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INDIA - PATENT PROTECTION FOR PHARMACEUTICAL
AND AGRICULTURAL CHEMICAL PRODUCTS

Notification of an Appeal by India under
paragraph 4 of Article 16 of the Understanding on Rules
and Procedures Governing the Settlement of Disputes (DSU)

The following notification, dated 15 October 1997, sent by India to the Dispute Settlement Body (DSB), is circulated to Members. This notification also constitutes the Notice of Appeal, filed on the same day with the Appellate Body, pursuant to the *Working Procedures for Appellate Review*.

1. Pursuant to Article 16 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) and Rule 20 of the Working Procedures for Appellate Review, India hereby notifies its decision to appeal to the Appellate Body from certain findings and conclusions of the Panel on *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R).

2. India requests the Appellate Body to review the following issues of law covered in the Panel report and legal interpretations developed by the Panel.

(A) Article 70.8 of the TRIPS Agreement.

- (i) Whether Article 70.8(a) of the TRIPS Agreement creates the obligation "to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated".

Subparagraph (a) of Article 70.8 of the TRIPS Agreement obliges the developing country Member concerned to:

"...provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for [pharmaceutical and agricultural chemical products] can be filed."

This provision establishes merely a procedural obligation to create a means of filing, commonly referred to as a "mailbox". The rights to be accorded on the basis of mailbox applications are set out in subparagraphs (b) and (c) of Article 70.8, which apply only after a transitional period of ten years.

The Panel concluded in its report that:

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

dates, so as to eliminate any reasonable doubts regarding whether mailbox applications and eventual patents based on them could be rejected or invalidated..." (paragraph 7.31, emphasis added)

The ruling that subparagraph (a) of Article 70.8 requires the establishment of legal certainty as to the future treatment of mailbox applications effectively incorporates into this provision obligations arising only after a ten-year transitional period under subparagraphs (b) and (c) of that Article. India, therefore, considers that the Panel erred in interpreting Article 70.8(a) of the TRIPS Agreement.

(ii) Whether developing country Members intended to give up their right to determine the validity, under their domestic law, of any mailbox established pursuant to Article 70.8 of the TRIPS Agreement.

There is no dispute that India has established a mailbox under its current administrative practice under which it continues to receive applications. Despite finding that India's reliance on this administrative practice was "not unconstitutional", the Panel found that "there would remain doubt during the transitional period regarding the eligibility of these products [covered by the mailbox applications] for future patent protection". (paragraphs 7.37 and 7.38)

On a proper interpretation of the ordinary meaning, context and object and purpose of Article 70.8 and on the basis of the negotiating history thereof, India considers that a developing country Member has fulfilled its obligations under Article 70.8 if it establishes a mailbox based on its own determination of the validity of the mailbox under its domestic law.

Subsidiarily, among other issues, India wishes the Appellate Body to examine whether the Panel did not reverse the burden of proof in violation of established principles by requiring India to demonstrate that its mailbox could not be subjected to a possible legal challenge in the future.

(B) Whether Article 70.9 of the TRIPS Agreement requires the establishment of a system for the grant of exclusive marketing rights.

Article 70.9 of the TRIPS Agreement obliges India to grant exclusive marketing rights to pharmaceutical or agricultural chemical products that meet 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 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.

The Panel found that India had not denied the grant of exclusive marketing rights to any product meeting the above conditions. The Panel nevertheless concluded that India did not comply with its obligations under Article 70.9 of the TRIPS Agreement because it had failed to establish under its domestic law "a system" for the grant of exclusive marketing rights as of the entry into force of the WTO Agreement (paragraph 8.1). However, Article 70.9 of the TRIPS Agreement does not require the establishment of a system for the grant of exclusive marketing rights. While there are many provisions in the TRIPS Agreement that explicitly require Members to create the authority for the grant

of certain rights in their domestic law, Article 70.9 was drafted as a transitional provision merely requiring the grant of exclusive marketing rights to specific products after the occurrence of specified events. India therefore considers that the Panel erred in interpreting Article 70.9 of the TRIPS Agreement.

- (C) Whether a Panel is authorized to make findings and recommendations on a matter on which the complaining party had not requested findings and recommendations.

The United States requested the Panel to find that India had failed to implement the obligation in Article 70.8 of the TRIPS Agreement to establish a "mailbox system". The United States further requested the Panel to find:

"In the alternative, if the Panel finds that India has had a valid mailbox system in place, India has failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement." (paragraph 3.1(c), emphasis added).

The Panel concluded that India's current mailbox system did not conform to the requirements of Article 70.8 but nevertheless ruled on the United States' Article 63 claim. Under Articles 3, 7 and 11 of the DSU, panels are to make findings and recommendations only on matters submitted to them by the parties to the dispute. India therefore considers that the Panel exceeded its authority under the DSU by ruling on the United States' subsidiary claim after accepting its principal claim.

In paragraph 6.44 of its interim report, the Panel had justified its initiative by declaring that the United States' subsidiary request was "better understood as an additional request". India objected to this characterization of the United States' request. In paragraph 6.11 of its final report, the Panel justified its decision by "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." Given the possibility of an appeal, the United States could have requested the Panel to present findings on Article 63 irrespective of the Panel's conclusions on Article 70.8. However, the possibility of an appeal did not authorize the Panel to present such findings on its own initiative.