Summary Report

Question Q 159

The need and possible means of implementing the Convention on Biological Diversity into patent laws

As stated in the Working Guidelines, the Convention on Biological Diversity (or biodiversity), signed at Rio de Janeiro in 1992, came into force on 29th December 1993. During its Rio Congress (24th-29th May, 1998), the AIPPI, in the context of workshop n° 5, studied the relations between genetic diversity and intellectual property. The report of this workshop is in the 1998/IX Yearbook, pages 94 ff.

Given the importance and topicality of the questions raised by the implementation of the Convention on Biological Diversity, in particular for developing countries, AIPPI considered that it should carry out a detailed study, using its traditional working methods, of the impact which the Rio Convention might, directly or indirectly, have on patent law.

The national groups were thus invited in the Working Guidelines to reply to a number of questions relating to this subject, and also to comment on any other question which had not been specifically raised but which nevertheless seemed relevant to the study.

The Reporter General has received reports from the groups of the following countries: Argentina, Australia, Belgium, Brazil, Bulgaria, Korea, Denmark, Egypt, Spain, Finland, France, Hungary, Ireland, Italy, Japan, Norway, the Netherlands, Ecuador, Romania, United Kingdom, Singapore, Sweden, Switzerland, Venezuela.

These reports represent a very interesting study in comparative law, and for the most part contain relevant and constructive observations on the position of the Rio Convention in the patent system.

A summary of the content of these reports is given below.

A) The national situation

1. It emerges from the reports of the groups which have replied that, with the exception of Bulgaria, all the States have ratified the Rio Convention. The French and Spanish groups also noted that the ratification had been performed both nationally and at the level of the European Union, which had signed the Rio Convention as such.

2. The great majority of the group reports considered that the Rio Convention was already applicable in their countries. The United Kingdom group however considered that in the absence of specific national legislation, the Rio Convention was not yet applicable in that country.

The Australian group however observed that many aspects of the Convention were not yet applicable in that country, in particular those relating to the access to genetic resources and their commercial utilization. The same situation exists in Singapore. According to the Egyptian group, new legislation on plant products and plant varieties would not take effect until after 1st January 2005, so that in this particular field, the Rio Convention would not apply before this date. The Finnish and Italian groups commented that the Convention on Biological Diversity did not contain exact provisions and obligations for the contracting parties: according to them, the Convention is a type of framework law which defines the objectives whose realization is a matter for national legislation. For the French group as for the Belgian group, it would be difficult to give direct application to provisions which are often declaratory and general. The French group also commented that some difficulties in interpretation of the Rio Convention have not yet been resolved, as a non-limiting example the question as to whether it applies to genetic resources of human origin. The same situation applied in Singapore.

The Swiss group also questioned whether the Rio Convention could be directly applicable in that country and, in its opinion, the majority of the provisions of the Convention on Biological Diversity were not directly applicable. However, it considered that the provisions relating to patent law were applicable.

3. On the question of whether specific legislation would be necessary to implement the Rio Convention in the country, the majority of the groups replied that such a law would be unnecessary, since the provisions of the Rio Convention had legal authority nationally by the fact that they were contained in an international treaty which the country had signed.

The United Kingdom group nevertheless considered that the provisions of the Rio Convention were too abstract to be adapted to the national level. The Belgian group judged that the Rio Convention is a convention whose direct applicability was not possible. Several legal studies are in hand on its adaptation into national law, including in the patent field.

The Australian group noted that, although the Rio Convention was not currently applicable in the country, the Australian government was very concerned about the protection and conservation of biodiversity and in 1999 had promulgated a law with these objectives: in the context of this law, further studies are taking place to take into account the obligations of the Rio Convention. The Italian group observed that, in its country, discussions are in hand on the national implementation of the Rio Convention, without however yet having reached a conclusion.

The Singapore group observed that studies are under way in the country to protect natural resources and that specific laws already exist in several areas.

According to the Brazilian group, the Rio Convention is partially applicable in some states of the country where a law coming into effect before 30th December 2000 will regulate the access to genetic resources.

The Spanish group considered that the Rio Convention contains provisions which, to be directly applicable in that country, would require specific legislation which does not yet exist. The same opinion was shared by the Dutch group.

