

REVIEW OF LEGISLATION

Responses from Brazil to the questions posed by Switzerland

By means of a communication from the Permanent Mission of Brazil dated 6 August 2001, the Secretariat has received the following responses to the questions posed by Switzerland, as circulated in document IP/C/W/239.

A. PATENTS

1. *In your law, are patents available for all categories of products? In particular, are all pharmaceutical products patentable? Are there any exceptions? If so please explain in detail what these exceptions are and how they comply with Article 27 of the TRIPS Agreement.*

According to Article 8 of the Brazilian Industrial Property Law (Law 9,279 of May 14, 1996), patents are enjoyable for inventions that meet the requirements of novelty, inventive step and industrial application. The only exceptions to patentability are defined in Article 10 of the Law, which fully complies with Article 27 of the TRIPS Agreement.

2. *In Brazil, Provisional Measure 2014-1, dated 30 December 1999, requires acceptance of pharmaceutical patent applications by the health agency ANVS. Please explain how this requirement complies with the obligation of Article 27.1 of the TRIPS Agreement that patents shall be available and patent rights enjoyable without discrimination as to the field of technology?*

Provisional Measure 2014-1 fully complies with Article 27.1 of the TRIPS Agreement. ANVISA is in possession of the necessary expertise to pronounce itself on the novelty, inventive step and industrial application of pharmaceutical inventions. In this regard, we note that Article 1.1 of the TRIPS Agreement states that "[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice".

3. *Does your law, in accordance with Article 27.1 in combination with Article 31 of the TRIPS Agreement, consider importation as "working a patent" (and therefore preclude compulsory licensing, if a product is being imported)?*

[Reply not received]

4. *Does your law make compulsory licenses subject to all the conditions enumerated in Article 31 of the TRIPS Agreement? Please cite the relevant provisions of law.*

Under the Brazilian Industrial Property Law, compulsory licences are subject to conditions enumerated in Article 31 of the TRIPS Agreement. The relevant provisions can be found in Articles 71 to 74 of Law 9,279 of 1996.

5. *Please explain how Article 2 § 2 of the Presidential Decree 3.201, providing that compulsory licences may be granted to support the socio-economic development, is compatible with Article 31 of the TRIPS Agreement.*

The TRIPS Agreement does not limit the grounds upon which to grant compulsory licences, but merely establishes procedural requirements to be followed by Members. Presidential Decree 3201 defines facts of primary importance to the technological or socio-economic development of the country as one possible situation of national interest that might lead to the issuance of a compulsory licence for public non-commercial use. Therefore, the aim of Presidential Decree 3201 is merely to define terms that TRIPS does not explain, in order to allow the issuance of compulsory licences in a TRIPS-compatible manner. These provisions of the Presidential Decree fully comply with the TRIPS Agreement, but they are also clearly based on its Article 8.1, which states that "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

6. *Does your legislation provide for the principle of the reversal of burden of proof in a process patent litigation? Please cite the relevant provisions of law.*

Yes. Please see Article 42, paragraph 2, of Law 9,279 of 1996.

B. PROTECTION OF UNDISCLOSED INFORMATION

7. *Please explain in detail if your legislation ensures that undisclosed and confidential test data or other data submitted by an applicant to the responsible State agency in the procedure for market authorisation of a pharmaceutical or of an agricultural chemical product is protected against disclosure and against unfair commercial use by a competitor, for example by prohibiting a second applicant from relying on, or from referring to the original data of the first applicant, when applying subsequently for market authorisation for his own product. Does your legislation provide for exceptions to this? If yes, under what conditions would such exceptions apply? Does your legislation provide for a defined period of protection for undisclosed information / for such test data of the first applicant?*

Please see Article 195, XIV, of Law 9,279 of 1996, and Article 154 of the Penal Code. Concerning exceptions, see Article 195, paragraph 2, of the same Law. Furthermore, it should be noted that the period of time is not defined.
