which developing country Members might, according to Article 65.4, delay the application of the provisions on product patents in areas of technology not protectable on 1 January 1996, i.e. the period between 1 January 2000 and 1 January 2005. The purpose of Article 70.9 was thus to give inventors of pharmaceutical and agricultural chemical products the economic privilege of an exclusive marketing right for the five-year period preceding 1 January 2005 if their products were denied patentability even beyond the normal five-year transitional period for developing countries. It would be completely contrary to this purpose to interpret Article 70.9 as giving rise to obligations before 1 January 2000. That Article 70.9 essentially related to events that the drafters expected to take place during the period covered by Article 65.4 became obvious when one analysed the practical operation of Article 70.9. In order to be eligible for the grant of an exclusive marketing right, a United States' inventor must have filed a patent application in the United States after 1 January 1995 and have been granted the patent in the United States and marketing approval in both the United States and in India. Common sense and practical experience indicated that all these steps took a long time and normally the products in question would not get on the market in a developing country before the expiry of the ten-year transitional period. The provision had been made for the grant of exclusive marketing rights of up to five years only to tide over the gap between the obtaining of marketing approval and the grant of patent protection for the product in question in a developing country benefiting from the ten-year transitional period, so that inventions that met the criteria for patentability on or after the date of entry into force of the Agreement would become eligible for protection in such countries by the time that protection became of commercial significance, either by the grant of a patent after the expiration of the ten-year period or by an exclusive marketing right for products getting marketing approval before that time. Commentators had confirmed these practical implications.[33]

- That the object and purpose of Article 70.9 were not to oblige developing countries to make exclusive marketing rights available immediately upon the entry into force of the WTO Agreement but to tide over the gap between marketing approval and patentability during the five years preceding the end of the ten-year transitional period could also be deduced from commercial realities. In general, it simply made no commercial sense to obtain an exclusive marketing right for a five-year period unless that period was immediately followed by the grant of the exclusive rights to be conferred on patent owners under Article 28 of the TRIPS Agreement. If the inventor of a pharmaceutical product obtained an exclusive marketing right in 1997 and made his product known and widely used in India, his competitors could enter the market in the year 2002 and free-ride on the inventor's marketing efforts for three years. Only in the year 2005 could the inventor again enjoy the exclusive rights of a patent owner. Thus, even if an inventor had succeeded in obtaining a patent in the United States and marketing

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

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

approval in the United States and India within a period of less than five years, he would nevertheless in most situations have a commercial interest to request exclusive marketing rights only in the year 2000 so as to ensure a seamless transition from exclusive marketing rights to the exclusive rights of a patent owner. The economic purposes of Article 70.9 would thus not be furthered if it were interpreted to give rise to obligations before 1 January 2000.

- Article 70.9 obliged a Member to grant exclusive marketing rights for a particular product only "until a product patent is granted or rejected in that Member". Under Article 70.9 developing countries were thus explicitly given the right to choose between the grant of exclusive marketing rights and the grant of patentability. The economic impact of the grant of an exclusive marketing right was very similar to that of the grant of the exclusive rights to be conferred under Article 28 on the owners of patents. Moreover, exclusive marketing rights must be granted even for those products for which a patent could be rejected consistently with the TRIPS Agreement. The function of Article 70.9 was thus not only to create rights for holders of patents in other Members but also to give developing country Members an incentive to opt for patentability. Under the United States' interpretation the provision could not fulfil this function.

- According to the United States' interpretation of Article 70.9, developing countries would be obliged to take a decision on the patentability of pharmaceutical and agricultural chemical products immediately while being able to postpone that decision with respect to all other products until 1 January 2000. This interpretation therefore frustrated the basic purpose of the transitional regime established by Articles 65 and 70, which was to give developing countries the right to postpone sensitive decisions beyond the date of entry into force of the WTO Agreement. In fact, this interpretation would turn Article 70 on its head because it would oblige developing countries to decide on the patentability of pharmaceutical and agricultural chemical products *before* having to implement the TRIPS Agreement with respect to other products (*emphasis by India*).

- Examination of the 14 notifications submitted to the TRIPS Council under Article 63.2 of the TRIPS Agreement showed that not one of these notifications provided that exclusive marketing rights were made available as from 1995 in the domestic law.

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

- As was the case with Article 70.8, India had made it clear that modifications to its intellectual property system were necessary to implement the requirements of Article 70.9.[35] While India was correct in its claim that Members were free to determine the manner in which

[34]Reference was made to the Appellate Body report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India" *(Wool Shirts)*, WT/DS33/AB/R, p. 13. Additionally, the *Superfund* report made clear that "the impact of a measure inconsistent with [an applicable agreement] is not relevant for a determination of nullification or impairment by the CONTRACTING PARTIES" ("United States - Taxes on Petroleum and Certain Imported Substances" *(Superfund)* adopted on 17 June 1987, BISD S34/136, at 156).

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

they implemented their obligations, Members were not free to determine whether their obligations must be implemented at all. India had repeatedly made clear that, unless its laws and regulations were modified, it would not have implemented its obligations under Article 70.9. Having made this matter clear, it was unable to assert now that, because it had discretion as to the manner in which it fulfilled its Article 70.9 obligations, it could decide to do nothing.

- Regarding India's claim that it was in compliance with its obligations under Article 70.9 because no person had been denied exclusive marketing rights in India and that this was a matter for future implementation, the United States said that right holders had not been denied exclusive marketing rights because they had not sought such rights and they had not sought such rights because there were no such rights under Indian law or regulations to seek. Right holders would not even know to whom they should apply, let alone the procedures and costs involved or, since India had also failed to establish a mailbox application system, who would be eligible to request such protection had a system been in place. Even now, nearly two and a half years after the TRIPS Agreement had come into force, India had not stated where applications could be filed, what procedures would be followed, what authority would be responsible for reviewing applications, and the way in which rights would be enforced. In the absence of relevant information, it was impossible for a national of a WTO Member to request such protection, even if it were available.

- Even though the level of actual damages suffered by United States' interests was irrelevant, since the United States had made a *prima facie* showing that India had failed to implement its obligations under Article 70.9 and it was, consequently, unnecessary for the United States to identify particular companies that would be eligible for exclusive marketing rights, the United States understood from its private sector that, had a mailbox system been in place since 1 January 1995, and had exclusive marketing rights been provided in accordance with Article 70.9, some companies would have begun seeking exclusive marketing rights under Indian law. Their ability to do so was dependent on the Indian health authorities processing their applications, but they had met all the requirements for such protection other than those dependent on the actions of the Indian health authorities. Evidence of this could be found in the letter to Ambassador Barshefsky from Dr. Harvey E. Bale, Jr.[36]

- The obligation in Article 70.9 to establish a system for the grant of exclusive marketing rights was not distinguishable from any other obligation in the TRIPS Agreement and did require changes in India's laws. Article 70.9, like Article 27, required the grant of certain rights upon the fulfilment of specified conditions. In the case of Article 27, a patent must be granted if an application was filed that was drawn to an invention that met the criteria of novelty, non-obviousness and industrial application. In the case of Article 70.9, exclusive marketing rights must be granted if a mailbox application was filed that met the criteria set out in Article 70.9. Both provisions demanded the establishment of a system for the grant of the specified rights.

