

**COMMENTS MADE BY MEMBERS AND OBSERVERS OF THE SCP  
ON DOCUMENTS SCP/13/3 (EXCLUSIONS FROM PATENTABLE SUBJECT MATTER AND  
EXCEPTIONS AND LIMITATIONS TO THE RIGHTS)  
SCP/14/7 (PROPOSAL FROM BRAZIL)  
AND SCP/15/3 (EXPERTS' STUDY ON EXCLUSIONS FROM PATENTABLE SUBJECT MATTER  
AND EXCEPTIONS AND LIMITATIONS TO THE RIGHTS)**

**I. 15<sup>th</sup> session of the SCP, October 11-15, 2010  
[Excerpts from the Report (document SCP/15/6)]**

1. Discussions were based on documents SCP/13/3, SCP/14/7 and SCP/15/3.

2. The Delegation of Belgium, speaking on behalf of the European Union and its 27 Member States, stated that the preliminary study clearly summarized and contextualized the current legal framework: provisions under the international legal framework and the provisions contained in national and regional laws, as well as the policy objectives. In relation to the study prepared by the external experts, the Delegation stated that the study provided an excellent and comprehensive survey of exclusions and exceptions and explored their interrelationship both at the international and the national/regional levels. The document was carefully prepared and contributed significantly to knowledge about the state of laws around the world in relation to the topic. Further, the Delegation stated that, given the length of the study, it would greatly benefit from a summary document translated in the working languages of the Committee. The Delegation also suggested that in order to maximize the result and efficiency of the organization, all discussions on substantive patent law should be held in the SCP. The Delegation stated that it carefully considered the proposal from the Delegation of Brazil in respect of exceptions and limitations to patent rights. It recognized the importance attached to that issue. The Delegation reaffirmed that a strong intellectual property system with enforcement provisions was fully consistent with exceptions and limitations. Regarding the exclusions from patentable subject matter and subject matter not considered to be an invention, the Delegation observed that the international legal framework was provided for in the TRIPS Agreement, whereas the Paris Convention and the Implementing Regulations of the Patent Cooperation Treaty touched upon those issues indirectly. The Delegation recalled that, in Europe, a considerable level of harmonization had been achieved in that area through EU Law and the EPC, which resolved those issues at the European regional level. With regard to exceptions and limitations to patent rights, the Delegation stated that the Paris Convention, the Convention on International Civil Aviation (the Chicago Convention) and the TRIPS Agreement with the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, were the relevant international instruments. Within the framework of the European Union, the issues relating to compulsory licensing for pharmaceuticals, experimental use in the context of pharmaceutical and biomedical research, the patentable subject matter in biotechnology and farmer's privilege and breeder's exception had been harmonized. Further, the Delegation pointed out that in cases of exclusions from patentability, exceptions or limitations to patent rights, an appropriate balance between the right holders and the interest of the general public should be maintained. Concerning future steps, the European Union and its 27 Member States were of the view that exclusions from patentability, exceptions and limitations to patent rights should not be discussed to the detriment of other substantive issues of patentability which the SCP had focused upon, such as the definition of prior art, novelty and inventive step. The Delegation stated that the European Union and its 27 Member States were convinced that a more balanced approach would be desirable to reach the objectives of the Committee. In that regard, the Delegation reiterated its hope that a balanced work program for the Committee would be established in a timely manner.

3. The Delegation of Brazil, speaking on behalf of the DAG, welcomed the experts' study on exclusions from patentable subject matter and exceptions and limitations to the rights. The Delegation stated that the correct understanding of that paramount issue should help Member States to calibrate their national IP systems in order to achieve the fundamental trade-off of the patent system, which was to guarantee the monopoly of a given product or process in order to stimulate, not stifle the innovation.

Observing that the experts' study recognized the cost-benefit analysis underpinning the system, and that patents should be granted only to the extent necessary to rectify market failure, the Delegation referred to what the chief economist of WIPO had said, that in most cases, markets would not foster innovation on their own, and that in those cases, patents should be granted. Therefore, the DAG believed that the experts' study brought elements for a discussion which accepted the complexity of the subject, avoiding simplistic assumptions which ignored the systemic implications and the diversities of concrete realities. The Delegation agreed with Professor Bently who had stated that the TRIPS Agreement had extensively reduced the flexibilities available for countries in general. Therefore, a full understanding of the exclusions and limitations available was vital for a calibration of the national systems, considering the particularities of the countries and their socio-economical environments. The Delegation further observed that the important rationales which were developed in the study included the relation between human rights and intellectual property or the necessity of adjusting the legal provisions in order to reach the highest degree of innovation with the lesser possible social cost. Nevertheless, the DAG believed that the main goal of the study should be a comprehensive reflection on the patent system by analyzing the exceptions and exclusions, in order to provide real utility for governments, such as transfer of technology and correct disclosure of patent information. The Delegation considered that any statement on "a common core" or "a set of standards" under no condition should imply harmonization of legal provisions or limitations on the reach of exclusions and limitations, for the particular characteristics of the countries which were expressed in the different patent systems. In addition, the Delegation stated that the seeming favoring of exceptions over exclusions was not coherently explained in the experts' study. The Delegation explained that, in some cases, exceptions may raise litigation costs or stimulate sham litigation, while the possibility of ulterior legal liability for patent violation may reduce the incentive for investment of individuals in what they believe to be an exception, thus reducing innovation. Therefore, in the view of the Delegation, there was no conflict between exclusions and exceptions: they were complementary tools necessary to assure the systemic equilibrium and the policy space countries demanded to achieve their development. As professor Bently had emphasized, the Delegation considered that the utility of exceptions depended on the way they were interpreted by courts in countries with different legal traditions and by the dispute settlement system of WTO. The Delegation observed that due to dispute settlement understanding of WTO, in many legal systems, exceptions should be interpreted restrictively. If the supposed superiority of exceptions over exclusions depended on their being interpreted broadly, a strong case could be made against such rationale. Further, the Delegation stated that there was an urgent need of discussing the economic theory underlying the study, since the lack of a theoretical approach of the relation between intellectual property and innovation suggested an automatic and positive relation between them, a relation which was not observed in the reality. Overall, the DAG considered that those studies represented a positive step in the direction of the proposal made by the Delegation of Brazil. As regards the proposal presented by the Delegation of Brazil in document SCP/14/7, the Delegation stated that the proposal intended to provide a wide and sustained debate on exceptions and limitations to patent rights in three phases. The first phase should promote the exchange of detailed information on all exceptions and limitations provisions in national or regional legislations, as well as on the experiences of implementation of such provisions, including jurisprudence. That phase should also address why and how countries use, or how they understand the possibility of using, the limitations and exceptions provided in their legislations. In that connection, the Delegation noted that to a certain extent, the studies on exclusions from patentable subject matter and exceptions and limitations to the rights contained some elements of the first phase, which needed to be further developed. The second phase should investigate what exceptions or limitations were effective to address development concerns and what were the conditions for their implementation. The Delegation stressed the importance of evaluating how national capacities affected the use of exceptions and limitations. The third phase should consider the elaboration of an exceptions and limitations manual, in a non-exhaustive manner, to serve as a reference to WIPO Member States. The Delegation explained that the manual should help each country to adapt the international agreements to its internal IP system, maintaining the adequate policy space for its development needs. The Delegation noted that the optimal arrangement for the United States of America was not necessarily so for India or Malawi. Therefore, the DAG believed that the proposal

should be promptly implemented, as the establishment of such working program would be an important step in the implementation of the Development Agenda.

4. The Delegation of Argentina stated that the SCP needed to continue discussions on exclusions, exceptions and limitations to patent rights as they were related to fundamental issues of development and were of real importance for the implementation of the Development Agenda of WIPO. The Delegation stated that the exclusions, limitations and exceptions were tools which countries could use in conformity with the flexibilities provided by the international treaty. Further, the Delegation welcomed the proposal made by the Delegation of Brazil with regard to the establishment of a work program on exceptions and limitations in the SCP. In its view, the proposal could be an important phase in the implementation of the Development Agenda. The Delegation was concerned about the limited use of exceptions and limitations by developing countries and therefore underlined importance of the manual to be prepared at the third phase of the proposal which would suggest ways of avoiding restrictions to the use of exceptions and limitations and other possibilities which could promote development.

