

REPORT
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HEAD OF PATENTS

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Ref.: REQUEST FOR INFORMATION – STANDING COMMITTEE ON PATENTS (SCP)

This report is submitted in response to the receipt in the patents service of the Industrial Property Division of a request for information by the World Intellectual Property Organization in accordance with the decision of the Standing Committee on Patents (SCP) at its twentieth session.

I. BACKGROUND

I.1. NATIONAL INTELLECTUAL PROPERTY SERVICE

Pursuant to Law No. 1788 of September 1, 1997, the Industrial Property Registry and the Copyright Registry were merged to form the National Intellectual Property Service (SENAPI), centralizing information and guaranteeing operational decentralization of the system.

As stipulated by Supreme Decree No. 27938 of December 20, 2004, partially amending Article 2 of Supreme Decree No. 28152 of May 17, 2005, “the National Intellectual Property Service (SENAPI) is a decentralized institution with nationwide powers; it shall be legally and technically autonomous and shall operate under the authority of the Ministry of Economic Development”, which is now the Ministry of Productive Development and Plural Economy.

Moreover, in order to determine the procedures for the registration of distinctive signs, patents, utility models, integrated circuit layout designs, industrial designs, as well as enforcement action for opposition, offenses or unfair competition, SENAPI relies in the first instance on Decision No. 486 of the Andean Community Commission, together with Administrative Procedure Law No. 2341 and its regulations as approved by Supreme Decree No. 27113.

Additionally, the organizational structure of SENAPI includes a Technical-Operational Level, comprised of the Department of Copyright and Related Rights and the Department of Industrial Property in accordance with Chapter 111, Article 11 of the aforementioned Supreme Decree No. 27938, while the Department of Industrial Property is composed of the Patents service and the Trademarks and Distinctive Signs service.

II. REPORT

II.1. EXCEPTIONS AND LIMITATIONS TO THE RIGHTS CONFERRED BY PATENTS

II.1.i. Acts carried out to secure regulatory approval

The regulatory framework established by Decision 486 of the Andean Community of Nations is the main legal instrument governing exceptions and limitations to the rights conferred by patents.

Nonetheless, in Supreme Decree No. 29004 of January 9, 2007, the State of Bolivia introduced a Prior Consent step in procedures for patent application for pharmaceutical products and/or processes, stipulating the following.

Article 1. (Object). The present Supreme Decree is intended to establish Prior Consent in applications for patents for the invention of a pharmaceutical product and/or process.

“Article 2. (Prior Consent). For the purposes of the present Decree, Prior Consent shall be understood to be the practical mechanism establishing whether the content and scope of the work for which protection is sought by means of the patent application does not interfere with the right to health and access to medication.

Article 3. (Granting of Patents). The granting of patents for the invention of pharmaceutical products and procedures shall depend on the Prior Consent issued by the Medicine and Medical Technology Unit (UNIMED).

Article 4. (Competent Bodies). The competent bodies shall be the following:

- (a) The National Intellectual Property Service (SENAPI), which shall be responsible for analyzing patent applications and the registration procedure.*
- (b) The Medicine and Medical Technology Unit (UNIMED), whose main function is to issue the Prior Consent in respect of an application for a patent for a pharmaceutical invention.*

Article 5. (Responsibility). Responsibilities of the competent bodies.

- (a) SENAPI, with regard to prior grant of a pharmaceutical patent, will forward the relevant file to UNIMED.*

(b) Where the result of the Prior Consent is positive, UNIMED shall return to SENAPI the pharmaceutical patent application, adducing grounds for the Prior Consent result. Where the result of the Prior consent is negative, UNIMED shall return the patent application to SENAPI, founding the rejection in like manner, together with documentary evidence.

Article 6. (Prior Consent Technical Committee). In accordance with Article 1 hereof, UNIMED shall establish a Prior Consent Technical Committee to enable objective decision-making in the analysis of pharmaceutical patent applications submitted to SENAPI, save for exceptions relating to acts performed to secure the regulatory approval of the authorities for supplemental regulations”.

II.1.ii Exhaustion of patent rights

Article 54 of Decision 486 of the Andean Community of Nations is the sole legal instrument for granting patent rights. It states the following in this regard:

A patent shall not confer on its owner the right to proceed against a third party making commercial use of a product protected by a patent once that product has been introduced into the commerce of any country by the owner or another person authorized by the rightholder or with economic ties to that patent owner.

For the purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent, or when a third party is able to exert such influence over both persons.

Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes.

Bolivia does not have complementary legislation governing exceptions and limitations to the exhaustion of patent rights.

II.1.iii. Compulsory licensing and government use

Chapter VII of the Compulsory Licensing Regime, (Articles 61, 62, 63, 64, 65, 66, 67, 68 and 69 of Decision No. 486), is the legal instrument governing patents in this area. Moreover, Bolivia has not sought compulsory licensing through this service.

II.1.iv. Farmers’ and/or breeders’ use of patented inventions

Article 20 of Decision 486 says the following in relation to inventions excluded from patentability:

(a) Inventions whose commercial exploitation in the territory of the Member Country concerned must be prohibited with a view to protecting public order and morality,

provided that such exclusion is not solely because the exploitation is prohibited or regulated by a legal or administrative provision;

(b) inventions whose commercial exploitation in the Member Country concerned must be prohibited in order to protect human or animal life or health, or to preserve plants or the environment, provided that such exclusion is not solely because the exploitation is prohibited or regulated by a legal or administrative provision;

(c) plants, animals and essentially biological processes for the production of plants or animals other than non-biological or non-microbiological procedures;

(d) diagnostic, therapeutic or surgical methods for the treatment of human beings or animals.