The Swedish group indicated that, in the absence of specific national rules, the Rio Convention is not directly applicable in their country, but that numerous legislative studies are under way on subjects covered by the Convention.

In contrast, the Argentinian, Egyptian, French (with the above reservations), Norwegian, Romanian, Venezuelan and Japanese groups asserted that the Rio Convention was directly applicable with no need for specific legislation. According to the Danish group, the Rio Convention can be applied in their country since national legislation already conforms with the Convention, but as do the Finnish, French and Italian groups also, they consider that it will be difficult to put into practice.

For the purposes of the present study and except for specific points, it is reasonable to consider that the Rio Convention is now widely applicable in the world (it has been signed by 168 countries).

4. The groups were invited to state whether, in their countries, apart from the Rio Convention or a possible law to implement it, there were national provisions regulating the access to natural (genetic) resources, the conditions of exporting such resources, the sharing of the results of their utilization or the transfer of technologies for their exploitation.

According to the reports received from the groups, almost all the countries had no national legislation comparable to or more restrictive than the Rio Convention. However, many countries had special regulations in the areas covered by the Biodiversity Convention.

Thus, the French group observed that, in its country, the access to genetic resources was in general subject to the prior authorization of their owner. However, in all cases, it was the common regime of civil law which applied. According to the Hungarian group, an order from the Ministry of Agriculture was issued for the preservation and utilization of plant genetic material, in the spirit of the Rio Convention. But this order only regulated the access to genetic resources and contained no provisions for sharing the results of the utilization of these resources, nor the transfer of related technologies.

Similarly, the Norwegian group stated that its country had a law regulating the access to living resources, for example fish, and discussions were taking place on the access to other genetic resources of the country. The Romanian group analogously cited laws and orders concerning the commercialization of genetically modified organisms, as well as the protection of the environment (forests, waters). The Korean group mentioned several legislative texts for the protection of natural resources from their country and cited an orchid in the process of becoming extinct which it is forbidden to export, as an example.

The United Kingdom group described particular features of national legislation, notably on the protection of wild animals and the use of human genetic resources.

The Japanese group noted that there were fairly numerous provisions in its country regulating the protection of the environment, birds, animals, plants, and in particular endangered species. The Japanese group added that the access to these genetic resources was subject to the prior authorization of their owner. In contrast, the Netherlands group stated that there were no national legal measures more restrictive than the Rio Convention, and in particular no measures requiring the prior authorization of the owner.

The Italian group reported studies under way in its country on the application of a plan for national biodiversity and stated that very contradictory opinions had been expressed in the biotechnology field. The Italian government had thus decided to join in the action initiated by the Netherlands government at the European Court of Justice to contest the application of the European Directive of 6th July 1996, mentioned in the Working Guidelines.

The Venezuelan group reported the existence in the Constitution of its country of provisions comparable to some of those in the Rio Convention. It also referred to the Andean pact on biodiversity.

The Ecuadorian group stated that national patent law required that, in the case where the invention which was the object of the patent utilizes genetic resources, proof must be provided that these genetic resources had been legally acquired. It also referred to the resolution of the Commission of the Andean Community coming into force on 1st December 2000, according to which patents concerning genetically modified organisms and/or processes for the production of these organisms must have obtained prior authorization from the National Agency for Biological Safety.

The very detailed report from the Belgian group described the regulation of the environment and export controls.

5. In most countries, the practitioners knew of the existence of the Rio Convention, but were poorly informed as to its content or considered that it was too vague and theoretical to be implemented in practice.

The Romanian group wished that its patent law be modified to require the applicant to state the country where the biological material had originated and to specify whether the acquisition of this material had been subject to explicit consent as to its utilization. The 1998 Romanian law on the protection of plant varieties already contains this type of provision.

The Brazilian group observed that the Rio Convention is not at present well known in the country, but that new legal measures due to be taken shortly will change this situation.

The Belgian group explained that the Rio Convention is better known in the research sector, for example on micro-organisms, and cited the "MOSAICC" project supported by the European Commission.

The Korean group is of the opinion that the Rio Convention is seriously taken into consideration and that it has a great influence on patent law.

6. The groups of all the countries which had replied stated that TRIPS agreement had been signed and ratified in their respective countries.