- As with the obligation to establish a fully functional mailbox system under Article 70.8, the obligations in Article 70.9 established expectations on the part of WTO Members and potential applicants that exclusive marketing rights would be available. As long as India did not have in place a system for the grant of those rights, potential applicants would not be able to request the grant of such rights, let alone make informed business decisions with the understanding that such rights might be requested and granted. The expectations created by

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

the inclusion of Article 70.9 in the TRIPS Agreement would be frustrated until India had established a clear and stable system for the grant of such rights. The *Superfund* case was thus relevant to this matter because it clarified that Members were obligated "to protect expectations" of other Members as to the "competitive relationship" between their respective products. Moreover, in applying the principle behind the *Superfund* decision to the present case, there was no need to wait for a violation to take place or speculate on whether it would take place, since the present case concerned a failure to take an affirmative action to implement a specific obligation in a WTO agreement.

- The grant of an additional five years in Article 65.4 to implement the provisions on product patent protection in Article 27 of the TRIPS Agreement had been balanced against the inclusion of obligations to establish fully functional mailbox and exclusive marketing rights systems in Articles 70.8 and 70.9. India could not now be permitted to pocket the benefit of an additional five years of transition and not implement the corresponding obligation. The Appellate Body recently had made this clear in the *Wool Shirts* case, in which India had argued that under the Agreement on Textiles and Clothing (ATC) the burden of proof should be shifted to the importing country taking temporary safeguard action. In rejecting the Indian argument, the Appellate Body had clarified that the ATC was a transitional arrangement containing "carefully negotiated language..... which reflects an equally carefully drawn balance of rights and obligations of Members.....".[37] This characterization was equally applicable to the balance between the transitional rules in Article 65.4 of the TRIPS Agreement and the obligations established in Article 70.8 and 70.9 of the TRIPS Agreement. As the Appellate Body succinctly had stated in the *Wool Shirts* report "[t]hat balance must be respected".[38] The *quid pro quo* for taking advantage of the transitional period was the grant of exclusive marketing rights. Far from turning Article 70.9 on its head, this represented the core balance in this area of the Agreement. If India did not want to grant patents, then it must grant exclusive marketing rights; conversely, if it did not want to grant exclusive marketing rights, then it must grant patents.

- There was nothing in the Agreement indicating that the obligation to provide exclusive marketing rights arose only after 2000. When the drafters of the Agreement intended a transitional period to apply to a particular obligation, they had specifically included the transition in the Agreement. There was no such transition with respect to the obligations in Article 70.9. On the contrary, Article 70.9 specifically stated that the obligation to provide exclusive marketing rights applied "notwithstanding the provisions of Part VI" of the TRIPS Agreement, which established the transitional periods. As a result, just as with Article 70.8, the obligations of Article 70.9 must be fulfilled as of the date of entry into force of the WTO Agreement.

- India had provided no support for its argument that the obligation to comply with Article 70.9 had not yet arisen. None of the commentators India had quoted had stated that it was impossible for a pharmaceutical or agricultural chemical product to fulfil all the criteria for the grant of exclusive marketing rights. They all left open the possibility that those criteria might be fulfilled long before the end of the transitional period and none of them suggested that the obligation to implement Article 70.9 did not arise on 1 January 1995. Moreover, as

[37]Appellate Body Report on "United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India" p.16, citing the Appellate Body Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", adopted 25 February 1997, WT/DS24/AB/R, p.15

[38]*Id.*

Dr. Bale's letter[39] showed, there was at least one company that was seeking exclusive marketing rights in India in respect of two pharmaceutical products.

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

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

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

- If the United States' argument that it would be easier to plan business if the transitional provisions of the TRIPS Agreement were interpreted to require legislative changes before the end of the transitional period were accepted, it would have to be applied to all the transitional arrangements contained in the WTO agreements. Thus, it would arguably be easier for Indian textiles' producers to plan business if all textiles-importing WTO Members had legislation presently in place providing for the elimination of textiles import restrictions on the date of the termination of the Agreement on Textiles and Clothing. Unfortunately, however, the obligation to bring the textiles restrictions into conformity with the GATT would arise only in the future just as the obligation to grant patents or exclusive marketing rights only arose in the future. Until the end of the transitional periods accorded under different WTO agreements, the source of predictability could therefore only be the relevant WTO agreement. The CONTRACTING PARTIES had never applied the principles invoked by the United States in the manner suggested by the United States. To do so would constitute an unanticipated change in obligations that could not legitimately be brought about by way of interpretation, and to do so only in the field of intellectual property rights but not in the many other areas covered by transitional arrangements would be fundamentally unfair.

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

- India's research had not revealed any case in which a product for which a patent application had been filed after 1 January 1995 had received marketing approval in India and had thus become eligible for exclusive marketing rights in India under Article 70.9. The letter from Dr. Bale produced by the United States merely stated that one company "has received a patent and marketing approval for a drug in the United States and Europe and is ready to request the grant of exclusive marketing rights from the Indian health authorities". The request that this company intended to submit to the Indian health authorities was obviously a request for marketing approval; only when that approval had been obtained would this product become eligible for exclusive marketing rights. There was no evidence available in India of any such case. It should also be noted that before any applicant could make such a request, it must first request the Indian health authorities, i.e. the Drugs Controller General of India, to grant marketing approval.

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

4.30 The **United States** reiterated that it knew of two pharmaceutical products that were now becoming eligible for exclusive marketing rights under Article 70.9. The only step remaining was the establishment by India of a system for the grant of such rights so that an application for marketing approval/exclusive marketing rights could be filed and processed. The United States' pharmaceutical company Eli Lilly Corp. had two pharmaceutical products that were the subject of a patent application filed in the United States after 1 January 1995 and had been granted patent protection and marketing approval after that time. This company was in the process of determining how to apply for exclusive marketing rights in India and had asked the United States' Government for any information it had on the process for doing so. The United States could not say, for example, whether the company must indicate in its application for marketing approval that it was a candidate for exclusive marketing rights, and whether it must include a fee to preserve its ability to get those rights. Alternatively, the United States could not say whether any special procedure for the grant of exclusive marketing rights had been established (i.e. whether the application for marketing approval would result automatically in the grant of exclusive marketing rights). The United States indicated that companies would be wary about

proceeding without knowing what the system for the grant of such rights was, for fear of losing their ability to receive those rights because of some procedural problem. The United States' Government had no information on the Government of India's intended system for the grant of these rights.

