

IMPLEMENTATION OF ARTICLES 70.8 AND 70.9

The present document reproduces the responses provided by Argentina, at the meeting of the Council for TRIPS of 17 February 1999, as posed by the United States and distributed in document IP/C/W/113.

1. *In addition to the information provided in your notification concerning the filing of patent applications directed to pharmaceutical or agricultural chemical product inventions, please:*

- (a) *identify the basis in your law that governs the handling of patent applications by the responsible Government agency in situations where the application is directed to subject-matter that is not eligible to be patented; and*

Argentine law lays down the same patentability requirements as the TRIPS Agreement. These criteria are applied to patent applications filed as of the entry into force of the new legislation, and if they are not met, patent protection is not granted.

In the case of pharmaceutical products for which applications were filed on or after 1 January 1995, the patentability requirements laid down in the TRIPS Agreement, approved by Argentina under Law 24.425, are applied.

- (b) *confirm that the measures specified in your notification will ensure that any patent application directed to pharmaceutical or agricultural chemical product inventions that was filed on or after 1 January 1995, can serve as the basis for a grant of a patent with a term that expires no earlier than 20 years from the date of its filing, once your Government extends patent protection to inventions consistent with the scope of Article 27 of the TRIPS Agreement.*

We confirm that any patent application directed to pharmaceutical product inventions (which are in a transitional period) serve as a basis for a grant of a patent with a term that expires no earlier than 20 years from the date of its filing.

2. *Please identify the provisions of your law that govern the granting of exclusive marketing rights for products covered by Articles 70.8 and 70.9 of the TRIPS Agreement.*

During the transitional period, applications for exclusive marketing rights are to be filed with the National Industrial Property Institute (INPI) together with the necessary documentation certifying:

- (a) that the product is the subject of a patent application before the said body;

- (b) that a patent application was filed after 1 January 1995 to protect the same product in another WTO/TRIPS Member with evidence that the two applications are the same;
- (c) that a patent has been granted after 1 January 1995 for that product in such other Member;
- (d) that marketing approval has been obtained for that product in such other Member after 1 January 1995.

Once it has verified these elements, the INPI decides on whether to grant exclusive marketing rights in Argentina for a period of five years after obtaining marketing approval in Argentina, under the proviso that the permission expires prior to that date if the patent application filed with the INPI is accepted or rejected or the marketing approval withdrawn.

The granting of exclusive marketing rights is conditional upon approval for the manufacturing and marketing of pharmaceuticals products, which has to be obtained from the Ministry of Public Health and Social Action.

3. *Please provide the identity and address of the government authority that is responsible for the granting of exclusive marketing rights.*

The National Industrial Property Institute, located at Av. Paseo Colón 717 in Buenos Aires, decides on the granting of exclusive marketing rights, which is conditional upon manufacturing and marketing approval for pharmaceuticals by the National Food, Drug and Medical Technology Administration (ANMAT), located at Avenida de Mayo 869, 3rd floor, Buenos Aires, and which is under the authority of the Ministry of Public Health and Social Action.

4. *Please explain the procedures to be followed by a private company or individual wishing to obtain exclusive marketing rights for a pharmaceutical or agricultural chemical product that fulfils the requirements of Articles 70.8 and 70.9.*

In the case of pharmaceuticals, the applicant must provide the INPI with documentation certifying that he has fulfilled the requirements laid down by Argentine law, which correspond to those contained in Article 70.9 of the TRIPS Agreement, and must obtain manufacturing and marketing approval from the ANMAT.

5. *Please identify the fee, if any, for obtaining exclusive marketing rights for a product or family of products.*

No fee is currently collected. Regulations setting the rates for such fees are currently being prepared.

6. *Please explain how an entity that has obtained exclusive marketing rights pursuant to TRIPS Article 70.9 can enjoy the benefit of such rights? In particular:*

- (a) *Can marketing approval be granted under any circumstances to another party prior to the expiration of the exclusive marketing rights period defined in Article 70.9?*

Marketing approval for a pharmaceutical product is governed in Argentina by Laws 16.463 and 24.766 and by Decree 150/92 (regulatory enactment by Decree 177/93). This regime does not provide for marketing approval for a particular drug exclusively, nor does it provide the possibility of cancelling an approval already granted for reasons that are not strictly related to health.

- (b) *What remedies or procedures are available to the holder of an exclusive marketing right to prevent the issuance of marketing privileges to another party in respect of a product that is the subject of the exclusive marketing rights?*

The holder of an exclusive marketing right for a given drug may appeal to the national courts and ask the competent judge to take the necessary measures to guarantee the effective protection of those rights.