7. Almost all the groups also stated that the TRIPS agreement was already applicable in their respective countries. As the Netherlands group observed, the question remains as to whether all the provisions of the TRIPS agreement are directly applicable in the country or whether, on the other hand, some of them, considered as insufficiently precise, would require specific legislation to be applicable.

8. Almost all the group reports considered that the decisions of their national patent offices on the granting of patents, or those of the courts, in particular in the biotechnology field, did not contradict the Rio Convention. On this subject, the French group emphasized that this Convention (see in particular article 16) does not call into question the possibility of granting patents relating to biotechnological inventions or genetic resources. It is only concerned with the possible effects of the exploitation of the intellectual property rights.

The Australian group stated that Australian patent law was harmonized with the TRIPS agreement in 1994 and that there had not been sufficient time to judge the possible consequences of the Rio Convention on the utilization of these patent rights.

The Egyptian group noted that the current legislation in its country did not allow the granting of patents relating to biotechnologies.

According to reports from the European groups, national practice conformed with the European Patent Convention. This was the case even for countries such as Bulgaria and Hungary, which are not yet part of the European patent system. Several reports from European groups mentioned the adaptation into their national law of the above-mentioned 1998 Directive on Biotechnologies. The Finnish group expressed a wish that the interpretation of the provisions of this Directive should be strict. As already stated, difficulties have occurred in the adaptation into European states such as France, Netherlands and Italy, which did not prevent the Italian group from citing, with supporting examples, cases of the granting of patents on transgenic animals and jurisprudence of courts confirming the patentability of biological materials, in particular DNA sequences.

B) Possible means for implementing the Convention on Biological Diversity into patent law

The groups were invited to reply to a number of questions which had been raised, particularly at the workshop of the Rio de Janeiro Congress in 1998.

Preliminary comment

The Working Guidelines (see paragraph 13) had stated that the Rio Convention did not contest the existence of patents, nor the importance of patent rights. As the Brazilian, Danish, Spanish, Finnish, French, Italian, Japanese, Dutch and Swedish groups particularly noted, the objectives of the Rio Convention do not call into question the patent system. The Convention applies only to the effects of the exploitation of these rights (article 16, paragraph 2) and it expressly invites (article 16, paragraph 5) the Contracting Parties to cooperate in order to ensure that patent rights are supportive of and not counter to the objectives of the Convention.

After a detailed and reasoned analysis of the most relevant articles of the Rio Convention, the introductory portion of the Danish group's report stressed that the Convention is in no way opposed to the patent system and that innovation allows the Convention's aims to be reached.

The French group added that it would be wrong to present the Rio Convention as an international instrument with higher value than others, in particular than the treaties and conventions relating to intellectual property.

This preliminary comment, based on the reports of several groups, and whose source is the text of the Convention on Biological Diversity itself, clarifies the replies made to many questions covered below.

9. Almost all the groups which had replied considered that there were no contradictions between the Rio Convention and the TRIPS agreement.

   The Belgian group, however, raised a number of provisions of the Rio Convention which seemed contradictory, or at the least difficult to reconcile with the TRIPS agreement, for example:

   - the concept of sharing the "advantages resulting from the commercial or other exploitation of genetic resources" could conflict with the principle of exclusivity in patent law, in particular when this results from the signature of licence contracts (article 28(2) of the TRIPS agreement),

   - article 27(2) of the TRIPS agreement provides that it will be possible to enjoy patent rights without discrimination, while the Convention could impose conditions on the access to and transfer of genetic resources,

   - article 16(5) of the Rio Convention is ambiguous and its application could be contrary to the TRIPS agreement.

   The Belgian group added that the Rio Convention only binds states which are contracting parties to this Convention, while patent rights do not in general belong to states. This situation could lead to difficulties in the practical application of the Rio Convention.

   The Argentinian group observed that the latter had been adopted after the Rio Convention and that if any possible contradiction emerged, it would be TRIPS which

prevailed. The Finnish group stated that each treaty had its own area of interpretation and application. Similarly, the Italian group considered that the two treaties were complementary and that the patent system could only encourage the application of the Rio Convention. The Romanian group shared the same opinion.

For the Swiss group, the absence of conflict between the TRIPS agreement and the Rio Convention followed from the text of the latter. It considered, like the Argentinian group, that if any difficulty emerged, it would be the TRIPS provisions which took precedence. The same opinion on the principle was shared by the Spanish, Japanese and Dutch groups.