(b) The scope of "exclusive marketing rights"

4.31 As regards the exclusive marketing rights to be provided in accordance with the standard set forth in the Agreement, the **United States** argued that Article 70.9 required India to grant exclusive marketing rights that were not subject to compulsory licences or any other form of use without the permission of the right holder. Since Article 70.9 did not define the term "exclusive" when used with marketing rights, either explicitly or through reference to other provisions of the TRIPS Agreement, this unqualified term should be applied based on its ordinary meaning.[1] The term "exclusive" was defined in the Oxford English Dictionary as meaning "[h]aving the power or the function of excluding" or "[e]xcluding all other persons from the rights conferred".[1] The ordinary meaning of the terms used would therefore indicate that no competitors were permitted on the market without the consent of the holder of the "exclusive" marketing rights. There was no basis to believe that the drafters had intended to depart from this ordinary meaning of "exclusive marketing rights".

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

- The United States was seeking a ruling on a potential future measure. The United States was apparently asking for this finding because of concerns it had about the nature of some provisions in the lapsed Patents (Amendment) Ordinance 1994 and the Patents (Amendment) Bill of 1995, which would have accorded the Government discretionary powers to subject exclusive marketing rights to certain conditions. However, even the said Ordinance and Bill did not make it mandatory for the executive authorities to grant exclusive marketing rights subject to compulsory licensing or other use. However, since neither of these instruments was in force in India, the scope of exclusive marketing rights was a matter that had not yet arisen. The United States was thus essentially asking the Panel to make a declaratory judgement on a potential future action that the executive authorities of India might be authorized to take on the basis of a law Parliament might adopt.

- The WTO dispute settlement procedures did not permit rulings on potential future measures. Article 64 of the TRIPS Agreement stated that the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the DSU shall apply to consultations and the settlement of disputes under the TRIPS Agreement except as otherwise specifically provided in that Article. The texts of Article XXIII:1(a) of GATT 1994, Article 19.1 of the DSU and Article 22.8 of the DSU made clear that the provisions defining the cause of action, the remedy available and the scope for retaliation all presupposed the existence of a measure that was *currently* nullifying or impairing benefits and capable of being brought into

[40]Reference was made to the Vienna Convention on the Law of Treaties, Article 31.1. The Appellate Body has recognized that both Article 31 and Article 32 of the Vienna Convention apply to disputes under the WTO Agreement. Appellate Body Report on "Japan-Taxes on Alcoholic Beverages" (adopted 1 November 1996), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, pages 10-13.

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

conformity with the obligations under the WTO Agreement (*emphasis by India*). The only WTO procedure that permitted the resolution of interpretative issues in the abstract was that set out in Article IX:2 of the WTO Agreement, according to which the WTO Ministerial Conference and the General Council had the power to adopt authoritative interpretations.

- The customary practice of the CONTRACTING PARTIES to GATT 1947 had been to examine under Article XXIII only measures that were currently applied. The CONTRACTING PARTIES had never ruled on potential future measures or what type of law might be required to meet *future* obligations (*emphasis by India*). They had proceeded on the assumption that a contracting party would meet its obligations under the GATT as long as its legislature had not yet taken a decision to the contrary or had left the executive authority the option of acting in accordance with the GATT.[42] According to Article XVI:1 of the WTO Agreement "the WTO shall be guided by the..... customary practices of the CONTRACTING PARTIES to GATT 1947.....". In *Japan - Taxes on Alcoholic Beverages*, the Appellate Body had noted that Article XVI:1 of the WTO Agreement brought the legal history and experience under GATT 1947 into the realm of the WTO in a way that ensured continuity and consistency. The customary practice of the CONTRACTING PARTIES, while not binding on panels, should be taken into account by panels where relevant to any dispute. The Panel could therefore not deviate from the customary practice of the CONTRACTING PARTIES without due cause and justification.

- Panel rulings on potential future measures would be regarded by the WTO Membership as an unacceptable interference in domestic decision-making processes. GATT contracting parties had generally refused to consult under the formal dispute settlement procedures on measures they had not yet taken. When asked to consult on provisions in the Treaty of Rome that accorded the European Communities the competence to impose quantitative restrictions inconsistently with the GATT, the European Communities had pointed out that "many contracting parties had permissive legislation of a general character which, if implemented in full, would enable them to impose restrictions in a manner contrary to Article XI. These countries were, however, not required to consult with the CONTRACTING PARTIES about their possible intentions as regards the implementation of such legislation".[43] The United States had shared this view in the past, as illustrated by its reaction to the report of the panel on *Wine and Grape Products*[44] which had examined a law which *mandatorily* imposed on the executive authority the requirement to apply a definition of industry for the purposes of anti-dumping and countervailing duty investigations of wine and grape products that was inconsistent with the Tokyo Round Subsidies Code (*emphasis by India*). When this report was adopted in 1992, the United States had declared that it "reserved its *position of opposition to the Panel's view that it was ripe for the Panel to consider a matter that did not involve an actual initiation of an action, but rather an abstract question* whether a proceeding, if initiated, would have been consistent with the Subsidies Code"[45] (*emphasis by India*). In a case involving countervailing duties, the United States had thus formally objected to a panel

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

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

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

[45]Reference was made to GATT document SCM/M/59, p.31.

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

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

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

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

- Unlike many other provisions of the WTO agreements, the TRIPS Agreement contained obligations to act affirmatively to establish rights, procedures and remedies in respect of intellectual property. The United States was not alleging that India had taken an action that was inconsistent with its obligations under the TRIPS Agreement; on the contrary, it believed that India had failed to take affirmative actions that it was required to take under the TRIPS Agreement. In defining how India had violated the TRIPS Agreement, the Panel must indicate with some specificity which affirmative obligation India had not met. It was important to distinguish between the request that the Panel define how India was out of compliance with its TRIPS obligations and the request that the Panel suggest a way in which India could meet those obligations. The requested finding above represented an example of a request to define what obligations India had not met. The request that the Panel suggest that India implement these obligations in a manner similar to the way in which Pakistan was implementing these obligations was an example of the second category. India was attempting to blur the

[46]Reference was made to the GATT Council discussion on unilateral measures in February 1989 (GATT document C/163)

distinction between these two categories and between the affirmative obligations in the TRIPS Agreement and the prohibitions found in other WTO agreements.

