Q-159

A) The national situation

1. Is the Rio Convention:

· signed by your country?
· ratified by your country?

Answer: YES

- The Convention of Biodiversity was signed by the Brazilian Government of June 5, 1992, the Act having been submitted to the National Congress which approved it on February 3, 1994.
- The Brazilian Government filed the instrument ratifying the Convention on February 28, 1994 and it came into force in Brazil on May 29, 1994.

2. Is, in your opinion, the Rio Convention already applicable in your country?

Answer: YES, the Brazilian Group considers the Convention already partially applicable in the Country in a few States such as Acre and Amapá which already have legislation of Access to Genetic Resources, a Provisional Measure Nr. 2052 in force already existing since June 29, 2000, which will be regulated till December 30, 2000 and provides about the genetic resources, the access to traditional knowledge, the distribution of benefits and the access to technology and transfer of technology.

3. If the Rio Convention is not yet directly applicable in your country and if its application would require specific legislation, does said legislation already exist? In the negative, are there plans or actual debates for such legislation in your country?

Answer: The Rio Convention was not yet fully applicable in Brazil for lacking a national legislation on the Access to Genetic Resources. In this respect, there are 4 Bills under proceduring in the National Congress for evaluation but the Convention will be fully applicable in a near future since a Provisional Measure aiming at remedying the lack of a specific legislation on that matter was published on June 29, 2000 regulating arts. 1, 8, item j, 10, item c, 15 and 16, items 3 and 4 of the Convention of Biological Convention in the Country. That measures provides on the access to genetic resources, the protection and access to related traditional knowledge, the distribution of benefits and the access to technology and transfer of technology for the conservation and use thereof. Such a Provisional Measure will regulated till December 30, 2000.

4. Apart from the Rio Convention or possible legislation for its enforcement, does there exist specific national legislation regulating the access to natural resources (genetic) of the country, the export provisions of such resources, the sharing of the results of their use or the transfer of technologies using them?

If such legislation exists, does it contain different provisions, in particular more extensive ones, than those of the Rio Convention? Especially, does the access to genetic resources require the prior consent of the owner of said resources?

Answer: YES. Some legislations regulate the access to genetic resources in Brazil, besides the Rio Convention.
They are, inter alia, Decree no. 98,830 as of 1990 already regulated, which provides on the collection of data and scientific material by foreigners in the Country, where the previous consent of the Ministry of Sciences and Technology is required for the field activities carried out by foreigners who collect and send abroad, inter alia, biological specimens, a Brazilian institution co-participation being required. Sharing of the results or transfer of technology was not provided therein.
There still exists Decree no. 3059 as of May 14, 1999, indicating that the Ministry of Environment shall implement, coordinate, supervise, guide and evaluate the control of the access to the use of genetic resources and as from June 29, 2000, a Provisional Measure was published that provides on the access to genetic resources, the protection and use of the related traditional knowledge, the distribution of benefits and the access to technology and transfer of technology for the conservation and use thereof.

5. Are the practitioners of your country aware of the impact on the patent law of the Rio Convention? Do they consider that relevant provisions of the Convention are still too theoretical and vague to affect patents in practice? Or, on the contrary, do they believe that the Rio Convention is to be taken into consideration at the present time?

Answer: The practitioners of the Country still have little information about the impact on the patent law of the Rio Convention for the alert on Biodiversity in Brazil is new, very probably because there was no specific national legislation on that matter up to present. As the Bills of Access to Genetic Resources were under study in the past 5 years, the provisions of the Convention were considered still vague to affect patents in practice. This situation will surely change, since through the Provisional Measure published in June 2000, full attention shall be given to the Convention from now on.

6. Is the TRIPS Agreement:

· signed by your country?
· ratified by your country?

Answer: Brazil is a signatory of the TRIPS Agreement, the Final Minutes of the Uruguay Round having been approved on December 15, 1995 by the National Congress and the Instrument of Ratification of said Final Minutes filed in Geneva on December 21, 1994, the Agreement coming into force in the Country on January 1, 1995.

7. Is the TRIPS Agreement already applicable in your country? If not, what is the deadline for its applicability?

Answer: The Brazilian Group considers the TRIPS Agreement applicable in Brazil since 1995. Between January 1, 1995 and January 1, 2000 there is a discussion about the applicability or not of

said Agreement automatically in the inner sphere, referring to the right contained in article 65.2 of the TRIPS. Wisely, however, most of the decisions confirm the applicability of the Agreement as from January 1, 1995.