The Brazilian group observed that article 1 of the Rio Convention provided that the transfer of technologies relating to genetic resources must take account of the rights over these resources and technologies, and that obviously patent rights were part of such rights.

As a result of the positions taken by the groups, the question of the possible application of the Vienna Convention on the interpretation of international treaties, which could arise if there were any contradiction between the Rio Convention and the TRIPS agreement, became completely secondary. Several groups nevertheless stated that they would be in agreement for an application of the Vienna Convention: this was the case for the Danish, Norwegian, Swiss and Spanish groups, while the French group observed that France had not ratified the Vienna Convention.

The conclusion from the group reports is that AIPPI could take the position in principle that the Rio Convention and the TRIPS agreement each apply in their respective areas and that there are no contradictions between them. In addition, in the case of any conflict, the TRIPS agreement should prevail.

10. Almost all the groups approved the principles raised by article 27(2) of the TRIPS agreement, and, with a few exceptions, the resolutions already adopted by AIPPI on questions Q114 and Q 128 during the Montreal Congress in 1995.

The Korean group did not agree with exclusions of patentability as mentioned in the Article 27(2) TRIPS.

The Hungarian group considered that it was unnecessary to approve these resolutions but that, if a patent was refused on the grounds that its object was considered as contrary to public order or morality, the interpretation and application of the provision of TRIPS article 27(2) must be strict.

The Venezuelan group did not approve resolutions Q114 and Q 128 and merely desired the application of TRIPS article 27(2).

The French group approved all the Montreal resolutions while however commenting that point 2.3 of resolution Q 114 could be reconsidered. Like the Hungarian group, it emphasized that a refusal to grant a patent based on the provisions of TRIPS article 27(2) could only apply to inventions clearly contrary to public order and would only be admissible if a parallel refusal of non-exploitation of the invention was pro-

nounced on the basis of national law. It would not be reasonable for such an invention to be exploited while its inventor could not profit from this.

All the other groups including the Korean group confirmed their approval of the Montreal resolutions.

Thus, for the Argentinian group, patent law should not be concerned with questions of public order or morality. The Finnish group stressed that it was not at the level of patentability but of exploitation that the criterion of public order or morality should be applied. The United Kingdom group shared the same opinion.

The Italian group added that abuses of patents could be sanctioned as anticompetitive practices. The Brazilian group also considered that laws other than the patent laws could regulate the exploitation of inventions. An invention could be patentable but this did not necessarily mean that it could be freely exploited. In the same sense, the Spanish group considered that it was common law which should regulate the conditions of exploitation, independently of the fact of whether the invention was patented or not. The Japanese and Swedish groups shared the same opinion.

11. All the groups which had replied, with the exception of Venezuela, approved the AIPPI resolutions on Questions Q 114 and Q 150. The Japanese group however observed that, for ethical reasons, some biotechnological inventions applicable to humans or animals should not be patented.

With the exception of the Venezuelan group, all the groups also considered that if the patentability of biological materials was excluded, this exclusion would not facilitate the application of the Rio Convention, in fact quite the contrary.

The Belgian group offered a more balanced opinion, since although it still approved resolution Q 114, it considered that the question could be reconsidered in the light of current discussions on the European Directive of 6th July 1998 concerning biotechnological inventions.

Thus, the Argentinian group observed that the exclusion of patentability of such inventions would have the effect of weakening the principles of the Rio Convention rather than strengthening them, given that effective protection of these inventions constituted the means for the effective transfer of technology and the viable exploitation of genetic resources. The Australian group noted that the patentability of living matter had no impact on the implementation of the provisions of the Rio Convention.

According to the French group, a superficial analysis of the question could lead to the conclusion that an absence of protection, allowing greater freedom, would encourage the implementation of the Rio Convention. But an absence of patent protection would inevitably lead to a reduction or withdrawal of investment in biotechnological inventions, would discourage research or encourage researchers to adopt a policy of secrecy, limiting the access of scientists to technology and impoverishing the information available on genetic resources. To the extent that patent right is accompanied by publication of the content of the patent application, it represents an ir-

replaceable tool for improved access to all the technologies relating to genetic resources.

