

**ARGENTINA - PATENT PROTECTION FOR PHARMACEUTICALS
AND TEST DATA PROTECTION FOR AGRICULTURAL CHEMICALS**

Request for Consultations by the United States

The following communication, dated 6 May 1999, from the Permanent Mission of the United States to the Permanent Mission of Argentina and to the Chairman of the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

My authorities have instructed me to request consultations with the Government of Argentina 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 Agreement) (to the extent that it incorporates by reference Article XXII of the General Agreement on Tariffs and Trade 1994) regarding (1) the absence in Argentina of either patent protection for pharmaceutical products or an effective system for providing exclusive marketing rights in such products; and (2) Argentina's failure to ensure that changes in its laws, regulations and practice during the transition period provided under Article 65.2 of the TRIPS Agreement do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.

The first issue on which my authorities seek to consult with the Government of Argentina concerns the obligation in the TRIPS Agreement on all Members of the World Trade Organization (WTO) that do not provide product patent protection for pharmaceuticals on the date of entry into force of the WTO Agreement (1 January 1995) to establish a system whereby exclusive marketing rights will be granted for products that are the subject of applications for patents for such inventions, subject to certain stated requirements. The TRIPS Agreement does not permit WTO Members to allow third parties to market products subject to exclusive marketing rights without the consent of the right holder.

Argentina's law currently does not provide product patent protection for pharmaceutical inventions, or a system that conforms to Article 70.9 of the TRIPS Agreement with regard to the grant of exclusive marketing rights. As a result, Argentina's legal regime appears to be inconsistent with Argentina's obligations under the TRIPS Agreement, including but not necessarily limited to Articles 27, 65 and 70 of the Agreement.

The second issue on which my authorities seek to consult with the Government of Argentina concerns the obligation in Article 65.5 of the TRIPS Agreement on all Members availing themselves of a transitional period under paragraphs 1, 2, 3 or 4 of Article 65 of the TRIPS Agreement to ensure that any changes in its laws, regulations and practice made during the transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement.

Prior to August 1998, the Government of Argentina provided a ten-year term of protection against unfair commercial use for undisclosed test data or other data submitted to Argentine regulatory authorities in support of applications for marketing approval for agricultural chemical products. Since the issuance in 1998 of Regulation 440/98, which *inter alia* revoked earlier regulations, Argentina has provided no effective protection for such data against unfair commercial use. As a result, Argentina's legal regime appears to be inconsistent with the obligation in Article 65.5 of the TRIPS Agreement in that changes to its laws, regulations or practice during the transitional period have resulted in a lesser degree of consistency with the provisions of Article 39.3 of the TRIPS Agreement.

We look forward to receiving your reply to the present request and to fixing a mutually convenient date for consultations.
