# WORLD TRADE ORGANIZATION

**WT/DS171/3**
**WT/DS196/4**
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**ARGENTINA – PATENT PROTECTION FOR PHARMACEUTICALS AND TEST DATA PROTECTION FOR AGRICULTURAL CHEMICALS (WT/DS171)**

**ARGENTINA – CERTAIN MEASURES ON THE PROTECTION OF PATENTS AND TEST DATA (WT/DS196)**

Notification of Mutually Agreed Solution
According to the Conditions Set Forth in the Agreement

The following communication, dated 31 May 2002, from the Permanent Mission of Argentina and the Permanent Mission of the United States to the Chairman of the Dispute Settlement Body, is circulated at the request of both parties.

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The Governments of the United States of America and the Republic of Argentina wish to notify the Dispute Settlement Body (DSB) that they have reached an agreement on all of the matters raised by the United States in document WT/DS171/1 (*Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*) dated 6 May 1999 and in document WT/DS196/1 (*Argentina – Certain Measures on the Protection of Patents and Test Data*) dated 30 May 2000.

Following the rounds of consultations held on 15 June 1999, 27 July 1999, 17 July 2000, 29 November 2000, 2 April 2001, 13 July 2001, 21 September 2001, 5 November 2001, and 14 April 2002, the United States and Argentina have reached a mutually satisfactory solution on the matters indicated in items 1 through 8(a). The mutually satisfactory solution on the matters indicated in items 4, 5 and 6 of the attached text is subject to the passage by the Argentine National Congress of the bills referred to in those items within one year of the date of the submission of this notification. The matters indicated in items 8(b) and 9 shall be subject to the conditions set forth in the respective paragraphs of this notification. This agreement is without prejudice to the rights and obligations of Argentina and the United States under the WTO agreements.

Please find attached the text of the agreement. We would ask you to circulate this notification and attachment to the relevant Councils and Committees, as well as to the DSB.

(s.) Mr. Alberto J. Dumont
Chargé d'Affaires, a.i.
Permanent Mission of Argentina

(s.) Mr. David P. Shark
Chargé d'Affaires, a.i.
Permanent Mission of the United States of America

**1. Compulsory Licenses**

The Governments of the United States and Argentina have analyzed Argentinean law and regulations, i.e., article 44 of the Law on Patents and Utility Models No. 24.481, as amended by Law No. 24.572, (Law No. 24.481) and article 44 of the Regulatory Decree of such law, Annex II, 20/03/96, No. 260 (Decree 260/96), under the provisions of Article 31(k) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Pursuant to this analysis, Argentina has confirmed that if any of the situations defining "anti-competitive" practices in article 44 of Law No. 24.481 were found to exist, such a finding will not in and of itself warrant an automatic determination that a patent owner is engaging in an "anti-competitive" practice. Pursuant to article 44 of Decree 260/96, in order to justify the granting of a compulsory license by INPI under this authority where one of these defined situations is established, a prior decision must have been handed down by the National Commission on the Defense of Competition (or the body that might substitute it in the future) analyzing the practice in question based on Law No. 25.156 (Law of Defense of Competition). According to this law, the existence of an abuse of a dominant position in the market must be established in order for a practice to be considered "anti-competitive." On this basis, Argentina and the United States agree that article 44 of Law No. 24.481, read in conjunction with article 44 of Decree 260/96, is consistent with Argentina's obligations under TRIPS Article 31(k), and that Argentina shall not grant compulsory licenses on the basis of a finding of anti-competitive practices except in situations consistent with these provisions.

**2. Exclusive Marketing Rights**

The Governments of the United States and Argentina have analyzed article 101, first paragraph of Law No. 24.481, article 101(III) of the Decree 260/96, and the practice of Argentina under the provisions of Articles 70.8 and 70.9 of the TRIPS Agreement. Pursuant to this analysis, Argentina has confirmed that, according to article 101(III) of Decree 260/96, INPI shall grant an exclusive right to a party to market a product for a period of five years after Argentina approves the marketing of the product or until a product patent is granted or rejected by Argentina, if the product (i) is the subject of a claim in a patent application filed in Argentina after January 1, 1995; (ii) is the subject of the grant of a patent in another WTO Member; and (iii) has been granted marketing approval in such other Member. On this basis, Argentina and the United States agree that article 101 of Law No. 24.481, read in conjunction with article 101(III) of Decree 260/96, is consistent with Argentina's obligations under Article 70.9 of the TRIPS Agreement.