5. The Delegation of the Plurinational State of Bolivia stated that the issue of patentability in the field of biotechnology was very important to its country, and noted that its comments were of preliminary nature, given the unavailability of Spanish translation of the full document. In its view, the experts' study provided a factual analysis of exclusions and exceptions based on the various different legislations, focusing in particular on the European and American legislations. However, the Delegation considered that the experts' study did not go beyond the factual description of the issues. The Delegation stated that given that it was an experts' study, it should have given the possibility of having a more open discussion and further contribution to the analysis made so far in the Committee on the issue. In its view, the main problem with the study was that it did not give responses to the mandate agreed upon by the SCP on the subject matter, as well the terms of reference agreed upon by the Secretariat and experts. The analysis of exclusions from patentability lacked analysis from a development and public policy perspective in that it did not look into factors which could justify the exclusion of human beings from patentable subject matter. The Delegation expressed concern that the authors of the study had interpreted the scope of work established in the terms of reference in a very narrow manner. In particular, the Delegation stressed that according to the terms of reference, the authors should have covered all areas, including exclusions, exceptions and limitations to reflect controversies, the area which was of high interest to the Plurinational State of Bolivia. The Delegation expressed its wish that the study include more information with regard to the political consideration given in some countries to exclude certain areas from patentability as well as implications of such exclusions on public policy and socio-economic development of countries. As regards the issues of patentability of human life, the Delegation stated that the experts' study should have better analyzed the links of patentability of life in multilateral agreements and free-trade agreements, in particular, the complexities which might be caused by those standards in society and their impact on fundamental rights, such as the right to food, health and development. The Delegation reiterated that patenting human life was not part of its country's culture and, therefore, it considered such development as posing a danger for the entire humanity. Further, the Delegation stated that another analysis that could be made in that area would be to revive the information on the trends that were taking place in patenting of human life, including the information on who were the owners of those patents and what type of biological life was being patented. The Delegation stated that, as had been shown in the experts' study, the United States of America and Europe allowed the patentability of discoveries of elements found in the human body and in nature on the basis of their isolation from their natural environment, and that that fact reinforced the belief of the Delegation that a review of Article 27.3(b) of the TRIPS Agreement was necessary to prohibit the patentability of animals, plants and any forms of human life. The Delegation further observed that the experts' study also mentioned the potential negative impact of protection of plants varieties for farmers which might get worsen with the implementation of the UPOV Convention 1991, which was mainly adopted by developing countries because of the pressure put on them by developed countries and obligations under the TRIPS Agreement. Referring to its proposal made in the TRIPS Council to review the relevant provision to prohibit all forms of patentability of human life, or life in general, the Delegation expressed its regret

that the experts' study did not include any references to such recent events in international law making. The Delegation stated that the Constitution of the Plurinational State of Bolivia prohibited the patentability of any life forms, because it was contrary to the values of indigenous people and that position had been communicated by the government of the Plurinational State of Bolivia in an official document to the TRIPS Council in March 2010. The Delegation stated that the topic should remain open in the future, and suggested that the Secretariat should translate the study in other official languages of WIPO to facilitate the further analysis of the issue. In addition, the Delegation supported the proposal made by other Delegations requesting that all the comments made on studies be compiled in an addendum to that document to allow people to have the opportunity of seeing various comments and observations made on the content of each study.

6. The Delegation of the Islamic Republic of Iran associated itself with the statement made by the Delegation of Brazil on behalf of the DAG. The Delegation welcomed the experts' study on exclusions from patentable subject matter and exceptions and limitations to the rights as it was important for developing countries to keep their national policy space in formulating their national IP systems to use IP as a tool for development. The Delegation expressed its belief that the main objective of that study should be a comprehensive reflection on the patent system from the exceptions and exclusions perspectives which allowed countries to benefit from. The Delegation was not of the view that the international norms limited exclusions and gradually favored exceptions over the exclusions. In its view, the fact that both exclusions and exceptions led to the same policy goals could not provide reasonable grounds to shift from exclusions to exceptions. The Delegation considered that such substitution could have serious developmental implications which should be assessed carefully. In its opinion, exclusions and exceptions were complementary tools necessary to assure the systemic balance and preserve the policy space for countries to achieve their development, and therefore, they could not substitute each other. Finally, the Delegation expressed support for the proposal made by the Delegation of Brazil on exceptions and limitations to patent rights, as the proposal suggested bridging the gap between the existing provisions on exceptions and limitations and their actual implementation, and to that end proposing new possible areas relating to technology transfer and other public policy issues. The Delegation reiterated that the issue was of importance to developing countries, and it should be incorporated in the work program of the SCP.

7. The Delegation of the Russian Federation stated that document SCP/13/3 prepared by the Secretariat, as well as experts' study contained in document SCP/15/3, constituted a good basis for further analysis of the problematic areas in that field. The Delegation stated that the topic was of particular importance to its country as legislation of the Russian Federation was undergoing the changes, in part, due to its accession to WTO. To that effect, on October 4, 2010, the President of the Russian Federation had signed the Federal Law on Amendments to Part IV of the Civil Code of the Russian Federation. One of those amendments concerned Article 1229 of the Civil Code which was amended to meet obligations under Articles 26 and 30 of the TRIPS Agreement. In particular, the amended provision read: "Limitations to the exclusive rights of patent holders or holders of industrial designs shall be established in individual cases, provided that such restrictions do not unreasonably conflict with normal exploitation of inventions or industrial designs and do not unreasonably prejudice the legitimate interests of right holder, taking into account the legitimate interests of third parties." Other amendments were included in Article 1362 in order to meet the obligations under Article 31 of the TRIPS Agreement. In addition, the Delegation stated that Article 1349 of the Civil Code listed, as non-patentable subject matter, the methods of cloning of a human being, and other inventions that were contrary to public interest, principles of humanity and morality, among others. The Delegation further informed the SCP that in the Russian Federation, there was a moratorium on research related to cloning of human being as codified in Federal Law N54-F3 of May 20, 2002. Noting the advancement of science in biotechnology and advantages that such development could provide in the area of medicine, the Delegation stated that it also raised the ethical problems, in particular, in relation to the use of human embryo. In that regards, the applications for a patent relating to the methods of extraction of stem cells from the human embryos were not patentable subject matter in the Russian Federation. The Delegation supported further studies in that area. It also supported the proposal made by the Delegation of Brazil. However, it stressed that exceptions and limitations to patent rights,

including compulsory licensing, should not become a barrier in effective functioning of the patent system directed towards innovative development of countries. The Delegation further informed the SCP that the Civil Code of the Russian Federation provided that the following actions would not constitute an infringement to patent rights: scientific research on a product or process incorporating an invention; use of an invention in emergency situations provided that the patent holder was notified as soon as possible and payment of a reasonable remuneration was made. In addition, there were provisions limiting the rights of patentees in cases of national security and national defense, as well as provisions related the right of prior use of an invention and compulsory licensing. The Delegation stated that above information was provided due to the fact that the experience of the Russian Federation on those issues was not reflected in the experts' study.

8. The Delegation of Australia stated that the scope of the issue under consideration was very broad, and that it was at the heart of the patent system that should balance the innovation versus the broader public policy objectives. The Delegation expressed its belief that the studies prepared by the Secretariat and external experts provided good basis for the work in that area. In relation to the proposal made by the Delegation of Brazil, the Delegation expressed its willingness to contribute to the proposed work program; however, it encouraged the SCP to take note of the information already made available and the work which was underway in other Committees on the subject matter.