8. In your opinion, are the decisions of grant of biotechnology-related patents rendered by your national patent office, as well as the rulings of your national courts, consistent with the Rio Convention? Whether the answer is positive or negative, groups shall illustrate their answer by quoting examples, where possible.

Answer: The Brazilian Group considers that the biotechnology-related patents granted in the Country fulfill the provisions contained in the TRIPS Agreement meeting the established patentability requirements. A direct relationship between the grant of patents meeting the patentability requirements and the direct consistency with the Biodiversity Convention was not discussed yet, for just on June 29, 2000, as a Provisional Measure, an outline for an eventual future national legislation on the Access to Genetic Resources was published, which in the future shall turn into a Convention directly applicable in Brazil. Therefore, there is no jurisprudence on the matter yet.

B) Possible means for implementing the Rio Convention into patent laws

9. If your country is a member both of the Rio Convention and of WTO, do you consider that contradiction may exist between the Rio Convention and the TRIPS Agreement? Further, if a subject liable to be contradictory does exist, could the Vienna Convention on the interpretation of international Treaties, particularly its Article 3 (a), be invoked, if same is applicable in your country?

Answer: The TRIPS Agreement aims an harmonization of domestic laws on industrial property of the member countries, taking, however, into account the differences existing among the domestic systems so as "to reduce misinterpretations and difficulties to the international trade".

It is one of the objects of the Rio Convention, as provided in article 1, the maintainable use of biodiversity, including the equitable distribution of the benefits arising from the genetic resources and the appropriate access to such resources through transfer of the relevant technologies taking into account all rights on such resources and technologies. Among such rights there are included the rights of intellectual property and the rights of the communities providing such resources.

The Brazilian Group does not believe there is any sort of conflict between the TRIPS Agreement and the Rio Convention, however the point of transfer of technologies provided in the Rio Convention shall be dealt with more carefully. Article 16 § 2 provides that in case of technology protected by patents or other form of intellectual property, the access and transfer shall be done under terms mutually agreed upon between the parties, which acknowledge and be consistent with the adequate and effective protection of the Industrial Property Rights. In paragraph 4 of article 16, it is provided that each contracting party shall adopt administrative, legislative or political measures aiming at facilitating the access to the technologies mentioned under paragraph 1 of said article. Therefore, in the Rio Convention we assume beforehand that the access to the technologies arising from the genetic resources will be facilitated through cooperation agreements signed by the contracting parties.

Now, in the TRIPS Agreement there is provided still another use of the subject matter of the patent without the owner's consent, as can be seen, for instance, in article 31 b). Such a provision could be used, for example, in case of refusal of a patent owner who evidently used the genetic resources from another providing Country, and is not facilitating the access to said technology or is not equitably sharing the results arising from said new technology with the Country providing said genetic resources.
Thus, the conclusion of the Group is that there would not be any sort of conflict between the Rio Convention and the TRIPS Agreement, however the provision on further use of the subject matter of the patent without the owner's consent would not be provided in the Rio Convention, having in mind that in this last part, we assume beforehand that the contracting parties would be equitably sharing the benefits resulting from the use of the genetic resources.

10. What is your opinion on the reservations of Article 27(2) of the TRIPS Agreement which make it possible to "exclude from patent protection invention whose commercial exploitation would be detrimental to "ordre public" or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment"? In this respect, do you consider that AIPPI should confirm the Resolutions adopted in Montreal in 1995 (see hereinabove)?

Answer: The Industrial Property Law in Brazil no. 9279 as of May 14, 1996 establishes in its article 18 that everything contrary to the morality, sound principles and security, and to the public order and health will not be patentable in the Country. Though the idea mentioned in article 27(2) of the TRIPS Agreement is specifically incorporated in the legislation of the Country, the Brazilian Group considers the Resolution adopted in Montreal by AIPPI should be kept.

The Sydney Resolution has already established that the problem of morality and ethics which could arise from the application of new techniques in biotechnology should be first regulated by specific laws dealing with such matters which the legislation of almost every country refers to, excluding from patentability the inventions contrary to the morality and order public.

In Montreal, making an analysis of question 114, AIPPI decided (2.3) that "the exploitation of inventions shall fulfill the general laws. The patent law should not intend to control researches, development and exploitation of inventions by restricting the protectable subject matter.

In discussions about the topic "Patents and Environment Protection" (Question 128), AIPPI called the attention to the fact that the mere determination that a given invention is considered non-patentable does not assure its subject matter may not be commercially exploited.