**3. Import Restrictions**

The Governments of the United States and Argentina have analyzed article 36(c) of Law No. 24.481 and article 36 of Decree 260/96 in light of the provisions of Articles 6 and 28.1 of the TRIPS Agreement. Pursuant to this analysis, Argentina has confirmed that, according to its law and regulations, the owner of a patent granted in the Argentinean Republic shall have the right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling or importing the patented product in the territory of Argentina. However, a voluntary licensee in Argentina authorized by the Argentinean patent owner to import the patented product may import the product if he proves the product has been put on the market in a foreign country by the owner of the Argentinean patent or by a third party authorized for its commercialization. On this basis, Argentina and the United States agree that article 36(c) of Law No. 24.481, read in conjunction with article 36 of Decree 260/96, is consistent with Argentina's obligations under the TRIPS Agreement.

**4. Product by Process Patent Protection**

The Governments of the United States and Argentina have analyzed article 8(b) of Law No. 24.481 in the light of Article 28.1(b) of the TRIPS Agreement. Pursuant to this analysis, the Government of Argentina will submit a bill to the National Congress containing a proposal to amend the present text of article 8(b) of Law No. 24.481 in the following terms:

> *"(b) where the subject matter of a patent is a process, to prevent third parties without his consent from the act of using the process, and from engaging in acts of use, offering for sale, sale or importation for these purposes of the product obtained directly by that process".*

**5. Shifting of the Burden of Proof in Process Patent Infringement Cases**

The Governments of the United States and Argentina have analyzed the Argentinean provisions in the light of Article 34 of the TRIPS Agreement. Pursuant to this analysis, the Government of Argentina will submit to the National Congress a bill to amend article 88 of Law No. 24.481 as follows:

"Article 88 is replaced by the following text:

> *1. For the purposes of civil procedures, where the subject matter of the patent is a process for obtaining a product, the courts shall order the defendant to prove that the process that he is using for obtaining a product is different from the patented process.*
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> *2. The courts, however, shall be empowered to order the plaintiff to prove that the process that the defendant is using for obtaining a product infringes the process patent if the product obtained by the patented process is not new. It shall be presumed that, in the absence of proof to the contrary, the product obtained by the patented process is not new if the defendant or if an expert appointed by the court at the request of the defendant is able to show that, at the time of the alleged infringement, there exists in the market a non-infringing product identical to the one produced by the patented process that originated from a source different from the right owner or the defendant.*
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> *3. In the adduction of proof under this Article, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account."*

**6. Preliminary Injunctions**

The Governments of the United States and Argentina have analyzed the Argentinean legislation in the light of the provisions of Article 50 of the TRIPS Agreement. Pursuant to this analysis, the Government of Argentina will submit a bill to the National Congress containing the following text to be incorporated into the current article 83 of Law No. 24.481:

> *"The judicial authorities shall have the authority to order provisional measures in relation to a patent granted in conformity with articles 30, 31 and 32 of the Law, in order to:*

*(1) prevent an infringement of the patent and, in particular, to prevent the entry into channels of commerce of goods, including imported goods, immediately after customs clearance;*

*(2) preserve relevant evidence in regard to the alleged infringement,*

*whenever the following conditions are met:*

*(a) there is a reasonable likelihood that the patent, if challenged by the defendant as being invalid, shall be declared valid;*

*(b) it is summarily proven that any delay in granting such measures will cause an irreparable harm to the patent holder;*

*(c) the harm that may be caused to the title holder exceeds the harm that the alleged infringer will suffer in case the measure was wrongly granted;*

*(d) there is a reasonable likelihood that the patent is infringed.*

*Provided that the above conditions are met, in exceptional cases such as when there is a demonstrable risk of evidence being destroyed, the judicial authorities can grant such measures inaudita altera parte.*

*In all cases, before granting a provisional measure, the judicial authority shall request that an expert appointed ex officio examine items (a) and( d) above within a maximum period of 15 days.*