Furthermore, by Law No. 300 of October 15, 2012: Framework Law for Mother Earth and Integrated Development for Wellbeing:

Article 24. (agriculture, livestock and fisheries). The foundation and orientation of Wellbeing through integrated development of agriculture and livestock are as follows:

1. Bringing about a revolution in productive community agriculture; establishing as fundamental objective the achievement of sovereignty and food security.

2. Maximizing production and energy efficiency to minimize the encroachment of the agricultural frontier, the irreversible effect on living areas and the use and enjoyment of other components of Mother Earth.

3. Establishing maximum use and enjoyment of the components of Mother Earth according to each area and way of life.

4. Developing harmonious, adequate, accountable and participatory policies for agriculture in accordance with the characteristics and regional distribution of each life system.

5. Prioritizing and incentivizing family agriculture, fisheries and animal breeding in communities and agroecology, according to the world view of each original indigenous rural and intercultural Afro-Bolivian community, adopting a diversified, rotary and ecological approach, for sovereignty and food security, seeking the exchange of knowledge.

6. Promoting and encouraging agriculture and livestock businesses wherever they incorporate technologies and practices that guarantee the capacity for regeneration of living space and systems and the increase in diversified and ecological productivity, in order to ensure sovereignty and food security.

7. Developing action to protect the genetic heritage of agrobiodiversity, prohibiting the introduction, production, use, release into the environment and sale in the territory of the Plurinational State of Bolivia, of genetically modified seeds of which Bolivia is the center or origin and those that destroy the genetic heritage, biodiversity, health of life systems and human health.

8. Developing action that promotes the gradual elimination of the cultivation of authorized genetically modified organisms in the country, to be subject to specific rules.

9. Developing institutional, technical, technological and legal capacity for the detection, risk-analysis and control of genetically modified organisms and their derivatives in transit conditions, as well as for the monitoring of those present in the country with a view to their gradual elimination.

10. Developing appropriate research, technological innovation and information systems and a system to regulate the production and marketing of food products taking into account volumes, quality, time and the constitution of reserves.

11. Prohibiting the production of agrofuels and the sale of agricultural products for their production given that it is the priority of the Plurinational State of Bolivia to achieve sovereignty and food security.

12. Improving access to inputs, production infrastructure, technical assistance and capacity-building.

13. Regulating the use of pesticides and other agricultural inputs which are nefarious to human health, according to specific norms.

14. Promoting and incentivizing urban and periurban agriculture for family consumption in harmony and balance with Mother Earth.

15. Building organic, productive, processing, marketing and funding capacity among original indigenous rural communities, intercultural communities and Afro-Bolivian communities from an intercultural perspective which draws on ancestral wisdom, practices and knowledge.

16. Identifying, classifying and measuring the total arable land on the basis of intended use of the land in order to promote increased productivity in agricultural activities, avoiding the extension of the agricultural frontier with respect to sovereignty and food security. (The underlined paragraphs are our concern).

Moreover, Supreme Decree No. 24676 of June 21, 1997 sets forth the regulations pertaining to Decision 391 on the Common Regime for Access to Genetic Resources, stating the following:

Article 1. The object of the present Supreme Decree is to regulate Decision 391 of the Cartagena Agreement Commission of July 22, 1996 to regulate the Common Regime for Access to Genetic Resources between the applicant and the State of Bolivia with regard to access to any of those genetic resources referred to in the following article; the said contract sets forth the scope of the rights and obligations of each contracting party.

Article 2. The present regulations shall apply to the genetic resources whose country of origin is Bolivia, together with their derivatives, associated intangible components and the genetic resources of migratory species which, for natural reasons, are found in the territory of Bolivia.

II.2. TRANSFER OF TECHNOLOGY

II.2.1. Incentives and impediments in the area of patents relevant to technology transfer

One of the main objectives of the outreach recently conducted by the National Intellectual Property Service concerning patents is the transfer of technology from patents granted by its office, although to date there has been no history or experience in this area.

II.3 NATIONAL OR REGIONAL LEGISLATION AND PRACTICE IN THE CONFIDENTIALITY OF COMMUNICATIONS BETWEEN PATENT LAWYERS AND THEIR CLIENTS

Relationships and/or communications between legal representatives and their clients as concerns intellectual property are private, there being no specific regulation governing patent confidentiality. However, in general, professional lawyers in the State of Bolivia are bound by the Code of Professional Ethics for Lawyers which governs issues such as responsibility towards the client, professional secrecy, documents and items provided by the client, etc.

III. CONCLUSION

The Bolivian National Intellectual Property Service is governed by Decision 486 of the Andean Community of Nations, since Bolivia is a contracting state. In terms of procedures it is governed by Law No. 2341 setting forth administrative procedures, with the relevant regulations contained in Supreme Decree No. 27113.

Nonetheless, other legal provisions have been issued, such as Supreme Decree No. 29004 of January 9, 2007 to establish Prior Consent for application for patents for pharmaceutical products and/or processes; Law No. 300 of October 15, 2012, Framework Law for Mother Earth and Integrated Development for Wellbeing, with reference to the limitations on the import, use and sale of genetically modified seeds; and Supreme Decree No. 24676 of June 21, 1997 setting forth regulations pursuant to Decision 391 with reference to the Common Regime for Access to Genetic Resources, which are all legal provisions related to patents.