- India had not contested, nor could it contest, that the TRIPS Agreement required that exclusive marketing rights be granted so that competitors were not permitted on the market without the consent of the right holder. There was no basis in the TRIPS Agreement to conclude that the drafters had intended to depart from the ordinary meaning of the terms used. Whenever they had intended a type of right to be subject to permissive or mandatory exceptions, they had provided specifically for such exceptions in the text defining the right.[47] Likewise, where the permissive or mandatory exceptions applying to one type of right were intended to apply to another type of right, this had specifically been provided in the text of the Agreement.[48] Therefore, had the drafters of the Agreement intended the exclusive marketing rights to be subject to a permissive or mandatory exception, they would have either included such exception in the text of Article 70, or they would have incorporated by reference an exception in another part of the Agreement. India had failed to grant to the holder of marketing rights the exclusive right to control the entry of competitors onto the market during the period of those rights and, thereby, to implement Article 70.9.

Request for a suggestion that India implement its obligations under Article 70.8 and 70.9 in a manner similar to the way in which Pakistan had implemented these obligations

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

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

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

- It had serious doubts whether a panel constituted to resolve a dispute on the basis of rights and obligations enshrined in a multilateral agreement should formally endorse a settlement bilaterally negotiated between two sovereign States in the context of their particular overall relations.

- There were technical reasons that would make it inappropriate to transpose the system adopted by Pakistan to India. Pakistan had agreed with the United States that the relevant date of filing

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

[48]According to the United States, the example of this approach to exceptions could be found in the TRIPS Agreement's Section on lay-out designs of integrated circuits (Article 37.2).

[49]Reference was made to document IP/D/2/Add.1

[50]For a further elaboration by India of this argument, see above in relation to Article 63.

for the purposes of Article 70.8 would be the date on which a patent application had been filed not in Pakistan, as foreseen in Article 70.8, but *in another Member* (*emphasis by India*). In India, patent applications for pharmaceutical and agricultural chemical products had been filed and a filing date had been given to each of these applications. The United States' request for a panel suggestion would therefore imply that applications made in other Members would have to be inserted by India into the queue of applications already made. Consequently, the order of priority of the applications would have to be changed in a manner that was not foreseen in the TRIPS Agreement and that favoured some Members over others. The United States was therefore requesting that the Panel suggest a solution whose consistency with the TRIPS Agreement would be doubtful in the case of India.

V. ARGUMENTS PRESENTED BY THIRD PARTY

European Communities and their Member States

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

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

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

- Questions arose as to what were the precise terms of the administrative instructions, where they had been published and what were the guarantees in case of a dispute before the Indian courts. In answering these questions, India would have to admit that simple administrative instructions did not fulfil the requirements laid down in Articles 70.8 and 70.9.

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

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

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

VI. INTERIM REVIEW

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

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

- In respect of Article 70.8 of the TRIPS Agreement, India did not share the Panel's assessment of the legal situation in India;

- It was procedurally and legally incorrect for the Panel to rule on Article 63 of the TRIPS Agreement, mainly because the United States had requested a ruling on this provision only in case the Panel were to find that India had a valid mailbox system in place; and

- The Panel's discussion of Article 70.9 of the TRIPS Agreement did not define the issue presented to the Panel correctly and did not fully take into account India's arguments.

The Panel carefully examined these assertions, as elaborated below.

Article 70.8

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

6.4 The Panel was not persuaded by these arguments. As explained in paragraph 7.31 below, the obligation under Article 70.8 was a special obligation imposed on those Members benefitting from the transitional arrangements, clearly distinguishable from the obligation to provide full patent protection under Article 27. Regarding the assessment of the legal situation in India, as stated in paragraph 7.40 below, the Panel felt that the United States had successfully raised questions as to the legal security of the current "mailbox" system in India and that India had failed to rebut these challenges. In the Panel's view, India's explanation on why the mailbox system that it had put in place administratively was not in contradiction with current law nor with the Constitution[51] did not remove concerns on the legal security of the system.

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

Article 63

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

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

6.8 The Panel was not persuaded by this argument. The Panel felt that India's reading of the term "made effective" was unduly narrow. The consistency of a measure with a Member's international obligations under the WTO Agreement and the putting of the measure into effect in the Member's

[51]Paragraph 4.12 above

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

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

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

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

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

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

[52]Article 68 of the TRIPS Agreement

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

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

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

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

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

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

Article 70.9

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

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

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

6.16 India further objected to the summary of India's arguments which now appears in paragraphs 7.57 to 7.62. According to India, India did not argue that Article 70.9 applied only as from certain dates or only during certain periods, nor could India be reasonably expected to indicate such dates. India's essential argument was that, because operators would "normally" be interested in exclusive marketing rights only in the five-year period preceding patentability, the objective of Article 70.9 could not have been to oblige developing countries to change their laws as from the entry into force of the WTO Agreement. The gist of India's argument was that there was simply no economic or political reality

[55]Appellate Body Report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India", adopted on 23 May 1997, WT/DS33/AB/R, page 19

[56]Appellate Body Report on "Canada - Certain Measures Concerning Periodicals", adopted on 30 July 1997, WT/DS31/AB/R, page 22

behind the assumption that Article 70.9 had been drafted with the objective to make developing countries change their laws as from the entry into force of the WTO Agreement. For reasons expressed in paragraphs 7.58 and 7.59 below, the Panel did not agree with India's argument, and did not find it necessary to change its conclusions in this respect. However, at the suggestion of India, the Panel modified what is now paragraph 7.57.

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

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

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

6.18 The interim report contained a heading entitled "Practical Considerations" immediately preceding what is now paragraph 7.60. India stated that it did not understand why the Panel had created a separate section given that such considerations were only relevant to the extent that they elucidated the context, object and purpose of Article 70.9. India suggested the deletion of the heading, which the Panel accepted.

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

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

[58]Appellate Body Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", adopted on 25 February 1997, WT/DS24/AB/R, page 17

Suggestions by the Panel

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

VII. FINDINGS

A. Claims of the parties

Introduction

7.1 This dispute arises essentially from the following facts. Section 5 of the Indian Patents Act 1970 does not permit product patents to be granted in respect of "substances intended for use, or capable of being used, as food or as medicine or drug".[59] Only "claims for the methods or processes of manufacture shall be patentable" in respect of those substances.[60] Thus, India currently does not make available patent protection for pharmaceutical and agricultural chemical products commensurate with the obligations of Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), which requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology ... " subject to certain exceptions not applicable in this case and to the transition provisions of Articles 65.4 and 70.8 of the TRIPS Agreement.

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

7.3 The Ordinance had been issued in exercise of the powers conferred upon the President by Article 123 of the Indian Constitution, which enables the President to legislate when Parliament (either House or both Houses) is not in session and the President "is satisfied that circumstances exist which render it necessary for him to take immediate action". However, such Presidential actions expire six weeks after the reassembly of Parliament. Thus, under the relevant provisions of the Indian

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

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

[61]Section 12 sets out the procedure for the reference of patent applications by the Controller to examiners (see Annex 1 of this report).