*In the case of granting of any of the measures provided for under this article, the judicial authorities shall order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuses."*

Pursuant to the above analysis, the Government of Argentina will submit a bill to the National Congress amending article 87 of the Patent Law, which will read as follows:

*"In cases where provisional measures were not granted pursuant to article 83 of the Law, the plaintiff may demand security from the defendant not to interrupt the defendant's exploitation of the invention where he wishes to continue with such exploitation."*

**7. Patentability of Micro-organisms and other Subject Matter:**

Regarding the matter of the consultations referring to the patentability of:

(a) micro-organisms, per se (e.g. yeasts, bacteria, unicellular organisms);

(b) a composition that includes as one element a micro-organism (e.g., a culture containing a yeast, bacterium, etc.);

(c) a chemical compound, per se (i.e., the chemical compound not in combination with other materials);

(d) a composition containing a chemical compound that had an industrial application other than use as a pharmaceutical composition;

(e) a chemical compound or a purified composition containing a chemical compound (in the form of a nucleic acid comprising a specified sequence of nucleoside (i.e., a nucleotide sequence); a peptide, polypeptide or protein (i.e., an amino acid sequence); a lipid; or a polysaccharide);

(f) a chemical compound having a structure identical to a chemical compound isolated from a plant, animal, micro-organism or other naturally occurring sources;

(g) a purified composition containing a chemical compound having a structure identical to a chemical compound isolated from a plant, animal, micro-organism or other naturally occurring source, such that the composition is not identical to a composition containing the chemical compound as it would be found in its natural state; and

(h) a chemical compound or a composition containing that compound where the composition does not have a predominantly pharmaceutical application,

the Governments of Argentina and the United States have analyzed the legislation and practice of Argentina in the light of Article 27.3(b) of the TRIPS Agreement. Pursuant to this analysis, the Government of Argentina has elaborated and published guidelines about its practices relating to patentability of micro-organisms in INPI Resolution 633/2001 (Official Gazette, dated 22 October 2001).

**8. Transitional Patents**

(a) Article 70.4 of the TRIPS Agreement

The Governments of the United States and Argentina have expressed their respective points of view regarding the obligations under Article 70.4 of the TRIPS Agreement, and have examined the Argentinean legislation in the light of this provision, in particular paragraph 3 of article 101 of Law No. 24.481 and article 101(II) of Decree 260/96. Pursuant to this analysis, Argentina has confirmed that article 101, paragraph 3 of Law No. 24.481, which can only be read in conjunction with article 101(II) of Decree 260/96, establishes that only third parties who completed investments in preparation for using a patented invention prior to January 1, 1995, can continue to use the invention upon payment of fair and reasonable remuneration to the patent holder. On this basis, Argentina and the United States agree that article 101, paragraph 3 of Law No. 24.481, which can only be read in conjunction with article 101(II) of Decree 260/96, is consistent with Argentina's obligations under TRIPS Article 70.4.

(b) Article 70.7 of the TRIPS Agreement

The Governments of the United States and Argentina agree that Argentina will fulfill its WTO obligations on this matter through its legal system and practices, including decisions of the Supreme Court of Justice.

**9. Protection of Test Data Against Unfair Commercial Use**

The Governments of the United States and Argentina have expressed their respective points of view on the provisions of Article 39.3 of the TRIPS Agreement, and have agreed that differences in interpretations shall be solved under the DSU rules. The Parties will continue consultations to assess the progress of the legislative process of approval of items 4, 5 and 6 of this notification, and in the light of this assessment, the United States may decide to continue consultations or request the establishment of a panel related to Article 39.3 of the TRIPS Agreement.

In addition, the Parties agree that should the Dispute Settlement Body adopt recommendations and rulings clarifying the content of the rights related to undisclosed test data submitted for marketing approval according to Article 39.3 of the TRIPS Agreement, and should Argentinean law be inconsistent with Article 39.3 as clarified by the above-mentioned recommendations and rulings, Argentina agrees to submit to the National Congress within one year an amendment to Argentinean law, as necessary, to put its legislation in conformity with its obligations under Article 39.3 as clarified in such recommendations and rulings.

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