Thus, specific laws for protection of security/conditions of the environment should exist so that a given invention could be patented, independent of whether the subject matter claimed and, at the same time, its commercial exploitation could be set or not within an environment legislation in which the exploitation of the subject matter of the invention was prohibited should its potential hazard to the environment be evidenced.

The Montreal Resolution establishes that "patents relating to environment technologies should be granted on the basis of the established patentability prerequisites and any environment considerations should be left to the appropriate environment authorities.

The Brazilian Group is therefore of the opinion that a given invention should not be deemed as non-patentable merely because its subject matter relates to the environment, human, animal or plant health, or because it could harm "morality" or impair the "ordre public".

An invention showing novelty, having inventive activity and industrial applicability should be potentially deemed as patentable.

This does not mean its subject matter may be freely commercialized and/or exhibited to the public.
Both the Civil Law legislation and the specific provisions of environment and public health protection will determine whether a patented invention can be commercially exploited within a given territory. Morality varies greatly from Nation to Nation, influenced by traditions and cultures specific of each Nation and should be considered appropriately.
However, the Brazilian Group also considers that, in case the examiner of the Patent Department comes across an application for privilege referring to an invention which falls within the scope of the provision in article 27(2) of the TRIPS Agreement, it will be his sole discretion to insert a proviso in the letters patent and as a note, that the subject matter of the invention is within the ambit of the specifications of the above-mentioned article of the TRIPS Agreement, the competent authorities being in charge of nullifying its exploitation or not.

11. Some problems exist on the patentability of biological material such as DNA, living tissues etc. Do you think that AIPPI can confirm the Resolution adopted in Montreal on Q 114? Attention should also be paid to the position expressed by AIPPI on Q 150 studied during the Executive Committee held in Sorrento in April 2000. Do you think that, if national legislation excludes from patentability such inventions, this exclusion would be such as to facilitate the application of the Rio Convention or, on the contrary, that this exclusion would have no influence for putting in practice the provisions of the Rio Convention on the access and use of genetic resources of a country?

Answer: The Group again agrees with the Resolution adopted by AIPPI in Montreal for Q 14 with regard to the patentability of biological material. We consider the patentability of invention governed by the TRIPS Agreement and national laws of patents should not exclude certain biological material, discriminating them, once they show, per se, the patentability requirements. The Convention of Biodiversity shall be governed by laws of Access to Genetic Resources and the application of such laws of Access will not be facilitated by the lack of grant of patents for certain biological material. We are discussing here subject matters of different analyses. A subject matter refers to inventions and their main requisites of protection and another subject matter refers mainly to Agreements of Access to Genetic Resources.

12. What do you think of the reservations of Article 27(3) of the TRIPS Agreement which make it possible to exclude plants and animals from patent protection? Do you think that this exclusion by national legislation would be such as to facilitate the application of the Rio Convention or, on the contrary, that this exclusion would have no influence on putting in practice the provisions of the Rio Convention on the access and use of genetic resources of the country?

Answer: The Group agrees with the conclusion of Q 114 given by AIPPI in Montreal in 1995 which expresses hopes of a review of Art. 27 (3) (b) of the TRIPS Agreement in the sense of withdrawing

the exclusions for patentability in the field of biotechnology, which are discriminating, prohibitive of the sciences and technology development in this field.
The patentability or not of plants and animals hitherto DID NOT prevent the destruction of Biodiversity nor it facilitated the application of the Convention of Biodiversity. Moreover, to avoid patenting in specific fields cause the lack of potential improvements in such fields and avoid investments necessary to development to the detriment of populations which really need such developments (especially in health and foodstuffs).

13. The Rio Convention challenges neither the existence of patents nor the importance of patent rights. Articles 15 and 16 (see hereinabove) are however designed to determine the conditions of access to a technology making use of genetic resources.
Groups are invited to provide their comments regarding the possible practical solutions which are to be considered for the allocation of ownership of patent rights where the subject inventions are achieved due to information concerning genetic resources or by means of genetic resources themselves (for example: a plant or a microorganism). Is the signature of research and/or development agreements an appropriate path to explore with a view to solving the patent rights ownership allocation issue?
Examples for such agreements have been given during the workshop N V of the Rio Congress, as mentioned in the Introduction.
Groups of countries already having experience in this respect are welcome to illustrate their answer with relevant examples.