[62]See document IP/N/1/IND/1

Constitution, the Patents Ordinance 1994 lapsed on 26 March 1995.[63] In March 1995, the Indian administration introduced the Patents (Amendment) Bill 1995 into Parliament to implement the contents of the Ordinance on a permanent basis. However, the Bill lapsed because of the dissolution of Parliament on 10 May 1996. The expiry of the Ordinance was not publicized, nor was it notified to the Council for TRIPS.

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

7.5 Under the current Indian legislation, there is no legal basis - procedurally or substantively - for the grant of exclusive marketing rights when a product which is the subject of a patent application under Article 70.8 (commonly called a "mailbox" application) becomes eligible for protection under Article 70.9 of the TRIPS Agreement. So far, no request for the grant of exclusive marketing rights has been submitted to the Government of India.

Claims of the Complainant

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

Claims of the Respondent

7.7 India essentially claims that (i) India has provided a means for filing patent applications for pharmaceutical and agricultural chemical products that is consistent with Article 70.8 of the TRIPS Agreement; (ii) India is not obligated to establish a system for the grant of exclusive marketing rights under Article 70.9 before all the conditions for the grant of the rights stipulated therein have been met in

[63]See paragraph 2.3 above

[64]See paragraph 2.11 above

[65]See paragraph 2.8 above

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

respect of a specific product; and (iii) the United States' requests for the findings described in (b) and (e) of the previous paragraph are requests for specific remedies or declaratory judgements inconsistent with Article 19 of the DSU in that they do not relate to the legal consistency of the existing measures but to the ways in which India is to implement its obligations. Regarding the United States' alternative claim on transparency (i.e., item (c) in the previous paragraph) and its request that the Panel suggest how India should implement its obligations under Article 70.8 and 70.9 (i.e., item (f) in the same paragraph), India requests the Panel to dismiss them because (iv) the Panel's terms of reference do not cover the United States' Article 63 claim and the scope of factual and legal claims cannot be expanded after the first written submission; and, in the alternative, (v) Article 63 does not apply to India until 1 January 2000 under Article 65.2 of the TRIPS Agreement and, in any event, the means of filing that it has established is based on the Patents Act 1970, which has been published.

B. Procedural Issues

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

Article 6.2 of the DSU provides that:

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

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

> "While a reference to a specific provision of a specific agreement may not be essential if the problem or legal claim is otherwise clearly described, in the absence of some description of the problem, a mere reference to an entire agreement or simply to 'other' unspecified agreements or provisions is inadequate under the terms of Article 6.2. Accordingly, we find that references to a WTO agreement without mentioning any provisions or to unidentified 'other' provisions are too vague to meet the standards of Article 6.2 of the DSU."[69]

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[67] WT/DS50/4

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

[69] *Id*., para. 7.30

Furthermore, the panel stated that:

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

7.9 While we do not disagree with the general conclusions of the *Bananas* panel on this point, there is an important difference between the *Bananas* case and the present case: this Panel ruled, at the outset of the first substantive meeting held on 15 April 1997, that all legal claims would be considered if they were made prior to the end of that meeting; and this ruling was accepted by both parties. However, we do not intend to cut off India's objection solely based on this ground. It would seem unfair to do so in view of the fact that India had not heard the new United States' arguments when the ruling was made.

7-10 We now look at the admissibility of each of these requests in turn, first that relating to the transparency obligations under Article 63 and then that relating to implementation.

Transparency

7.11 In respect of the transparency issue, there are two other significant differences between the *Bananas* case and this case. First, as noted above, Article 6.2 of the DSU requires the panel request, which effectively sets a panel's terms of reference in most cases, to "provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly". The United States argues that the "problem" in this case is India's failure to implement a mailbox system that allows and grants legal status to submissions of certain patent applications. In its view, if India has a valid system in place, its failure to make that system known to WTO Members is part of this "problem".[71] We agree. The *Bananas* panel noted in the passage quoted above that: "a reference to a specific provision of a specific agreement may not be essential if the problem or legal claim is otherwise clearly described". Here, there is a more detailed description of the "problem" that the United States alleges in respect of Indian non-compliance with the TRIPS Agreement. In our view, the panel request in this case does describe the problem sufficiently to raise the issue of whether, assuming India has a valid mechanism for receiving mailbox applications, it is in compliance with Article 63 of the TRIPS Agreement.[72]

7.12 Second, and more fundamentally, we note that the United States' claim concerning Article 63 was a direct response to the Indian argument in its first written submission to the effect that India had a valid mailbox system in place. The United States asserts that this argument by India was a surprise because it had not been told by India during the consultations that India had such a system in place. In support of this assertion, the United States submitted that written questions it posed to India in this regard during the consultations had not been answered until the proceedings before this Panel started. To counter this assertion, India submitted to the Panel its internal record of the consultations indicating

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[70] *Id*., para. 7.57

[71] See paragraph 4.19 above

[72] The panel request includes the following passage: "The legal regime in India currently does not make patent protection available for inventions as specified in Article 27 of the TRIPS Agreement, or provide systems that conform to obligations of the TRIPS Agreement regarding the acceptance of applications and the grant of exclusive marketing rights. As a result, India's legal regime appears to be inconsistent with the obligations of the TRIPS Agreement, *including but not necessarily limited to* Articles 27, 65 and 70" (*emphasis added*).

that India had informed the United States about the fact that "product patent applications in the pharmaceutical and agrochemical sector were being received under the provisions of the Patents Act of 1970" and that "the Patents Act 1970 has provided the necessary legal scope for receipt of applications for product patents".[73] In our view, however, this is mere factual information regarding the filing of product patent applications and does not amount to a legal claim for the existence of a valid mailbox system. In this regard, we note that it is agreed that under the Patents Act it is possible to *file* a patent application for these products. The issue is how such applications are handled (*e.g.*, whether they are subject to examination and rejection) and the Indian statements do not address this issue. Accordingly, it would seem unreasonable to require that the United States should have anticipated the particular line of Indian defence in advance and should have included its alternative claim on transparency in its panel request or in its first written submission.

7.13 It is true that the interests of parties involved, including those of third parties, would be harmed if a panel would freely accept new claims and arguments which had not been reflected in the first written submissions. However, it should also be recognized that the panel process is a dynamic one where claims by the parties become refined and elaborated through arguments and counter-arguments.[74] Thus, in an exceptional case like this, we are of the view that a new argument which is a direct response to a party's first written submission is acceptable, provided that such an argument is presented, at the latest, by the close of the first substantive meeting. Moreover, in this particular case, we note that the parties had an opportunity to elaborate their arguments on this issue through oral and written submissions to the Panel.[75]

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

7.15 Put another way, our view is that the examination of the United States' claim on transparency is within the terms of reference of this Panel, cited in paragraph 1.2 above. Since this claim is a direct response to the Indian argument on the existence of a valid mailbox system in India, which in turn was a rebuttal to the United States' argument in its request for the establishment of a panel as elaborated in its

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[73]Paragraph 4.20 above

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

[75]See paragraph 1.3 above

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

[77]Article 10.4 of the DSU

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

first written submission, it constitutes part of "the matter referred to the DSB by the United States in ... document [WT/DS50/4]".

