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Dated: May 19, 1998.

**Nicholas E. Tagliareni,**

*Reports Clearance Officer, Social Security Administration.*

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## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301-106]

### Determination Under Section 304 of the Trade Act of 1974: Practices of the Government of India Regarding Patent Protection for Pharmaceuticals and Agricultural Chemicals

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice of determination, termination and monitoring.

**SUMMARY:** The United States Trade Representative (USTR) has determined that certain acts, policies and practices of India violate, or otherwise deny benefits to which the United States is entitled under, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This determination is based on the report of a dispute settlement panel convened under the auspices of the World Trade Organization (WTO) at the request of the United States, and the report of the WTO Appellate Body reviewing the panel report. The Appellate Body report and the panel report (as modified by the Appellate Body report) were adopted by the WTO Dispute Settlement Body (DSB) on January 16, 1998 ("the WTO reports"). On February 13, 1998, India stated its intention to comply with its WTO obligations with respect to this matter and, on April 22, 1998, stated that it would amend its law no later than April 19, 1999. In light of the foregoing, the USTR will not take action under section 301 of the Trade Act of 1974 ("the Trade Act") at this time and has terminated this investigation. However, the USTR will monitor India's implementation of the WTO reports, and will take action under section 301(a) of the Trade Act if India does not come into compliance.

**EFFECTIVE DATE:** May 8, 1998.

**ADDRESSES:** 600 17th Street, N.W., Washington, D.C. 20508.

**FOR FURTHER INFORMATION CONTACT:** Claude Burcky, Director of Intellectual Property (202) 395-6864; GERALYN S.

Ritter, Assistant General Counsel (202) 395-6800.

**SUPPLEMENTARY INFORMATION:** On July 2, 1996, the USTR initiated an investigation under section 302(b) of the Trade Act (19 U.S.C. 2412(b)) regarding India's provision of patent protection for pharmaceutical and agricultural chemical products, and requested public comment on the issues raised in the investigation and the determinations to be made under section 304 of the Trade Act. (61 FR 35857 of July 8, 1996). This investigation specifically concerned India's failure to comply with its obligations under Articles 70.8 and 70.9 of the TRIPS Agreement to establish a "mailbox" mechanism for filing product patent applications for pharmaceuticals and agricultural chemicals, and to provide a system of exclusive marketing rights for these products. As required under section 303(a) of the Trade Act, the United States held consultations with India under the procedures of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) on July 27, 1996. A dispute settlement panel was established on November 20, 1996.

Pursuant to Section 304(a)(1)(A) of the Trade Act (19 U.S.C. 2414(a)(1)(A)), the USTR must determine in this case whether any act, policy or practice of India violates, or otherwise denies benefits to which the United States is entitled under any trade agreement. If that determination is affirmative, the USTR must take action under section 301 of the Trade Act (19 U.S.C. 2411), subject to the specific direction of the President, if any. However, pursuant to section 301(a)(2)(B), the USTR is not required to take action under section 301 if the USTR finds, *inter alia*, that the foreign country is taking satisfactory measures to grant the rights of the United States under the trade agreement.

#### Reasons for Determinations

##### (1) India's Acts, Policies and Practices

The WTO panel in this case released its report on September 5, 1997, and found that India had failed to comply with its obligations under Articles 70.8 and 70.9 of the TRIPS Agreement. India appealed all of the panel's adverse findings. On December 19, 1997, the Appellate Body issued its report confirming all the major panel findings against India, and reversing the panel report on a procedural issue regarding the panel's jurisdiction to consider claims outside its terms of reference. On January 16, 1998, the DSB adopted the Appellate Body and the panel report (as

modified by the Appellate Body report). The WTO reports include findings that India has failed to comply with Article 70.8 of the TRIPS Agreement because it has failed to establish a legally secure mailbox system for filing patent applications for pharmaceutical and agricultural chemical products that preserves the novelty and priority of those applications. The WTO reports also include findings that India was obligated as of January 1, 1995, to have established a system for granting exclusive marketing rights for certain products that are the subject of mailbox application, and that India had failed to establish such a system in violation of Article 70.9 of the TRIPS Agreement.

Thus, based on the results of the WTO dispute settlement proceedings, the public comments received and appropriate consultations, the USTR has determined that certain acts, policies and practices of India violate, or otherwise deny benefits to which the United States is entitled under, the TRIPS Agreement.

##### (2) U.S. Action

At a meeting of the DSB on February 13, 1998, India stated its intention to "meet its obligations under the WTO with respect to this matter" and "to comply with the recommendations and rulings of the DSB." At the DSB meeting on April 22, 1998, India committed to amend its law to meet its TRIPS obligations "as early as possible," and no later than April 19, 1999. In light of India's commitment to implement its WTO obligations, pursuant to section 301(a)(2)(B)(i) of the Trade Act, the USTR will not take action at this time under section 301(a) of the Trade Act and has terminated this investigation. However, pursuant to section 306 of the Trade Act, the USTR will monitor India's implementation of the WTO reports and will take action under section 301(a) of the Trade Act if India does not come into compliance.

**Irving A. Williamson,**

*Chairman, Section 301 Committee.*

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## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

#### Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Notice.