Answer: Information referring to genetic resources through traditional knowledge is one the several steps in the way of a patentable invention and the companies do not make direct use of such information as the one and only means of obtaining patents. After getting the information, specific technologies are employed which no more belong to traditional knowledge, for separating active compounds, purifying them, synthesizing them, manufacturing the final product, testing it and putting it into the market. Thus, a patent has as the final result, a result completely different from that of the invention arising from the original indigenous information. The Groups joins to the practical opinion hold by Nuno Pires de Carvalho from WIPO in his article "From the Shaman's Hut to the Patent Office: *How long and winding is the road*?" (published in the ABPI Magazine no. 41). Therein an indigenous data base system was suggested which makes use of the three provisions contained in the protection of test data, as adopted by the TRIPS Agreement in its article 39.2, namely,
a) the establishment of rights to data bases;
b) the validation of the rights to data bases;
c) the non-settlement of predetermined term of protection or, alternatively, the settlement of term of protection as from the date of first authorized commercial exploitation of the data.

We however do not have any experience in this field to report.

14. In your opinion, what means could empower a State or an institutional owner of genetic resources to work or allow the working in the host country of patens filed by third parties which make use at least partially of such resources? Do you consider, for example, that a State should be entitled to constrain a patent owner to grant a compulsory license, or even to sell the subject patent? The reply thereto should take into account the TRIPS Agreement, whose Article 31 in particular provides for the

possible working of a patented invention without the owner's consent, subject to the fulfillment of several conditions.

Groups are invited to report detailed comments as to how States could be theoretically empowered to regulate the utilization of their natural biological resources, attention being paid to the practical conditions imposed by the TRIPS Agreement for such regulations.

As for previous question 13, groups of countries having experience on this subject are warmly invited to illustrate their comments by concrete examples.

Answer: The Rio Convention mentions in its preamble and also its articles 3 and 15.1 the sovereignty of the States on their natural resources and authority for determining access thereto.

Article 15, item 7, of the Rio Convention, establishes that the contracting parties must share on a fair and equitable basis the results from researches and the benefits derived from the commercial use of genetic resources.

For such a distribution to happen it is necessary that the origin of the genetic resource be indicated, as well as the previous consent for accessing such resources.

Article 2 of decree no. 98,830/90 grants the Ministry of Sciences and Technology ("MCT") the jurisdiction power to evaluate and consent the collection of genetic resources by foreigners. Moreover, article 10 of said Decree subjects the commercial use of genetic resources to an agreement executed between the interested party and the MCT.

Article 6 of the Industrial Property Law LPI no. 9279/96 – LPI assures the author of the invention the right to obtaining a patent assuring him the ownership.

In case of non-compliance with the provisions above, we observe an abusive exertion of the patent rights and a shift from its social role.

The remedies for restraining such abuses are provided in articles 8 and 31 of the TRIPS, which contemplate the hypothesis of two forms of compulsory license, especially those provided in article 8, that is, those of social interest, in the fields of health and nutrition. Therefore said articles are in accordance, through article 2.2 of the TRIPS, with article 5 of the Paris Convention, which expressly provides the grant of a compulsory license, and with articles 68, 69, 70 and 71 of the LPI, which dealt with the same subject.

Finally, in case of non-observance of article 6 of the LPI, there is still a possibility of the State or Institution holding the property rights of genetic resources claiming, by a proceeding, the patent award, according to article 49 of the Industrial Property Law LPI no. 9279/96.

Thus, the access and use of genetic resources provided in the Rio Convention are in accordance with the international treaties, that is, the TRIPS, CUP and the rule of law existing in Brazil, the LPI and Decree no. 98,830/90, with regard to the abuses of the patent rights.

However, the Brazilian group understands that it would be necessary to prepare a federal rule of law establishing specific rules, deemed indispensable, for an effective control of the commercial relationships for accessing such resources. They are: definition of the contractual system of access; definition of the system of access to genetic resources; definition as to the system of distribution between owners of technologies and the State, resulting from the access, the use of genetic resources and transfer of technology; definition of the system of priorities for the conservation of ecosystems, species and genes; and definition of the system of administrative, criminal and civil sanctions. There are 4 bills under proceduring in the National Congress aiming at regulating the subject. They are: no. 04751/98, 04842/98, 04579/98 and 01953/99.

Moreover, while the above bills are not voted by the National Congress and taking into account the importance of the subject matter, the Federal Government issued, on June 29, 2000, the Provisional Measure no. 2052, which regulates the access to genetic resources in Brazil.

15. The Rio Convention distinguishes between the resources which have been acquired prior to its entry into force (in which case the Convention does not apply to their working) and the resources acquired later. For instance, data obtained from collections or data bases established before the date of entry into force of the Convention do not fall within its scope.