9. The Delegation of Spain expressed support for the statement made by the Delegation of Belgium on behalf of the European Union and its 27 Member States. The Delegation expressed its appreciation for the experts' study on the issue of exclusions from patentable subject matter, exceptions and limitations to patent rights. The Delegation stated that the documents contributed to the objective of shedding light on a very complex topic and it requested that the study be translated into other working languages of the Committee as soon as possible. The Delegation further stated that, due to the complexity and length of the study, it should have been accompanied by a summary translated into the working languages of the Committee, which would include the most relevant conclusions of the study. In relation to the content of the experts' study, the Delegation stated that there should have been a greater coordination of all parts of the study to avoid duplication, especially in the annexes. While appreciating the efforts made by the Delegation of Brazil to contribute to the work of the Committee and enrich the debate on issue at stake, the Delegation made some comments on some aspects of the proposal. In particular, in relation to paragraph 6 of the proposal, the Delegation stated that it was surprising that compliance was placed at the same level as the debate about the limitations and exclusions in patent law. In its opinion, those areas operated on different levels: namely, on the one hand, the establishment of the substantive rights and, secondly, the necessary protection of those rights. Referring to paragraph 16 of the proposal, the Delegation underlined the need for the disclosure of the invention in patent application in a manner sufficiently clear to enable a person skilled in the art to put it into practice. In that regard, the Delegation noted the efforts of the Spanish Patent and Trademark Office to improve the quality of processed and issued patents through the implementation of ISO 9001: 2000 for the processing of PCT applications in 2007, and support for the policy of the EPO entitled "Raising the bar" which aimed at increasing the requirement level for the granting of patents within the framework of the EPC. Regarding paragraph 21 of the proposal, which stated that Paris Convention for the Protection of Industrial Property (Paris Convention) does not expressly prescribed specific provisions on exceptions and limitations to patent rights, the Delegation quoted Article 5A(2) of the Paris Convention which provided that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." Regarding the creation of a work program for the SCP on that subject matter, the Delegation made the following comments: first, it requested the Delegation of Brazil to identify which specific aspects related to exceptions and limitations to rights conferred by patents were not in the studies already presented by the Secretariat and whether such omissions, if any, would justify re-doing from the beginning what had already been done. Second, the Delegation emphasized that there was an overlap between the studies made for the SCP regarding exceptions and limitations to rights conferred by patents and the studies submitted to CDIP. In particular, the Delegation referred to document CDIP/5/4, entitled "Patent Related Flexibilities in the Multilateral

Legal Framework and their Legislative Implementation at the National and Regional Levels” and stated that activities and studies concerning that matter should preferably be conducted in the SCP in the future in order to avoid overlap between the two Committees. Reiterating its support for the Brazil’s proposal, the Delegation stated that the consideration of those issues should not be detrimental to other SCP’s issues such as prior art, novelty and inventive step.

10. The Delegation of the Republic of Korea stated that the experts’ study on exclusions from patentable subject matter and exceptions and limitations to the rights provided meaningful information in that it provided comparison on how each country formed its patent system and how it limited rights conferred by patents in order to contribute to the public interest. In addition, the Delegation noted some inaccuracies found in Annex VI of document SCP/15/3 in relation to its patent system, and stated that it would submit the amendments to the Secretariat in writing.

11. The Delegation of India expressed its appreciation for the study prepared by external experts contained in document SCP/15/3, as well as for the proposal made by the Delegation of Brazil. Referring to the content of document SCP/15/3, Annex II, the Delegation expressed its dissatisfaction with the following phrase contained in paragraph 3.34: “it has been suggested that the section 3(k) amendments effectively incorporated software patents into Indian patent law through the back door”. In addition, referring to another part of the same paragraph, which stated that four Indian patent offices took differing interpretations on the question of computer programs as patentable subject matter, and that some of the Indian Patent Offices had modelled themselves on the approach at the EPO, the Delegation stated that such wording could give the impression that computer programs were not protected in India. The Delegation clarified that computer programs had been excluded *per se* from the patentable subject matter by the amendments which took place in 2002. The Delegation noted that the interpretation of those provisions had been done for many years and that the approach which had been followed by Indian patent offices was not simply an approach following the EPO, but patentability of such inventions were decided after considering various aspect of the technical effect of the software-related inventions. The Delegation further stated that, although the experts’ study in other cases stated that the computer program protected under copyright law, such information was omitted in relation to India. In its view, the experts should have indicated that the computer programs at least were protected under copyright law of India. In addition, the Delegation stated that the analysis of the Indian provisions on the limitations to the patent rights only highlighted the compulsory license in case of public health. However, the Delegation noted that Indian patent law also provided provisions relating to the compulsory license in case of extreme emergency, as well as provisions related to the Doha Declaration on the TRIPS Agreement and Public Health allowing exportation of pharmaceutical products to countries with insufficient or no manufacturing capacities. The Delegation also observed that Annex IV only provided information in relation to certain provisions relating to public health omitting, for example, provisions such as Section 47 of the India’s Patent Act where the government could manufacture the patented product for distribution of the medicines to the hospitals and other public institutions. In conclusion, the Delegation stated that the provisions of the patent law in India were there to promote public health, in that they were not restricted only to the compulsory license in general, but there were other provisions where the government could acquire the patents in the public interest for governmental use.

12. In response to the questions raised by the Delegation of Spain, the Delegation of Brazil explained that the Brazilian proposal consisted of three phases. The objective of the first phase was to promote the exchange of detailed information concerning all exceptions and limitations provisions in national and regional legislations as well as of the experience of implementation of such provisions, including jurisprudence. The first phase also addressed why and how countries used and how they understood the possibility of using the limitations and exceptions provided in their legislations. The Delegation noted that the study coordinated by Professor Bently had given the Committee a very good first step in that direction. The Delegation observed that the study covered the exceptions and limitations that existed in the national legislations, but was more conceptual and did not go in detail in how those provisions were applied in national legislations. While the study had a specific focus on the United States and the European jurisprudence, the Delegation considered it important to analyze how

those provisions were applied in other national and regional legislations. The Delegation further explained that the second phase of the proposal was to investigate which exceptions and limitations were effective to address development concerns and what were the conditions for their implementation. In that phase, it was important to evaluate how national capacity affected the use of exceptions and limitations. The Delegation was of the opinion that the experts' study had identified several exceptions and limitations which might have positive consequences for development, for instance, the Bolar exception in the United States of America. In its view, however, some other exceptions and limitations had a neutral effect. For example, the exception concerning ships and vehicles in transit was logical and useful, but did not necessarily have an impact on development. The Delegation further explained that, in the third phase, the Committee would take all those exceptions and limitations, gather them in a compilation as a non-exhaustive manual, which might serve as a reference to countries for their national legislations.

13. The Delegation of Norway supported the statement made by the Delegation of Belgium on behalf of the European Union and its 27 Member States. Referring to its statement made at the 14<sup>th</sup> session of the SCP, the Delegation considered it important to put exclusions, exceptions and limitations in the context of, and to consider them together with, substantive standards for protection in a given territory. The Delegation expressed the view that the study prepared by the external experts illustrated the need for a contextual approach.

14. The Delegation of the United Republic of Tanzania noted that the legislature had the reason for having provisions on exceptions and limitations, and stated that unless there were reasons to take a u-turn from those accomplishments by the legislature, there was no need for change. The Delegation considered that exceptions were interpreted differently from one country to another, and making a demarcation line between reasonable and outrageous positions was difficult. Nevertheless, the Delegation expressed the opinion that Article 27 of the TRIPS Agreement had not lost its meaning. The Delegation posed a question as to whether the Committee really needed to go into a particular situation where a country was interpreting the exceptions taking an outrageous position. In its view, it could be directed to a particular country, and countries were at liberty to have the provisions if they thought the provisions still had their meaning or had a particular purpose for which they had been enacted in their legislation. The Delegation suggested being careful in taking another route without taking into account the local accomplishments surrounding the legislature.