Request for Suggestion Concerning Implementation

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

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

C. Interpretation of the TRIPS Agreement

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

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

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

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

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

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

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

Since the TRIPS Agreement is one of the Multilateral Trade Agreements, we must be guided by the jurisprudence established under GATT 1947 in interpreting the provisions of the TRIPS Agreement unless there is a contrary provision. As the Appellate Body indicated in the *Japan -Alcoholic Beverages* case, adopted panel reports "create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute".[80] Indeed, in light of the fact that the TRIPS Agreement was negotiated as a part of the overall balance of concessions in the Uruguay Round, it would be inappropriate not to apply the same principles in interpreting the TRIPS Agreement as those applicable to the interpretation of other parts of the WTO Agreement.

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

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

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[80]Appellate Body Report on "Japan - Taxes on Alcoholic Beverages", adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS13/AB/R, page 14

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

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

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

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

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

D. Article 70.8

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

> "Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:
>
> (a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
>
> (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
>
> (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b)."

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

Nature of the Obligations

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

7.25 Subparagraph (a) starts with the phrase "notwithstanding the provisions of Part VI". This indicates that this provision is an exception to the transitional arrangements contained in Part VI of the TRIPS Agreement. Thus, if a Member does not make available as of 1 January 1995 patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under

[85] See paragraph 7.18 above

Article 27, that Member cannot avail itself of a transitional period under Article 65 regarding the operation of this subparagraph. This is clear from the textual analysis, and in any event is not in dispute between the parties. The substantive obligation to be assumed by such a Member as from 1 January 1995 is to provide "a means" by which applications for patents for inventions in respect of pharmaceutical and agricultural chemical products "can be filed". The analysis of the ordinary meaning of these terms alone does not lead to a definitive interpretation as to what sort of "means" is required by this subparagraph.

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

7.27 Furthermore, the object and purpose of Article 70.8 must be taken into account in our analysis. There seems to be a common understanding between the parties to the dispute regarding the object and purpose of subparagraph (a). India concedes that the purpose of subparagraph (a) is to "*ensure* that each patent applicant obtains a date of filing on the basis of which patent protection [can] be granted as from the date on which Article 27 applies and that exclusive marketing rights [can] be granted to products at the point at which they are eligible for such rights" (*emphasis added*).[86] We affirm this view. The object and purpose of Article 70.8(a) can be derived from the structure of the TRIPS Agreement. Article 27 requires that patents be made available in all fields of technology, subject to certain narrow exceptions. Article 65 provides for transitional periods for developing countries: in general five years from the entry into force of the WTO Agreement, i.e. 1 January 2000, and an additional five years to provide for product patents in areas of technology not so patentable as of 1 January 2000. Thus, in such areas of technology, developing countries are not required to provide product patent protection until 1 January 2005. However, these transitional provisions are not applicable to Article 70.8, which ensures that, if product patent protection is not already available for pharmaceutical and agricultural chemical product inventions, a means must be in place as of 1 January 1995 which allows for the entitlement to file patent applications for such inventions and the allocation of filing and priority dates to them so that the novelty of the inventions in question and the priority of the applications claiming their protection can be preserved for the purposes of determining their eligibility for protection by a patent at the time that product patent protection will be available for these inventions, i.e. at the latest after the expiry of the transitional period.

7.28 In order to achieve the object and purpose of Article 70.8, there must be a mechanism to preserve the novelty of pharmaceutical and agricultural chemical inventions which are currently outside the scope of product patent protection and the priority of applications claiming their protection, for the purposes of determining their eligibility for protection by patents. Once these inventions can be protected by product patents, Article 27 requires them to be available for, at least, those inventions that are (i) new, (ii) involve an inventive step and (iii) are capable of industrial application. In accordance with the normal meaning of these conditions, an invention is new and involves an inventive step if, at the filing date or, if applicable, the priority date of the application in which patent protection is claimed, the invention did not form part of the prior art and required an inventive step to be deduced from that prior art by a person skilled in the art. Thus, in order to prevent the loss of the novelty of an invention in this sense, filing and priority dates need to have a sound legal basis if the provisions of Article 70.8 are to fulfil their purpose. Moreover, if available, a filing must entitle the applicant to claim priority on the

[86]Paragraph 4.9 above

basis of an earlier filing in respect of the claimed invention over applications with subsequent filing or priority dates. Without legally sound filing and priority dates, the mechanism to be established on the basis of Article 70.8 will be rendered inoperational. In our view, preservation of novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions so as to provide for effective future patent protection after examination of the applications as of, at the latest, 1 January 2005 is the central object and purpose of Article 70.8(a). This is a special obligation imposed on those Members benefitting from the transitional arrangements.

7.29 The findings above can be confirmed by the negotiating history of the TRIPS Agreement.[87] We note that in the negotiation of the TRIPS Agreement the question of patent protection for pharmaceutical and agricultural chemical products was a key issue, which was negotiated as part of a complex of related issues 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 that not only appropriately allows for the entitlement to file mailbox applications and the allocation of filing and priority dates to them, but also takes away any reasonable doubts as to whether mailbox applications and eventual patents based on them could be rejected or invalidated because, at the filing or priority date, the matter for which protection was sought was unpatentable in the country in question.

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

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

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

[88]See paragraphs 7.20 and 7.21 above

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

applications *will* lead to the grant of patents after 2005 if the conditions foreseen in paragraphs (b) and (c) of Article 70.8 are met. Rather, as indicated in paragraphs 7.28 and 7.29 above, our view is that Article 70.8(a) requires the Members in question to establish a means that not only appropriately allows for the entitlement to file mailbox applications and the allocation of filing and priority dates to them, but also provides a sound legal basis to preserve novelty and priority as of those dates, so as to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated because, at the filing or priority date, the matter for which protection was sought was unpatentable in the country in question. Since we are not concluding that immediate action should be taken to give effect to the conditions of competition that must prevail after 1 January 2005 through the mechanism of Article 70.8 (b) and (c), we do not consider our findings would have the implications for the transitional periods under other WTO agreements to which India has alluded.[90] We are, however, of the view that India does have an obligation to take legislative measures as from 1 January 1995 to the extent that such measures are necessary in India to implement Article 70.8(a) in the way indicated above. In other words, we do not agree with India that the transitional arrangements of the TRIPS Agreement necessarily relieve India of the obligation to make legislative changes in its patent regime during the first five years of operation of the Agreement. As indicated in paragraph 7.28 above, Article 70.8(a) is a special obligation linked with the possibility of some developing country Members to avail themselves of an extended transitional period until 1 January 2005. Not to require this provision to be implemented with a sound legal basis would upset the delicate balance of the transitional arrangements of Articles 65, 70.8 and 70.9 that was negotiated during the Uruguay Round.

