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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

[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

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.

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,

(..continued)
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.

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
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> (a) to the matters with respect to which Parliament has power to make laws; and
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> (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:
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> 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 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

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[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.

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.

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[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.

[Parties' arguments in Sections IV and V deleted from this version]

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

[51] Paragraph 4.12 above

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

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

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

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

[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

> 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.
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> "...The Panel therefore considered that the allocation of back-dated quotas did not conform to the requirements of Article XIII:3(b) and (c). It also interpreted the requirements of Article X:1 as likewise prohibiting back-dated quotas. It therefore found that the EEC had been in breach of these requirements since it had given public notice of the quota allocation only about two months after the quota period had begun."[54]

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

> "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

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[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

[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

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 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

[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

context, object and purpose of Article 70.9. India suggested the deletion of the heading, which the Panel accepted.

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

Suggestions by the Panel

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

VII. FINDINGS

A. Claims of the parties

Introduction

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

[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).

Property Rights ("Council for TRIPS").[62]

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

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

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

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

[63]See paragraph 2.3 above

[64]See paragraph 2.11 above

[65]See paragraph 2.8 above

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

Claims of the Respondent

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

[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

> 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]

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

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[69] *Id.*, para. 7.30

[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*).

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

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

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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

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

Request for Suggestion Concerning Implementation

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

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

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:

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[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.

7.22 In conclusion, we find that, when interpreting the text of the TRIPS Agreement, the legitimate

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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

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.

<u>Nature of the Obligations</u>

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

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

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[85] See paragraph 7.18 above

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 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

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[86]Paragraph 4.9 above

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 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

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[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

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" 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

[90]See paragraph 4.9 above

[91]See paragraphs 4.3 and 7.3 above

[92]See paragraph 4.6 above

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 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]

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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

[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.

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.

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

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[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

[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

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

[101] See paragraph 7.30 above

[102] See paragraph 4.7 above

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 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

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[103] See paragraphs 6.6 to 6.12 above

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

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

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

7.49 With respect to its notification obligations under Article 63.2, it is evident that India did not

[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

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

[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.

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 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

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[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

[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.

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 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.

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[113]See paragraph 4.27 above

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

[115]See paragraph 4.27 above

[116]See paragraph 7.28 above

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 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

[117]See paragraph 4.27 above

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

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

[120]See paragraph 7.41 above

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

Conclusion

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

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

G. Suggestions by the Panel

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

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

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

[122]See paragraph 7.39 above

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.