15. The Delegation of Uruguay stated that the study prepared by the external experts was of a very high quality, met a very high academic level and gave an overview and review from a technical point of view. The Delegation, however, considered that it lacked another component, i.e., how those provisions worked in the various different scenarios, particularly in relation to the issue of development. It was of the view that, while the study was a very important basis and a starting point for the work of the Committee, it was not fulfilling the objective for which the study had been requested, which was to analyze the effects in concrete situations particularly taking into account the issues of public policy, development and its practical implementation.

16. The Delegation of France, speaking on behalf of Group B, referred to a proposal made by the Delegation of India to include all comments made by Member States in an Addendum to the study. The Delegation noted that it was not a common practice in WIPO to compile Member States' comments in separate documents, since those comments were reflected in the Reports of the meetings. For that reason, and taking into account the new language policy adopted by the General Assembly, the Delegation was of the view that unnecessary additional documents should be avoided. Therefore, it saw no need for specific additional documents compiling Member States' comments on the study.

17. The Delegation of India recalled that the proposal referred to by the Delegation of France was a proposal made first by the Delegation of Brazil on behalf of the DAG, supported by the Delegation of India. The Delegation further recalled that there was a precedent in the CDIP, where comments of Member States had been appended in a separate document which had been considered in

conjunction with one particular study on technology transfer. In addition, the Delegation requested Group B to clarify its substantive difficulty with the proposal. It explained that the proposal was made for ease of reference for all who might be referring the studies. The Delegation stated that the proposal was made in a constructive spirit and with the objective of facilitating a greater understanding of the issues and appreciating various perspectives on the subject matter.

18. The Delegation of the Plurinational State of Bolivia supported the statement made by the Delegation of India, taking into account that the document had not been translated into Spanish and that several comments had been made by the Delegation with regard to the substantive issues in the study. In its view, it would be useful if anyone who had access to the study would be able to know the opinions of Member States on the contents of the study to be found in the addendum of that study.

19. The Delegation of Germany stated that the Committee had very exhaustive studies, and that every Member State was free to make comments on the studies and to deliver comments if the description was not correctly made by the Secretariat. The Delegation was of the view that the Committee should stick to that habit, and should not produce exhaustive additional documents, bearing in mind the cost for translation.

20. The Delegation of France clarified that Group B did not wish the proposed compilation of comments becoming a common practice of WIPO even if there had been a precedent. It further stated that the language policy of WIPO, adopted by the Member States and was applied retroactively to certain documents, should be an element that needed to be taken into account. In its view, there was no need to have comments separately annexed to the study, since they were reflected in the Reports of the meetings.

21. The Delegation of India clarified that the proposal was to extract comments made by Member States under each study and to put together in a separate document with a different number. It explained that the proposal did not ask for a compilation of Member States' comments on a particular study to be included in the study itself. The Delegation stated that, in the study, a cross-reference to the document compiling the comments could be made. It explained that the proposal was made to facilitate access to comments and observations made by Member States and other stakeholders on each of the studies. Therefore, in its view, the proposal would not increase the thickness of any document. The Delegation further stated that the translation load of WIPO would not be increased, since the comments had already been translated for the Reports. The Delegation considered that the compilation of comments could be simply on the website, and did not need to be printed out and distributed as documents for the following session of the SCP. As regards the issue of whether it was fundamentally necessary and how useful it could be, the Delegation acknowledged different perspectives, but expressed its belief that such a compilation would help the Committee appreciate the complex issues more comprehensively and more holistically, which was the final objective of the whole exercise.

22. The Delegation of Egypt referred to the WIPO language policy according to which a full implementation of that policy by the SCP was still under study, since it was being looked into and would be looked into by the Program and Budget Committee so as to be adopted at the next year's General Assembly. The Delegation stated that the study had to be based on the idea that the language policy should not have an impact on the objective work of the Organization. Therefore, in its view, if there was a need to summarize documents and not to enter into details, no doubt it would have consequences on all aspects of the Organization's work. In that light, the Delegation observed that if the comments of Member States on studies could not be added, requesting other studies to be undertaken might not be able to be called for, because that might also have a negative impact on the language policy.

23. The Delegation of Venezuela supported the statements made by the Delegations of India and the Plurinational State of Bolivia with regard to the compilation of comments by Member States, bearing in mind the fact that only the executive summary was translated into other languages. The

Delegation stated that the topic of exclusions and exceptions was linked to development and to avoid monopolies, and was relevant to daily life such as the right to life and the right to health. Referring to the argument that the flexibility issues could not be dealt with before dealing with the issues of rights, the Delegation considered it a senseless dichotomy, because the rights of a right holder needed to be applied with flexibility.

24. Recalling that the language policy did not provide any limitation to submissions made by Member States, the Delegation of Brazil stated that the volume of translation could not be a relevant argument against its proposal.

25. The Delegation of the Russian Federation regretted that there was no analysis on the legislation of its country in the study prepared by Professor Sherman concerning the patentability of software, and expressed its wish to share information in that regard. The Delegation noted that, in the Russian Federation, as provided by the Civil Code, computer programs were treated as literary work under copyright regardless of the language used and regardless of the type of program. It explained that computer programs were not patentable under the legislation of its country. The Delegation further explained that, with regard to algorithms of programs, they could be innovative if they provided a technical result of a material object using a specific material technology. In that case, there was a basis for recognizing them as a technical solution, and further looking into their patentability. The Delegation however, clarified that in order for an algorithm to be recognized as a technical solution, it should not be confined to a mathematical method or provision of mere information. The Delegation stated that the listing of programs in a programming language should not be regarded as disclosure of the invention, as in other cases, a description of the patent application should be presented in a natural language and be accompanied by flow charts, comments, etc., for it to be understood by average technical specialists in the field who were not specialists in programming but had a general understanding of computer technology.

26. The Delegation of the Plurinational State of Bolivia noted that there was a precedent in the SCP where comments on the Report of the International Patent System had been published in the Addendum to the Report.

27. The Representative of the EPO supported the statement made by the Delegation of Belgium on behalf of the European Union and its 27 Member States.

28. The Representative of ALIFAR stated that exceptions and limitations were an essential element of all patent legislation. She considered that they conferred the required flexibility to formulate public policies in the field of health and food security, among others, and maintained the balance between rights and obligations to which Article 7 of the TRIPS Agreement referred. She observed that some limitations such as compulsory licenses were usually disputed even though they were explicitly provided for under the TRIPS Agreement and the Doha Declaration on Intellectual Property and Public Health as well as under other legislation as mentioned in document SCP/15/3. The Representative noted that disputes arose both with regard to national legislation and where such legislation were applied to a specific case. In her view, however, at least in Latin America, the mechanism had been used very cautiously and only where it had not been possible otherwise to meet public health needs. The Representative observed that while it was an exceptional but useful and necessary mechanism, its implementation was problematic and, in many cases, hindered by legal or administrative obstacles that delayed and postponed the process. Regarding the August 30, 2003 WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the Representative noted that the mechanism was used once in seven years by one African country. She therefore considered that it would be timely to question whether during that long period there had not been any other countries without their own production capacity which had found the need to import medicines with compulsory licensing. In her view, it was probable that there were those countries but the system was not easy to use, and very often, compulsory licenses generated conflicts. While noting that the documents put forward by the Secretariat were of great value, she found it useful to go into further depth of some concrete experiences of the use of compulsory licensing and other

exception measures, such as the so-called Bolar exception with which some developing countries had a fair amount of experience. The Representative further observed that, in the few developing countries in which the Bolar exception was provided for, very often, its use was hindered by legal, administrative or commercial strategies to delay bringing generic medicines to the market. In her view, providing more detailed information on specific cases would enable a more individual approach to best practices as well as to specific problems encountered, so as to help countries find concrete solutions to accelerate access to medicines in the shortest time possible once the patents were expired. In addition, she noted that it would be interesting to find out how the only case implementing the Decision of August 30, 2003 of WTO had worked in practice. The Representative stated that the comprehensive analysis of specific cases, practices and case law would help countries to access information that was not always available in a clear and precise manner. In her opinion, such analysis enabled countries to use the experience of others for reviewing their own national legislation in order to establish clear rules and transparent and expeditious procedures that attained the objectives sought. The Representative stated that a non-exhaustive manual on exceptions and limitations as proposed by the Delegation of Brazil could be a very useful tool to inform and guide countries which had to implement exceptions and limitations.