The report of the Italian group developed similar arguments to show the advantages of the patent system in the implementation of the Rio Convention. The Swiss group similarly considered that the patentability of living matter could only encourage the implementation of the Rio Convention for technology transfers and the utilization of genetic resources. For the Brazilian group, the implementation of the Rio Convention would not be facilitated if inventions on living matter were not recognized as patentable. In common with many other groups, the Spanish group observed that patents, by their publication, enriched scientific knowledge and should thus encourage the implementation of the Rio Convention. The Japanese group, despite the reservations expressed on the delicate question of the patentability of living things, considered that exclusions of patentability of some types of inventions would have no impact on the implementation of the Rio Convention.

The Dutch group observed that the absence of patent protection would discourage research and that any exclusion of patentability would have the reverse effect to that sought for to encourage the implementation of the Rio Convention. Like other groups, it considered that this absence of protection would represent an obstacle to investment in this field.

Thus, among the groups which had replied, only the Venezuelan group expressed the opinion that the absence of protection on biological inventions would be liable to facilitate the application of the Rio Convention.

12. The groups were then invited to study the reservations of article 27(3) of the TRIPS agreement on the protection of plants and animals and to give their opinion on the question as to whether the exclusion of protection by national legislation would tend to facilitate the implementation of the Rio Convention or not.

On this point, the groups confirmed the opinion expressed in paragraph 11.

The Venezuelan group formed the conclusion that the absence of protection on plants and animals would facilitate the application of the Rio Convention.

The Romanian group, while approving the provisions of article 27(3) of the TRIPS agreement, considered that the exclusion of protection of plants and animals would facilitate the implementation of the Rio Convention, since this would oblige the owner of genetic resources and those who wished to utilize them to negotiate a contract for the access and exploitation of these resources.

This position was not shared by the other groups, for the same reasons as those stated in paragraph 11. The opinion of the groups is well expressed by the report of the Argentinian group for whom the weakening of intellectual property rights would not promote the achievement of the objectives of the Rio Convention.

The Italian group, in approving the provisions of article 27(3) of the TRIPS agreement, additionally commented that, for plants, the possible system of protection

both by plant variety protection certificates and/or patents was not the best solution, and that it would in general be preferable to provide for patent protection. According to this group, this would allow progress and development in agricultural technologies which could solve the world's food problems. The discovery of new genes able to improve the productivity of plants depended on the access to genetic resources existing in nature and such objectives could not be achieved if patent protection was not allowed for such inventions. The Italian group further observed that inventions relating to plants and animals often involved the manipulation of the initial biological material by genetic engineering techniques. The absence of patent protection for such inventions would have the same unfavourable effects on the practical implementation of the Rio Convention as those already stated in paragraph 11.

For the Brazilian group, the act of preventing protection, in particular by patents, of certain inventions on plants and animals would have the effect of inhibiting investment and discouraging improvements in areas such as health and food products in countries where these are most in need.

The Spanish group stated in general terms that on condition that the advantages are fairly distributed, it would be better to utilize natural resources than to provide for bans on protection.

The Japanese group confirmed that it did not approve, for the ethical reasons expressed in paragraph 11, of the patent protection of animals.

13. The groups were invited to give their opinion on the possible practical solutions for assigning the ownership of patent rights in the case of inventions made from information relating to genetic resources or from genetic resources themselves (for example a plant material or a microorganism). The Working Guidelines added that the signature of negotiated research and/or development conventions could be the preferred route for resolving problems of assignment of patent ownership.

13.1. The French group emphasized the fundamental distinction between the corporeal ownership of biological materials and the ownership of inventions which might be made with these materials. It added that, from a legal point of view, corporeal ownership in no way influenced the rules of assignment of the ownership of the inventions, except in the framework of contracts freely negotiated between the parties. The French group also stressed that the Rio Convention recognized the existence of intellectual property rights as defined in many international instruments.

The Japanese, Danish and Swedish groups, like the French, emphasized that the Rio Convention contested neither the existence nor the importance of patent rights.

The Argentinian, Hungarian and Italian groups stated that, to regulate the ownership of patents, the normal rules of patent law should be observed. Thus, for the Argentinian group, the principle to be respected is that the ownership of the patent belongs to the inventor. For the Hungarian group, the ownership of the patent should take account of the contributions of the part-

ners to the invention. The Brazilian group commented that the patented invention goes well beyond the simple initial information on the genetic resource.