Mechanism for Implementing the Obligations

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

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

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

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

[90]See paragraph 4.9 above

[91]See paragraphs 4.3 and 7.3 above

[92]See paragraph 4.6 above

for filing patent applications for pharmaceutical and agricultural chemical products in India.

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

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

> "Even if Massachusetts may not currently be using its police powers to enforce this mandatory legislation, the measure continues to be mandatory legislation which may influence the decisions of economic operators. Hence, a non-enforcement of a mandatory law in respect of imported products does not ensure that imported beer and wine are not treated less favourably than like domestic products to which the law does not apply."[95]

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

7.36 This legal insecurity is further compounded by the lapse of the Patents (Amendment) Ordinance 1994, which formally and publicly established legal procedures for the receipt of mailbox applications. This is a particular problem according to the United States because a group of Indian patent law experts advised the Indian Government that a formal legal basis for mailbox applications was required to give them legitimacy under Indian law. Although India counters that the group issued no

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[93]See paragraph 2.10 above

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

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

specific report on this issue and that the group contained patent law and not constitutional law experts, a press note issued at the time of the promulgation of the Ordinance indicates that the Ordinance was based in part on the group's recommendations.[96]

7.37 Second, even if Patent Office officials do not examine and reject mailbox applications, a competitor might seek a judicial order to force them to do so in order to obtain rejection of a patent claim.[97] If the competitor successfully establishes the illegality of the separate storage and non-examination of mailbox applications before a court, the filing of those applications could be rendered meaningless. The evidence submitted by India - two Supreme Court rulings on administrative practices - does not sufficiently demonstrate that a court will uphold the validity of administrative actions which apparently contradict mandatory legislation. One case cited by India involved a situation where the administrative practice was not contrary to the statutory provisions. In the other case, the Supreme Court reached a conclusion that administrative guidelines had no statutory force and conferred no right on any citizen to complain that they were not being met.[98] These cases may confirm the Indian position that its reliance on an administrative practice regarding the handling of pharmaceutical and agricultural chemical product patent applications is not unconstitutional, but they do not specifically answer the question we are facing, i.e., whether a court will uphold the validity of administrative actions which apparently contradict mandatory legislation.

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

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

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

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

[98]See paragraphs 4.10 and 4.12 above

[99]See Annex 3 of this report

7.40 The United States has raised these questions in a persuasive manner. As the Appellate Body report on *Shirts and Blouses* points out, "a party claiming a violation of a provision of the WTO Agreement by another Member must assert and prove its claim".[100] In this case, it is the United States that claims a violation by India of Article 70.8 of the TRIPS Agreement. Therefore, it is up to the United States to put forward evidence and legal arguments sufficient to demonstrate that action by India is inconsistent with the obligations assumed by India under Article 70.8. In our view, the United States has successfully put forward such evidence and arguments. Then, again to paraphrase the Appellate Body, the onus shifts to India to bring forward evidence and arguments to disprove the claim. We are not convinced that India has been able to do so.

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

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

7.43 In conclusion, we find that India has failed to take the action necessary to implement its obligations under subparagraph (a) of Article 70.8 because of the lack of legal security regarding the

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[100] Appellate Body Report on "United States - Measure Affecting Imports of Woven Wool Shirts and Blouses from India", adopted on 23 May 1997, WT/DS33/AB/R, page 16

[101] See paragraph 7.30 above

[102] See paragraph 4.7 above

status of product patent applications in respect of pharmaceutical and agricultural chemical products under the system it presently operates.

E. Article 63

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

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

> "1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.
>
> "2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967)."

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

> "1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.
>
> "2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5."

7.46 The issue before the Panel is whether this exemption should be understood to cover the transparency obligations under Article 63 or whether such a procedural obligation to publish and notify national laws and regulations should be understood as becoming applicable at the time that a Member is

[103] See paragraphs 6.6 to 6.12 above

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

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

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

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

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

[106]Panel Report on "United States - Restrictions on Imports of Cotton and Man-made Fibre Underwear", *op. cit.*, para. 7.65. This conclusion was upheld by the Appellate Body in its report on the same case, WT/DS24/AB/R, page 21.

[107]See Annex 2 of this report

subject to the publication requirement. In view of the fact that the Patents Act contains mandatory provisions which are contrary to the administrative practice, the text of the Patents Act alone would at best mislead the public regarding the existence of the mailbox system, and would not satisfy the requirement under Article 63.1.

7.49 With respect to its notification obligations under Article 63.2, it is evident that India did not notify to the Council for TRIPS the legal basis of the current system for the handling of mailbox applications after the expiry of the Patents (Amendment) Ordinance 1994.

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

F. Article 70.9

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

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

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

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

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

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

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

In our view, the answer to question (a) is yes for the following reasons. Most of the provisions in the WTO Agreement aim to prevent governments from taking measures that might be harmful to trade and, therefore, concern the existence of legislation requiring governments to act in a way that is inconsistent

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

Textual Analysis

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

7.55 India seems to have reached a different conclusion based on the wording of Article 70.9. First, India notes that Article 70.9, in contrast to Article 70.8(a), does not contain the phrase "provide as from the date of entry into force of the WTO Agreement". However, this difference is not significant in view of the fact that Article 70.9 is directly tied to Article 70.8(a). Article 70.9 applies "where a product is the subject of a patent application in a Member in accordance with paragraph 8(a)". Given that Article 70.8(a) must be implemented as of the date of entry into force of the WTO Agreement, one would expect the same implementation date would apply in the absence of a clear indication to the contrary.

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

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

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

[110]See paragraphs 7.18 and 7.24 above

[111]See paragraph 4.27 above

that they require a Member to establish a system for the grant of specific rights. Seen in this context, the terms "shall be available" and "shall be granted" can almost be used interchangeably.[112]

Context, Object and Purpose

7.57 The analysis of the context and the object and purpose of Article 70.9 does not change the above conclusion. Article 70.9, like all other provisions of the TRIPS Agreement, must be interpreted in good faith, taking into account legitimate expectations of other WTO Members. Clearly, Article 70.9 shares the object and purpose of Article 70.8, to which there is an explicit reference: i.e., to provide a degree of protection of the interests of inventors of pharmaceutical and agricultural chemical products during the transition period. India, while generally agreeing with this observation, tries to narrow down its scope by claiming that the purpose of Article 70.9 is to give such inventors the economic privilege of an exclusive marketing right only for the five-year period preceding 1 January 2005 if their product inventions remain unpatentable beyond the five-year transitional period for developing countries stipulated in Article 65.2. We are not convinced by this argument. The object and purpose of the provision is to provide for specific marketing rights. In context, they partly compensate for the absence of effective patent protection in countries which avail themselves of the transitional periods under the TRIPS Agreement. Such rights have to be granted as soon as the conditions are met any time after the entry into force of the WTO Agreement. Neither from the object and purpose of Article 70.9, nor from its context, nor from its text, do they take effect only after the year 2000.