29. The Representative of GRUR reiterated its support to the proposal made by the Delegation of Brazil. With respect to the compilation of comments, he stressed the importance of including contributions made by intergovernmental organizations and non-governmental organizations.

30. The Representative of FSFE noted that the study led by Professor Bently, which had provided a useful overview of the complex field, represented a starting point for future debates. He, however, regretted that the study and the mandate which the Committee provided had not included open innovation systems, of which free software was the most established example. He agreed with the Delegation of Brazil in highlighting that the patent system must strive for the equilibrium of rights among its users, including not only patent holders but also the society as a whole, so that the welfare of the society as a whole prevailed. In this view, they all constituted legitimate clients of the system. The Representative noted that the study highlighted the wide-spread consensus that computer programs should be excluded from patentability. He applauded the study for considering the economic context in which the costs and benefits of patents on computer programs must be considered. The study concluded that the costs of patenting in this particular area far outweighed any conceivable benefits. The Representative was of the opinion that the damage that software patents did to innovation and economic development struck at the very heart of the digital society. In his view, they created an incalculable business risk for anyone engaging in the development of software. Due to the fact that reliably identifying prior art in software went far beyond the capabilities of even the best-equipped patent office, he considered that software patents were routinely granted on inventions which had long existed, and were in fact not innovative at all. The Representative stated that it dovetailed with the conclusions drawn by leading independent experts in the field, such as the results of the 2008 Berkeley Patent Survey conducted by Pamela Samuelson, *et al.* According to that study, the startup executives interviewed in the survey had stated that patents generally had provided only weak incentives to engage in innovation. The Samuelson study found that a large share of startups, especially in the software industry, opted out of patenting altogether. While patents aided startups in the areas of hardware and biotechnology to capture competitive advantage, the Berkeley Patent Survey concluded that, for software and Internet companies, patents generally served a much less important function in almost all of the entrepreneurial activities. Moving on to the debate about exclusions and exceptions in the area of software, the Representative noted that Professor Bently's study strongly suggested that the cost-benefit calculation of patenting be improved by granting exceptions to patentee's rights. Contrary to the comments made by Professor Bently, the Representative considered that exceptions, which were merely defensive, did not suffice to mitigate the damage done by patents on software. As stated by the Delegation of Brazil on behalf of the DAG, the Representative also observed that the Committee must never lose sight of the fundamental trade-off at the root of the patent system: in order to provide an incentive to innovate, a monopoly was awarded. If the attendant risks for innovation and competition in the market were not carefully monitored, in his view, the market would be dominated by only a few companies. He was of the

opinion that that was already the case in software industry. The Representative agreed with the statement made by the Delegation of the Islamic Republic of Iran that exceptions carried with them the dangers of restrictive interpretation and private ordering. For that reason, the Representative considered exceptions to be unsuitable as a tool to stimulate software innovation. Instead, in his opinion, exclusions should be used, and their implementation strictly monitored. As SMEs and individuals were having to fight a pitched battle against overwhelmingly powerful corporate interests and entrenched monopolies in the software market, the Representative was of the view that they should not be needlessly put on the defensive side. He considered that, in the area of software, exclusions worked in favor of SMEs because they provided clarity if properly implemented. In his view, exceptions worked in favor of the incumbent monopolies, which had the legal firepower to shape jurisprudence in their own interest. He further observed that, while the study considered at length the practice of the EPO, it neglected to point out that the EPO's practice was in direct contravention to the letter and spirit of the European Patent Convention's Article 52, which stated that programs for computer were excluded from patentability. He agreed with the statement made by the DAG that patents should be granted only in areas where there otherwise existed a market failure to provide innovation. On that point, he reiterated his three step test for inclusion in the patent system which he had first proposed to the 13<sup>th</sup> session of the SCP, i.e., for any subject matter to be included in the patent system, there must be (i) a demonstrated market failure to provide innovation; (ii) demonstrated positive disclosure from patenting, and (iii) demonstrated effectiveness of the patent system in the area to disseminate knowledge. He considered that software failed all three steps of that test. The Representative stated that innovation in the software market was more vibrant than ever, and experience showed that patent-related disclosure was practically useless in the case of software. Further, in his view, the patent system in that field impeded the dissemination of knowledge instead of promoting it, and hence it followed that software should be excluded from patentability. The Representative supported the proposal of the Delegation of Brazil contained in document SCP/14/7 and the concrete suggestions therein on a work program for the SCP. The Representative, however, requested that exclusions from patentable subject matter should also be included in the debate, alongside the limitations and exceptions.

31. The Representative of IFPMA expressed his appreciation for the extensive study prepared by the external experts, which would enrich the debate within the Committee. The Representative considered that empirical evidence remained the key to achieving the desired result. In relation to the study prepared by Professor Visser in the context of health, the Representative expressed his belief that sustainable access to quality medicine could only be achieved by creating necessary incentives for medicine innovation. In his opinion, it was important to have a broader view of the policy objectives which was access to medicines rather than specifically focusing on certain tools to achieve that goal. The Representative further stated that other crucial pieces of the access picture included appropriate levels of health care infrastructure and financing, which were crucial factors for the effective operation. He was of the view that compulsory licensing by itself was not a sustainable approach, as it created strong disincentive to develop and market new medicines, which required passing through a costly and lengthy regulatory process often in the country in question. He considered that innovative companies were less likely to introduce products when copiers could immediately enter the market, which undermined R&D and investment. In his view, without a local approach or a launch of innovative products, generic companies might not also be able to obtain a necessary regulatory approval to serve their medicines. He considered that widespread use of compulsory licenses made efforts denied, or would delay patients' access to innovative products and hinder the introduction of good quality generic versions in the longer term. The Representative stated that the improvement of global health was a commitment shared by the research-based pharmaceutical industry and by WIPO Member States, and welcomed efforts by WIPO and the WTO to achieve that goal, working together in collaborative ways. He said that IP might be his organization's member companies themselves undertaking numerous multi-faceted initiatives to improve access to medicines and facilitate broader medicine development. He explained that such practical measures included training of researchers and healthcare workers as well as strengthening of local health care infrastructure. In relation to access to medicines which was a key part of the access picture, the Representative noted that numerous initiatives had been developed and deployed, such as tier pricing, donations, voluntary

licensing and capacity building. He stressed the necessity of innovation and platforms which incentivize, and not undermine, the innovation. The Representative stated that companies of his organization were fully committed to undertake the job they do best, which was researching and development of new and more effective treatments. He expressed his belief that ensuring the correct policy environment which remained the crucial role of governments was a critical aspect of the long term global health challenges faced by all.