The Swedish group pointed out that a valid patent right can only be obtained if the claimed invention fulfils the usual patentability criteria; thus a patent cannot cover a genetic resource taken as such and in its natural state.

The Australian group stated that, in its country, the patent law did not contain provisions regulating the ownership of patents whose inventions related to genetic resources, but that studies were in hand to adopt more precise legal measures, in conformity with the Rio Convention. These new developments however mainly concern the sharing of the fruits of the exploitation of resources and the respect of local biodiversity.

The Spanish group suggested that, if it clearly emerges from the descriptive part of the patent that the invention had been made from a genetic resource originating from a given country, the applicant should show that he had obtained this biological material in accordance with the rules in force in the country possessing said resources.

Similarly, the Ecuadorian group proposed that national patent legislation should require that genetic resources related to the patented invention had been legally acquired in the country which possessed them.

Some groups additionally noted that the regimes of joint ownership of patents were undesirable. This was the case for the Finnish group who considered that such regimes were complicated and difficult to apply in practice. The Italian group also noted that the joint ownership regime of patents over a wide international base could make their commercial exploitation difficult because of the wide differences existing between national legislations for exploiting jointly held inventions.

The conclusion from a large majority of the group reports received was that, in the absence of specific contracts, the normal rules of patent law should apply for determining the ownership and the patentability of inventions related to genetic resources.

13.2. As for negotiated research and/or development conventions, several of the groups which replied stated that they did not have enough experience to reply. This was particularly the case for the Argentinian, Bulgarian, Egyptian, Norwegian, Romanian and Brazilian groups.

For the other groups, research and cooperation agreements were extremely desirable. The Japanese group particularly commented that such contracts were specifically provided for in the Rio Convention. The groups which replied on this point also stated that these contracts regulate not only questions of ownership of patent rights, but also the modalities of access to genetic re-

sources and their conditions of future exploitation in return for financial compensation.

As the French group observed, technology transfer is initially materialized by access to genetic resources. The contract must define the means of ensuring the respect and maintenance of autochthonous communities and their culture. These same agreements may also provide for the sharing of the fruits of the exploitation (see also the Finnish and Swiss groups).

The United Kingdom group commented that, in addition to research and development conventions, agreements could also be concluded on the study of biological materials in collections.

The Italian group very pertinently stressed the difficulty of drafting general rules for such research and/or development conventions because of the very great differences which can exist between specific situations. The invention in question might be a product directly arising from a biological material constituting the genetic resource, the product being simply obtained by isolation. It might also be a product produced after very complex technical research on the original biological material. This material might also be utilized simply as a research tool in the genetics field. Despite this, the Italian group did not underestimate the advantage of standard contracts which could help the development of individual contracts. It cited in this area a project developed by the Commission of the European Union which could serve as a code of conduct for implementing the provisions of article 15 of the Rio Convention.

The Belgian group observed that, for localized transfers, of the type frequently performed for culture collections, it would be useful to have standard texts available, which would be easier and quicker to implement than research conventions negotiated case by case.

The Japanese group also desired standard contracts and a code of conduct.

The Hungarian group also favoured the negotiation of contracts regulating the ownership of the patent arising from the genetic resource. For the Swiss group, these research and/or development contracts are good but do not have a restrictive value for third parties. It thus suggested regulations at the level of the States possessing genetic resources to forbid subsequent utilization of illegally acquired (biopiracy) genetic resources by unauthorized third parties.

The Dutch group observed that the assignment of the ownership of patents arising from genetic resources must not be confused with the question of the real entitlement to the patent rights. If the patent had been applied for in violation of a legal or contractual obligation, common patent law should apply so that the rights are returned to their true holder.

On this point and after the group reports received, AIPPI should decide in favour of the signature of negotiated research and/or development conventions

which respect the objectives fixed by the Rio Convention. To satisfy the wishes of a number of groups, AIPPI could express a desire that additional studies are undertaken to establish standard contracts which may serve as a basis for a code of conduct and help the development of contracts taking account of specific situations. AIPPI could cooperate in this area with WIPO, especially as the latter organization must include the implementation of the Rio Convention at a global level in its programme of work.

14. The groups were invited to express their opinion on the means allowing a State or an institution which owns genetic resources to exploit or allow exploitation in the original country of patents at least partially using said resources. In the context of this question, the application of article 31 of the TRIPS agreement on compulsory licences is particularly relevant.