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

7.59 India further argues that the transitional provisions of the TRIPS Agreement accord developing country Members the right to choose between providing for the patentability of the product inventions in question and the grant of exclusive marketing rights and that it would be logically inconsistent with this right to opt out of the obligation to grant exclusive marketing rights if Article 70.9 were interpreted to oblige Members to provide in their legislation for the general availability of exclusive marketing rights

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

[113]See paragraph 4.27 above

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

as from the date of entry into force of the WTO Agreement.[115] We do not find this argument to be persuasive. As is the case with Article 70.8(a), the granting of exclusive marketing rights is a special obligation linked with the enjoyment by Members of the transitional arrangements under Articles 65 and 66 of the Agreement.[116] To accept India's interpretation on this point would be to exonerate those Members from this obligation, upsetting the carefully negotiated balance of rights and obligations during the transitional period.

7.60 Based on customary rules of treaty interpretation, we have reached the conclusion that under Article 70.9 there must be a mechanism ready for the grant of exclusive marketing rights at any time subsequent to the date of entry into force of the WTO Agreement. India suggests that this result ignores the fact that in reality it will take many years before anyone will be in a position to apply for the grant of exclusive marketing rights under Article 70.9. However, even if we accept that some delay after 1 January 1995 may well occur, we do not accept that the delay would extend to the date of the establishment of this Panel or that the result of our prior analysis should be changed. Under Article 70.9, exclusive marketing rights must be granted by India after a product meets the following conditions:

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

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

(c) The other Member has granted the patent;

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

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

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

7.61 We also note that steps (a), (b), (c) and (d) in the previous paragraph are events that are beyond the control of the authorities in India. In other words, they do not provide any definite basis for the postponement of the obligations under Article 70.9. Step (e) is under the control of the Indian authorities. However, if marketing approvals are denied purely for the purpose of delaying the grant of exclusive marketing rights, it would give rise to questions regarding good faith application of the TRIPS Agreement. Moreover, the range of products affected, i.e. pharmaceuticals and agricultural chemicals, is

[115]See paragraph 4.27 above

[116]See paragraph 7.28 above

[117]See paragraph 4.27 above

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

large and differing marketing approval regimes will apply according to the products in question.[119] For these reasons, we are not convinced that India can establish any specific date later than 1 January 1995 as the date by which it should have in place the legal means necessary to give effect to the exclusive marketing rights provisions of Article 70.9.

7.62 Postponement of the effective date cannot follow merely from the fact that there has been no request for the grant of exclusive marketing rights so far. Where, as we discussed with respect to Article 70.8, lack of legal security is likely to discourage potential applicants to file an application,[120] this is certainly the case if a system is non-existent. The lack of a system may discourage applications, and the lack of applications may prolong the lack of a system. This appears to be a real issue. We recall that the evidence put forward by the United States indicates that there is a possibility that at least one United States' manufacturer, which has received marketing approval in the United States and Europe, might apply for the grant of exclusive marketing rights in India. According to the United States, "[t]he company was wary about proceeding without knowing what the system for the grant of such right was, for fear of losing its ability to receive [exclusive marketing] rights because of some procedural problem".[121]

Conclusion

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

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

G. Suggestions by the Panel

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

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

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

[120]See paragraph 7.41 above

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

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

VIII. CONCLUSIONS

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

8.2 The Panel recommends that the Dispute Settlement Body request India to bring its transitional regime for patent protection of pharmaceutical and agricultural chemical products into conformity with its obligations under the TRIPS Agreement. The Panel further suggests that, in establishing a mechanism that preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period, India should take into account the interests of those persons who would have filed patent applications had an appropriate mechanism been maintained since the expiry of the Patents Ordinance 1994, as well as those who have already filed such applications under that Ordinance or the administrative practices currently in place.

[122] See paragraph 7.39 above

ANNEX 1

INDIA

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

Section 2

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

.....

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

(i) art, process, method or manner of manufacture;
(ii) machine, apparatus or other article;
(iii) substance produced by manufacture,

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

.....

(l) "medicine or drug" includes -

(i) all medicines for internal or external use of human beings or animals,
(ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals,
(iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals,
(iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants;
(v) all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to;

.....

Chapter II - Inventions not patentable

Section 5

In the case of inventions -

(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.

[123]The short title

Chapter III - Applications for patents

Section 6

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

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

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

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

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

Section 7

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

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

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

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

Section 8

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

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

(b)an undertaking that, up to the date of the acceptance of his complete specification filed in India, he would keep the Controller informed in writing, from time to time, of details of the nature referred to in clause (a) in respect of every other application relating to the

same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

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

Section 9

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

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

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

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

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

Section 10

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

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

(3) If, in any particular case, the Controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an

invention, such model or sample as he may require shall be furnished before the acceptance of the application, but such model or sample shall not be deemed to form part of the specification.

(4) Every complete specification shall -

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

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

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

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

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

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

Section 11

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

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

(b) a specification which is treated by virtue of a direction under 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 2

LOK SABHA

UNSTARRED QUESTION NO. 2601

To be answered on 2 August 1996

Amendment in Indian Patents Act, 1970

2601. SHRI ANAND RATNA MAURYA

Will the Minister of INDUSTRY be pleased to state:

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

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

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

ANSWER

THE MINISTER OF INDUSTRY (SHRI MURASOLI MARAN)

(a) to (c) The Patent Offices have received 893 patent applications in the field of drug or medicine from Indian as well as foreign companies/institutions up until 15 July 1996. The applications for patents will be taken up for examination after 1 January 2005, as per the World Trade Organization (WTO) Agreement which came into force on 1 January 1995.

ANNEX 3

May 2, 1997

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

Dear Ambassador Barshefsky:

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

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

PhRMA member companies do not believe that India has established a mailbox application system or a system for the grant of exclusive marketing rights. Few PhRMA companies have filed applications for pharmaceutical product patents in India, knowing that because a "mailbox" system was not in place, there is a considerable risk that those applications would not receive the legal status required by the TRIPS Agreement. These companies were willing to expend the resources and time necessary to file such applications in the hope that India may ultimately implement its TRIPS Article 70.8 obligations in a way that minimizes the damages created by the delay.

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

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

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

for the grant of exclusive marketing rights in place, at least one company and perhaps many others will incur significant additional losses.

Thank you for your attention to this matter.

Sincerely,

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