32. The Representative of ICC noted that the studies on exceptions and limitations provided a comprehensive and in-depth discussion of exclusions from patentability and exceptions and limitations to patentees' rights. While he had not had an opportunity to review the study and its Annexes in detail, given the depth of the analysis of the situation in a number of Member States, he considered that such an analysis would take considerable time and effort, and expressed his wish to provide appropriate input in due course. As general observations, first, the Representative recalled that ICC had long maintained that patents were critical to provide an incentive and reward for innovation and investment in R&D and future inventions in all fields of technology. He added that patents were also an essential mechanism to facilitate the transfer of technology as well as to facilitate foreign direct investment. He observed that exceptions and limitations provided for under international law and at the national level in patent systems were appropriate elements in a well-functioning patent system that included the grant of rights and their enforcement. The Representative, however, cautioned against any activity at the national or international level to broaden exclusions from patentability – such that the exception swallowed the general rule – and undermined the functioning of patent systems as a whole. The Representative observed that document SCP/15/3, Annex III, brought an interesting review of patent exceptions in the health context. In that regard, he stressed that negotiations with right holders on licensing were usually a better tool to achieving policy objectives such as improved healthcare, food security and tackling climate change. Second, the Representative observed that there were some points in the Annexes where the analysis of international law, in particular the TRIPS Agreement, should be more rigorous. For example, he noted that there were statements on page 23 of document SCP/15/3, Annex I, and page 36 of document SCP/15/3, Annex II, suggesting that certain requirements under the TRIPS Agreement had little or no meaning. He also referred to a text found in one of the Annexes stating that the WTO “contracting parties have considerable wiggle room to exclude subject matter from patentability on the basis that it does not constitute an invention (or an invention in a field of technology)”. While acknowledging that international agreements were subject to interpretation by the members of those agreements and their governing body, the Representative was of the view that such statement and similar ones were made with little or no analysis with reference to the Vienna Convention on the Law of Treaties or to relevant decisions by panels under the WTO's Dispute Settlement Understanding. The Representative considered that his view was consistent with that expressed by the Delegation of the United Republic of Tanzania, in particular in his point that Article 27 had lost its meaning. The Representative was concerned about such lack of rigor for two reasons. The first reason was that patents in all fields of technology played a critical role in incentivizing research and development, as well as facilitating the transfer of technology. In his view, suggestions that decisions as to whether and what to provide patent protection were uncertain ran counter to that role. The second reason was that business relied on legal stability to make investments, especially the long-term investments in research and development of new products and the work necessary to bring them to market. The Representative was of the view that, due to the lack of rigor of the analysis in the study and its Annexes, they suggested an unfortunate degree of uncertainty in the establishment and enjoyment of intellectual property rights. In his opinion, that uncertainty would frustrate the goals and aspirations of the patent system.

33. In relation to the statement made by the Representative of FSFE, the Representative of the EPO recalled that Article 52 of the EPC stated that programs for computers was excluded from patentability only to the extent to which a European patent application or European patent related to such subject matter *as such*.

34. The Representative of KEI took note of Professor Visser's study which examined selected case studies of countries where compulsory licenses had been granted for pharmaceuticals. The

Representative recommended that the SCP request the Secretariat to produce a comprehensive annual report documenting the use of compulsory licensing by Member States including empirical data on the royalty rates set in each case. He noted that policy makers had long expressed interest in State practices in setting royalty rates, and he expressed his belief that WIPO could play a constructive role in that regard. Concerning the compilation of comments by Member States and observers, the Representative also pointed out the precedent in the SCP.

35. The Representative of TWN considered that exclusions, exceptions and limitations to patent monopoly were important policy tools to address certain development concerns. He stated that there was ample empirical evidence on the benefits of using exclusions, exceptions and limitations by most of the WIPO Member States. Even though the TRIPS Agreement imposed mandatory patent protection for inventions on microorganisms and pharmaceuticals, the Representative considered that exclusions were still an important tool to address critical development concerns in agriculture, public health, etc. He observed that the history showed that many advocates of a strong IP regime had used to exclude pharmaceutical inventions from patent protection and had developed state of art pharmaceutical industries. He noted that, since the Doha Declaration on the TRIPS Agreement and Public Health, developing countries had used compulsory licenses at least 52 times mainly in the form of government use order to ensure affordable medicines to people, and observed that compulsory licenses were also very frequent in developed countries, hence compulsory licenses were an important and legitimate tool to curb the abuse of patent monopoly and to meet the critical needs of people. The Representative expressed its belief that the limited policy space available in the post TRIPS era still allowed developing countries to design more exclusions and exceptions to meet their development objectives, as reflected under Articles 7 and 8 of the TRIPS Agreement and in the Millennium Development Goals. The Representative appreciated the efforts of academic experts who jointly produced a 400-page study containing very useful information and interesting observations. He, however, pointed out the following important gaps in the study. First, the study directly and indirectly advocated for the use of exceptions over exclusions. It also stated that policy objectives behind exclusions could be achieved through exceptions. The Representative stated that exceptions were not substitute for exclusions, and that there was historical evidence on the concrete benefits of exclusions. Second, the study had not adequately covered the public policy implications on the exclusions, exceptions and limitations irrespective of such a requirement under the terms of reference of the study. Third, the exclusion of certain types of pharmaceutical patents was critical for ensuring access to medicine in developing countries because such exclusions prevented ever-greening of patents and brought competition in the pharmaceutical market. In his view, such exclusions were well within the boundaries of TRIPS obligations. The Representative was of the opinion that the study had not examined the current practices in exclusions with regard to patenting of medicines, and observed that the study was also silent on the scope of potential exclusions on pharmaceutical patents. Four, the study did not adequately deal with the scope of policy space available currently for countries to incorporate exclusions, exceptions and limitations on patents in domestic legislations. Five, most findings of the study were based on the jurisprudence of EPO and the United States of America. At the same time, the study did not analyze the development implications of such jurisprudence especially for developing countries. Hence the study did not offer any new direction or way forward with regard to implementation of exclusions, exceptions and limitations on patent rights. The Representative requested that all stakeholders, including civil society organizations, be given an opportunity to provide detailed written comments on the study. The Representative was of the view that the deliberation on exclusions, exceptions and limitations on patent rights should result in a work program, and considered that the proposal by the Delegation of Brazil was a move in the right direction. He urged Member States to keep discussions on exclusions, exceptions and limitations in a manner that was guided by principles and objectives reflected in Articles 7 and 8 of the TRIPS Agreement and the Millennium Development Goals.

36. The Representative of ITSSD reiterated that the use of exceptions was an avoidance mechanism to circumvent the need for critical infrastructure development and to circumvent the need to develop critical resources necessary to determine whether an application fell within the scope of patentability. In his view, it was almost like a default rule where there was the option of treating a

patent developed by private means as a public interest asset. In his view, that was not appropriate even temporarily until the time when the critical resources that were necessary to evaluate the patentability of an invention are in place. He explained that financing, skill training and critical infrastructure were the three main areas that were always brought up when it came to compulsory licensing, because in most instances, a compulsory license was not going to get the government medicines, clean technology or software that was needed by the population. In many instances, the method of getting the technology to the people is the primary issue to be considered and not the issue of the patent. With respect to Article 31 of the TRIPS Agreement, the Representative observed that everybody was speaking about Article 31 in a way as if they were certain as to the interpretation of the provision. The Representative noted that his comments to document SCP/13/3 had cited a number of studies which showed demonstrably that an abuse of the patent right was not the cause of the issuance of a compulsory license. In his view, most of the new causes seemed to be based on public interest rather than public emergency or actual empirical evidence of a patent abuse. The Representative highlighted the need to pay fair, full, adequate and complete market value, which was evident not only in Article 31 of the TRIPS Agreement but also in the Doha Declaration and in the waiver provision in Article 31*bis*. The Representative considered that the question at stake was what fair market value was and how to determine it, which might be a reason and a cause for a study of its own, considering that the fair market value was usually in a market in which a company was selling a product that the government wished to take by the issuance of a compulsory license. In his opinion, that was a market study, and it was not for the government to issue unilaterally a market price based upon their own assessment. The Representative therefore suggested that an analysis, or an example of how to undertake an analysis, to determine the fair market value in a developing country be undertaken under a future study, because, in the end, a compulsory license did not indicate a presumption that there was not a ready market with a willing buyer and a willing seller, which would be proven untrue in most cases.

37. In response to the question addressed to the Representative of WTO by the Delegation of Venezuela regarding the interpretation of Article 31 of the TRIPS Agreement, the Representative stated that the WTO Secretariat had no authority over the interpretation of the TRIPS Agreement.