14.1 It firstly emerged from the replies of the groups to the previous questions, in particular paragraph 13, that outside contractual provisions, the States or institutions possessing genetic resources could subject the access to the resources to official authorization. The Australian, Ecuadorian, Spanish, Dutch and Singapore groups particularly made this point. The Swiss group also suggested that States possessing genetic resources adopt rules for preventing uncontrolled utilization of the genetic resources as a measure against biopiracy.

14.2 The question raised is that of the possible forced exploitation of inventions derived from genetic resources, in the absence of contractual relationships between the States or institutions possessing said resources and the party wishing to exploit them.

The French group firstly emphasized the importance of the identification of the legal status of the body possessing the genetic resources. It suggested that the determination of the owner should be the responsibility of the States and should be resolved so as to ensure the maximum legal security to the holder of the intellectual property right. The Swiss group expressed a similar opinion.

Given this comment, it emerged from the majority of the group reports that they approved the application of article 31 of the TRIPS agreement which allows, under a number of limiting conditions, the exploitation of a patent without the authorization of the holder of the right. This was the case for the Argentinian, Belgian, Bulgarian, Egyptian, Finnish, French, Hungarian, Italian, Romanian, Swiss, Venezuelan, Spanish, Japanese, Dutch and Ecuadorian groups.

The Australian group did not agree with a compulsory licensing regime and desired that mutually negotiated contracts regulate the access to genetic resources with the consent of their owners, as well as the sharing of the results of the exploitation.

The Swedish group is opposed to the compulsory licensing system, since they think it not appropriate to resolve the problems linked to the implementation of the Rio Convention.

The Norwegian group recognized the existence of article 31 of the TRIPS agreement but did not think that a compulsory licence was a viable solution at the practical level. The exploitation of the resources could raise political and environmental protection problems which must be regulated by other legislation.

The Hungarian group stressed that the provisions of article 31 of the TRIPS agreement were strict and that a State should not be authorized to sell a patent, and it again declared that the utilization of biological resources was not a matter for patent law.

Like the Hungarian group, the Japanese group considered that TRIPS article 31 did not allow a State to sell the patent in question. The Belgian group added that this would be equivalent to expropriation of the patent.

The Swiss group observed that the procedure for granting a compulsory licence such as is provided for in article 31 of the TRIPS agreement implies an initial amicable negotiation between the parties. This negotiation is in every respect in accordance with the spirit of the Rio Convention and it is only in the case of failure that the courts must decide on the possible grant of the compulsory licence.

The Italian group observed that TRIPS article 31 does not allow States to take more restrictive measures on the exploitation of patents. However, it still remains possible for contracts to be agreed between the owner of the biological material and the party wishing to have access to it. The Italian group added that the objectives of the Rio Convention would be better fulfilled by measures encouraging the local exploitation of patents and the corresponding technology rather than to reward patents by royalties or lump-sum payments.

The Brazilian group stated that article 31 of the TRIPS agreement is not the only one to be considered: article 8 of this treaty also provides for a form of compulsory licence in the fields of health and food.

Several groups stated that their countries have legislation on the forced exploitation of patents. Thus, the Argentinian group mentioned specific provisions on the grounds of health emergencies or national security. The Brazilian group mentioned a law of 1990 concerning modalities of access to genetic resources and also referred to several draft laws under discussion for the utilization of the country's genetic resources.

On this point, the group reports showed that they generally approved the strict application of article 31 of the TRIPS agreement in the case where the

parties have not been able to reach an amicable agreement for the exploitation of the genetic resources.

15. The groups were invited to report their experience on the exploitation of resources acquired before the Rio Convention had come into effect. The Rio Convention in fact only applies to resources acquired after its coming into force.

The French group emphasized that the Rio Convention has no retroactive effect. This principle applies to genetic resources acquired before its coming into force, whether the information had been discovered or created before or after its coming into force.

Few groups replied by reporting their past experience.

The Danish group considered that this question has no link with patent law.

The Korean group reminded that their country had known in the past several cases of exports of biological materials from the country, which led to the filing of patents.