Groups are invited to report their possible experience regarding the working of resources acquired earlier than the date of entry into force of the Convention so that lessons may be drawn with a view to its application to future resources, as same will be subjected to the Rio Convention.

Answer: The Brazilian Group has not experiences to report on the exploitation of acquired resources before the enforcement the Convention but can declare that in the future and after the publication of the Provisional Measure, they will be able to report their experiences since article 10 of Provisional Measure no. 2052 as of June 29, 2000 says "... to the person in good faith who, till June 30, 2000, used or economically exploited any traditional knowledge in the Country, the right of continuing to use or exploit will be guaranteed, with no costs, in the previous form and under the previous conditions.

Only paragraph - The right granted in the form of this article can be assigned only together with the business or company, or a part of same having direct relationship with the use or exploitation of the knowledge, through alienation or leasing".

16. As indicated hereinabove, in particular as concerns article 15 and 16 of the Rio Convention, the latter contains provisions which can be implemented only upon mutually agreed terms. Negotiations between the party providing resources and the candidate desiring access and use will therefore become necessary.

Groups are invited to express their opinion as well as their comments on such negotiations. In this respect, it should be noted that article 31 (b) of the TRIPS Agreement also provides that the party seeking access to or the transfer of technology must have endeavored to obtain consent from the patent rights owner before a compulsory license is granted.

Generally speaking, do groups agree that amicable and free negotiations should prevail among contracting parties, including States, without any constraining schedule so that attention could be paid to the specificity of the host country as well to that of the subject resources? On the contrary, should pre-negotiated agreement forms be considered?

Answer: On this particular subject, as well as for the previous ones, groups are invited to report their experience gained in their country, where Conventions were negotiated regarding the utilization of natural resources in the sense of the Rio Convention.

The making of agreements among resources-providing communities and parties interested in accessing certain natural resources are still very new in Brazil. However, some examples can be mentioned:

a) agreement made among a contracting multinational company, an engaged national company and traditional knowledge-providing communities, for performing the screening of a data base of the biodiversity from Mata Atlantica and Amazonia Oriental, aiming at detecting in the Brazilian biodiversity active compounds against some diseases of world interest. This agreement, made in 1999, has foreseen the incidence of patents and the distribution of the benefits arising therefrom among all collaborators, including research centers and universities, observed their proper proportions. The contracting multinational company is the licensee and the one responsible for the commercialization of the patent subject matters;

b) partnership signed at the beginning of the year between Centro Nacional de De senvolvimento Sustentado das Populações Tradicionais (CNPT) - bound to IBAMA - and the cosmetic company Cognis (a subsidiary of the international company Henkel). This agreement aims at extracting vegetable oils from odd plants from the Amazonica forest, such as Guiana crabwood (*Carapa guianensis*), copal tree (*Copaifera officinalis*), castanha-do-pará (*Berthollelia excelsa*), cupuaçu (*Theobroma grandiflorum*, Spreng.) and murumuro (*A. murumuru*), for being used in cosmetics (moisturizers, liquid and solid soaps, shampoos, lipsticks etc.). Extraction and commercialization of said oils will be carried out by the communities themselves (extracting associations and cooperatives). An important point in this partnership is the obligatoriness of the use of a seal or certificate of the product origin, which must be placed on the products by each cooperative or association bound to the project, proving the authenticity of same and promoting the correct ecological way of cosmetic extractivism;

c) another agreement signed among institutions, providing communities and companies interested in the natural resources from Amazonia is a partnership between POEMATEC (Comércio e Tecnologia Sustentável da Amazônia Ltda.) and the German company Mercedes Benz. Such a partnership aims at using technology from the German company, in the processing of coconut fibers, the main buyer of such a product being Mercedez Benz itself. POEMATEC says the venture aims at promoting the social-economical development of the communities involved together with the proposal for environment preservation.

d) an agreement between Empresa Bioamazonica, a non-profit social organization, which signed a management agreement with the Federal Government and the Swiss company Novartis Pharma AG.

According to that agreement, Bioamazonia would send microorganism strains owned by Novartis which in turn would hold the right of property on the resulting inventions, assuring however the

royalties to Bioamazonia. That agreement meets all requisites contained in the Rio Convention and the rules regulating bioprospection in the Country, including that with the co-participation of a Brazilian institution.

It is important to point out that because of the Provisional Measure published on June 29, 2000 already referred to in other items of the Question, new rules have been inserted in the national legal system which will undoubtedly cause changes in all agreements previously signed.

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