**II. 14<sup>th</sup> session of the SCP, January 25-29, 2010**  
**[Excerpts from the Report (document SCP/14/10)]**

38. Discussions were based on documents SCP/13/3 and SCP/14/7.

39. Referring to the study relating to exclusions, exceptions and limitations commissioned to external experts, the Secretariat informed the Committee that it had identified a renowned academician, Professor Lionel Bently from the University of Cambridge, who would be coordinating the study and had been given all the instructions received from the Committee. Further, Professor Bently had been asked to identify five experts from five different regions of the world renowned for their knowledge in the field of intellectual property. Consequently, in addition to Professor Bently, the following experts would be involved in preparing the study: Professor Denis Barbosa (Brazil); Professor Shamnad Basheer (India); Professor Richard Gold (Canada); Professor Brad Sherman (Australia); and Professor Coenraad Visser (South Africa). The Secretariat further noted that the study would be submitted to the Committee at its following session.

40. The Delegation of Brazil presented its proposal on exceptions and limitations to patent rights (document SCP/14/7). The Delegation emphasized that the law of patents was essentially a trade-off between the granting of temporary and exclusive rights as a *quid pro quo* for the dissemination of technological progress to the benefit of the entire society. The patent system must therefore strive for a balance of rights among all its users. Accordingly, the interests of not only IP title holders, but also the society as a whole should be taken into account. The Delegation stated that exceptions and limitations were intrinsic elements of every law, and that that was also applicable to the various patent systems. The Delegation observed that exceptions and limitations of patent rights served a number of purposes by allowing both for the necessary flexibility to guarantee national security, for example, and for a space to shape public policies to meet development, competition policy and health policy goals. While noting that the proposal was of a straightforward nature, the Delegation clarified that it was not attempting to create new legislation. The first and foremost goal of the proposal was to introduce a three-phase work program on exceptions and limitations into the SCP. What it aimed at was an empirically-based exercise of sharing concrete national experiences and, in that sense, it was not a substitute for, but rather a complement to, the study that had been commissioned by the Secretariat and which would be ready by the following session. The Delegation welcomed that study, and especially the fact that it was going to take on board the views and experiences of different parts of the world. In presenting the proposal, the Delegation wished to provide for a different knowledge on how the system worked in practice as far as exceptions and limitations were concerned. The Delegation noted that the result of the exercise might be, for example, a compilation of a non-exhaustive handbook. It was of the view that such a handbook might form the basis for capacity building activities in developing countries in line with the Development Agenda. While emphasizing the importance of the start of the project, the Delegation concluded that there was a gap between the existing legal framework on exceptions and limitations and its effective use by developing countries. Therefore, the main goal of the proposal was to bridge that gap.

41. The Delegation of Ecuador supported the statement made by the Delegation of El Salvador on behalf of GRULAC. The Delegation supported the agenda of the SCP which, in its view, benefited all Member States and took into consideration the Development Agenda. The Delegation supported the Delegation of Brazil's proposal on the future work of the SCP as regards exceptions and limitations, which would include a process for identifying the exceptions and limitations in different legislations, an assessment as to their effectiveness in relation to development, and carrying out a non-exhaustive analysis of those flexibilities. The Delegation stated that Ecuador had analyzed and would continue analyzing the proposal which it endorsed. Furthermore, the Delegation offered its support in developing the proposal of the Delegation of Brazil, because the proposal was fully in line with Ecuador's IPR policy that considered IPR as a tool for development. As an initial step, the Delegation suggested that the proposal of the Delegation of Brazil include a description of experiences of countries with exceptions and limitations and the identification of case law in that area. Furthermore, the Delegation considered it important that the final result should be a reference document, advising

ways on how not to restrict exceptions and limitations and not exclude other possibilities which could benefit the development of countries.

42. The Delegation of Argentina endorsed the statement made by the Delegation of El Salvador on behalf of GRULAC. The Delegation stated that Argentina was particularly interested in the issue of exceptions and limitations which was closely related to the general principles of the WIPO Development Agenda. In particular, the Delegation welcomed the Delegation of Brazil's proposal in paragraphs 25 to 28 of document SCP/14/7. The Delegation was of the view that establishing a work program on exceptions and limitations would contribute to the effective implementation of the Development Agenda.

43. The Delegation of El Salvador, speaking in its national capacity, was of the view that the proposal of the Delegation of Brazil was extremely valuable and therefore should continue being part of the basic working document in order to continue promoting and strengthening the mobility of the work carried out in the Committee.

44. The Delegation of Spain, speaking on behalf of the European Union and its 27 Member States, thanked the Delegation of Brazil for preparing the document, which would contribute to enriching the discussions. Without considering the merits of the document, the Delegation expressed its surprise for the submission of the document on the first day of the Committee in one language and without it being available on WIPO's website. While noting that the European Union and its 27 Member States were ready to participate in the discussion, the Delegation expressed its concern about that kind of procedure which made it difficult for countries to participate in the process. The Delegation reminded the Committee that the document which was being prepared by the group of external experts for the following meeting would deal specifically with that issue. In its view, the discussion of both issues at the following meeting would give a complete overview of the situation and avoid duplication of work.

45. The Delegation of Guatemala supported the statement made by the Delegation of El Salvador on behalf of GRULAC. The Delegation noted that exceptions and limitations were part of the checks and balances of the international patent system, since they guaranteed the dissemination of technology embodied in the invention. It considered that developing countries should use those policies in a sensible way, draw the maximum benefit from intellectual property, and be able to adapt patent policies to their particular circumstances and realities. In its view, the Delegation of Brazil's proposal would assist developing countries in designing and implementing their public policies, particularly, as regards health and competitiveness. The Delegation stated that Guatemala supported the three-phase work program proposed by the Delegation of Brazil and hoped that it would be able to participate in the exercise in order to share its national experiences. Furthermore, the Delegation requested the Secretariat for clarification as regards the study that had been commissioned to external experts. In particular, the Delegation questioned whether the Committee had given the Secretariat a mandate to commission the study to a group of external experts, and whether the study would take into account the economic aspect of the issue. The Delegation hoped that the study would not just analyze the legal aspect of the issue, but would also focus on economic aspects which would enable the evaluation of the economic consequences of exceptions and limitations in various countries.

46. The Delegation of Germany thanked the Delegation of Brazil for the presentation of its proposal. The Delegation noted that it had expected the study by the external experts agreed upon on the previous session of the SCP to be presented in the current session. While the Delegation appreciated the explanation by the Secretariat on the issue, it nevertheless expressed its concern about the level of information Member States had enjoyed during the process of selecting and commissioning the external experts. The Delegation stated that Germany was looking forward to a constructive and fruitful debate on the issue of exceptions and limitations to patent rights once all relevant information became available in the forum. The Delegation concluded by saying that it fully supported the statement made by the Delegation of Spain on behalf of the European Union and its 27 Member States.

47. The Delegation of Sudan stated that technology transfer as well as exceptions and limitations represented a great interest for its country. With respect to technology transfer, the Delegation believed that it was very important to establish a patent system which was equitable and efficient. The Delegation underlined the importance of the issue of technology transfer to developing countries especially in the area of health, communication and information transfer.

48. The Delegation of Oman thanked the Delegation of Brazil for its proposal. The Delegation paid tribute to the proposal which outlined a three-phase process in order to establish a plan of action for the SCP, aiming at creating an effective strategy with respect to exceptions and limitations. The Delegation was of the view that, up to that time, the use of exceptions and limitations to patent rights had remained rather limited, especially in developing countries. The Delegation therefore supported the idea of further studies in that area.

49. In reply to the query from the Delegation of Guatemala concerning the scope of the study commissioned to external experts, the Chair stated that the study would include the economic aspects of the issue, and it would also reflect on the comments made by the Members of the Committee.