The Italian group stated that to the best of its knowledge, the normal practice for access to genetic resources consisted of a single payment to the owner, with no other obligation on the part of the recipient. There were also purely commercial agreements on the supply of biological material. In the opinion of the Italian group, these experiences were not a suitable basis for future practice.

The Brazilian group, while observing that it had no past experience, observed that the temporary measures which will apply in its country from 2002 will preserve rights acquired before 30th June 2000.

The Japanese group stated that in the past, interested third parties had consulted collections of biological materials of the country concerned, but that no sharing of the results of the exploitation had been provided for.

The Belgian group added that the work of cataloguing and storing data was essential for the application of the Rio Convention.

16. Articles 15 and 16 of the Rio Convention contain provisions which can only be implemented with common agreement or according to mutually agreed procedures.

The groups were invited in the Working Guidelines to give their opinion on the amicable negotiations provided for between the party possessing the genetic resources and the party wishing to have access to or to exploit them. The groups were more specifically invited to say whether it was advisable that these negotiations were not constrained by terms fixed in advance or whether in contrast standard agreements should be used.

It emerged from the majority of the reports that these clearly favoured negotiations for access to genetic resources and their exploitation. This was the case for the Ar-

gentinian, Australian, Belgian, Danish, Egyptian, Finnish, French, Hungarian, Italian, Romanian, Swiss, Brazilian, Spanish, Japanese, Dutch and UK groups.

The Danish group emphasized that Article 31 of the TRIPS agreement only provides for the granting of a compulsory licence on the patent, but that if a technology transfer is to be carried out according to the Rio Convention, the terms of such a transfer can only be decided on the basis of mutual agreement, i.e. by contract.

The Finnish group observed that such negotiations constitute the only means of taking account of the particular circumstances relating to genetic resources.

The French group considered that a route involving negotiation with the countries or communities possessing the genetic resources was to be favoured over any state intervention, especially since this priority for negotiation is clearly in the spirit of the Rio Convention. The Hungarian group shared this opinion.

The Italian group also agreed with the principle of negotiation, given that in its opinion, standard contracts did not offer practical advantages.

The Swiss group observed that negotiations leading to research and/or development contracts led to a fair division of ownership of inventions relating to genetic resources. This group also hoped that countries possessing genetic resources would establish the necessary legislation to implement the Rio Convention, able to allow such negotiations. In the absence of such legislation, those States possessing genetic resources would be avoided by third parties because of the resulting legal uncertainty.

The Brazilian group gave very relevant examples of recently signed contracts which regulated the access to and exploitation of genetic resources, for example work on a database on regional biodiversity, extraction of products for cosmetic uses from plants, industrial utilization of a plant material, and research on microorganism strains. These examples clearly illustrated how situations can vary from one case to another.

The Spanish group emphasized the specificity of situations, and the very varied character of genetic resources. However, it was in favour of general directives and even suggested ranges of royalty rates for cases of exploitation of resources.

The French group, although in favour of negotiated solutions, considered that the production of standard contracts should not be ruled out, or, more generally, that some standardization of practices in the field concerned would be beneficial.

The Belgian group again referred to the standard agreement and code of practice developed in the context of MOSAICC.

The Dutch group observed that contracts agreed after negotiations might lead to abuses of rights.

The Venezuelan group felt that it was premature to give an opinion on this question.

C) Additional comments

The groups were invited to make additional comments on any points and a number did so.

The Brazilian, Belgian and French groups stated that in addition to rights arising from patents and plant variety protection certificates, it was also necessary to consider databases which may be important in the case of genetic resources.

The Australian group observed that the Rio Convention should lead to a fair division of the fruits of the exploitation of natural genetic resources, but in such a way that this exploitation does not affect the viability or conservation of a species.

The Swedish group considered that as concerns the implementation of the Rio Convention, AIPPI has to limit their study only to questions linked to patent law.

The French group, after restating that the essential objective of the Rio Convention is the conservation of biological diversity, expressed the wish that control mechanisms should be set up to ensure that money given in exchange for access to and exploitation of genetic resources is actually used for the conservation of biodiversity and for the benefit of humanity.

In addition, the French group raised the inherent difficulties in interpreting the Rio Convention, particularly the following points: the definition of the country of origin of the resources, the applicability of the Convention to human genetic resources, the national and international legal qualification of genetic resources, the legal nature of in situ and ex situ gene banks, and the definition of sustainable development.