50. The Delegation of Switzerland thanked the Delegation of Brazil for the proposal and the presentation which further clarified the goal of the initiative. The Delegation however noted that, due to the late submission of the proposal, it required further time to study it in detail in order to provide comments. The Delegation expressed its interest in looking at how the proposal could be integrated into the further work of the SCP. The Delegation was of the view that it was important to wait for the results of the study commissioned to external experts on exceptions and exclusions to have a complete overview of the situation before any determination of the future work program on the issue was made. While the Delegation reaffirmed its commitment to the discussion and active participation in the debate, it however observed that it was premature to take a decision on the proposal made by the Delegation of Brazil at the present session of the SCP.

51. The Delegation of India thanked the Delegation of Brazil for the very positive proposal and noted that exceptions and limitations to IP rights were an extremely important issue for India, since they related directly to access to knowledge, access to educational resources, transfer of technology, etc. Therefore, the Delegation expressed its full support for the steps proposed in paragraphs 25, 26 and 27 of document SCP/14/7, and viewed the suggestions as a productive manner of taking forward the deliberations on that issue in the Committee. The Delegation urged for the work in that area to be undertaken along the lines proposed in that document. Further, the Delegation requested the Secretariat to clarify the terms of reference for the study commissioned to external experts in order to shed light on what to anticipate from the study. In addition, the Delegation advised that constraints in implementing the limitations and exceptions in the patent law should be included in the Brazilian proposal. While noting that the document was very exhaustive, the Delegation thought that the proposal shed little light on the rule of exceptions and limitations. Therefore, the Delegation considered that the rule of exceptions and limitations should be highlighted in more detail, particularly with reference to implementing the policies by the governments with regard to public health and other issues. Further, the Delegation noted that there were certain inaccuracies in the document prepared by the Secretariat in relation to provisions on compulsory licenses in the Indian patent law. In particular, the Delegation noted that apart from the general provisions on compulsory licenses that were mentioned in the document, there were some special provisions on the grant of compulsory license when there was immediate urgency in the case of a public health crisis. The Delegation requested those provisions to be reflected in the preliminary study.

52. The Delegation of China stated that exceptions and limitations as well as exclusions from patentable subject matter were an extremely important subject in patent law. Noting the current crisis in the area of public health, as well as food security, the Delegation emphasized the importance of carrying out a detailed study on exceptions and limitations. The Delegation, therefore, supported the Brazilian proposal and noted that the three phases mentioned in paragraphs 25, 26 and 27 of document SCP/14/7 would be simple to implement.

53. The Delegation of the United States of America thanked the Delegation of Brazil for its proposal on exceptions and limitations. The Delegation recalled its intervention at the SCCR in December 2009. The Delegation expressed its belief that strong intellectual property rights and enforcement provisions were not inconsistent with exceptions and limitations, and pointed out that exceptions and limitations complemented strong intellectual property rights and enforcement. Therefore, the Delegation noted that it was pleased that the Secretariat had commissioned a study on exceptions and limitations to be conducted by academic experts from various countries. The Delegation observed, however, that the issue should be studied systematically, and that therefore, the study should be the first deliverable that it wished to consider on exceptions and limitations. The Delegation was of the view that the rationale and systematic evaluation of whether more work was needed in the area could be made after that deliverable had been produced.

54. The Delegation of the Plurinational State of Bolivia supported the proposal of the Delegation of Brazil on exceptions and limitation to patent rights. Referring to document SCP/13/3, the Delegation stated that some of the elements in that document needed to be developed further. The Delegation stated that the Government of the Plurinational State of Bolivia had been following the Committee's work with great interest, because patentable subject matter, when it related to life, was very important. The Delegation recalled that the Committee had decided in its last meeting to commission a study to external experts which would include the issue of patentability of life forms. The Delegation wished to transmit to the group of experts and the Secretariat certain elements to be taken into account upon analyzing the study, including the current trends in patentability of life forms. The Delegation observed that, since the adoption of the TRIPS Agreement, there had been a great proliferation of patents and patent applications for life forms, such as plants, animals, genes and other living organisms. The Delegation stated that according to a recent report from the Action Group on Erosion, Technology and Concentration on Patents and Climate Change, a big number of major plant companies were filing patent applications on plant seeds that could withstand natural disasters. The Delegation further reported that there were ten companies that owned more than two-thirds of intellectual property on seeds. The Delegation emphasized the fact that in many countries, patent claims were not just covering genetically modified organisms (GMOs), but also plants and animals which had been bred by traditional means. The Delegation believed that the study should focus on the trends on patentability of life forms, the sectors where such patentability had the greatest impact, the type and the nature of patent protection with regard to life forms and the countries of origin of patent applications relating to life forms. Further, the Delegation was of the opinion that the study should include an analysis of the ethical and moral aspect of patentability of life forms. The Delegation considered that the patentability of life forms had negatively affected many cultures. Therefore, in the Plurinational State of Bolivia, there was a prohibition on the patentability of plants, animals, microorganisms and all other life forms. Moreover, the Delegation was of the view that the study should take into account the economic, social and cultural impact of patentability of life forms in developing countries, particularly the impact on public policies, indigenous people, agricultural producers and their traditional practices, as well as the right to keep and exchange their seeds and sell their harvest. The study should also take into account anti-competitive practices which stem from the patentability of life forms. The Delegation stated that it was very important to deal with the subject from a historical perspective focusing, for example, on developing countries and the impact of GMOs on their culture, food security and public policy. In conclusion, the Delegation reiterated that the study should focus on the patentability of life forms, socio-economic development and public policy. The Delegation expressed the hope that the contents of the study would be objective, evidence based, adequately referenced and include the analysis of the issues that it had raised in its statement, particularly because of the importance that they held for developing countries. The Delegation requested information on the external experts, including their biographies.

55. The Delegation of Angola, speaking on behalf of the African Group, welcomed the proposal made by the Delegation of Brazil which, in its view, represented a way to set up a three-phase working plan on exceptions and limitations of the patent system. The Delegation stated that the African Group reserved its right to revert to the issue during the course of the current session after having had further

consultations with the Delegations of Brazil and GRULAC. In principle, the African Group did not have any objection to the proposal, and therefore, wished to contribute to supporting the proposal in a constructive manner.

56. The Delegation of Egypt supported the proposal of the Delegation of Brazil on the issue of exceptions and limitations to patent rights. The Delegation believed that the proposal pertained to some very important issues, primarily because it analyzed and offered a diagnosis of a current ailment in the international patent system. Referring to paragraph 6 of the proposal, which stated that the current IP system was heavily characterized by ensuring rights to the IP title holders, while those claims were undoubtedly legitimate, they were certainly incomplete from the public policy perspective. Paragraph 10 of the proposal further pertained to the possibility of a way out which was delving into the fundamentals of the patent system, particularly, a need to revisit and revise old assumptions and to recover the essentials of the patent system. The Delegation noted that while the proposal pertained directly to issues of development and of particular concerns raised by developing countries, it was undoubtedly an issue that was cross-cutting in terms of the interest of the membership across the spectrum in the organization, because it essentially entailed to consumers and users of the patent system *vis-à-vis* the owners. The Delegation expressed the opinion that the three-phase approach proposed by the Delegation of Brazil would enable the Committee to learn from the developed countries who had developed systems that protected consumers through exceptions and limitations in the patent system. The Delegation stated that the three-phase approach elaborated in paragraphs 25 to 27 was a solid way forward, and supported the links between the proposal and the Development Agenda as reflected in paragraph 28 of the document. In addition, the Delegation appreciated the global approach that the proposal offered to the issue of exceptions and limitations. In its opinion, only through a global approach would the Committee be able to develop proper policies and strategies in relation to exceptions and limitations, rather than adopting a piece-meal approach to the issue. Further, referring to the study commissioned to external experts, the Delegation noted that there was no expert from the Arab Region. In its view, the group of experts should include an expert from the Arab Region, as such expert would be able to elaborate and would have a better grasp of the issue in relation to that region.

57. The Delegation of the Islamic Republic of Iran stated that exceptions and limitations played an essential role in creating a balanced IP system and could provide an important policy space for policy makers in managing their development process. The Delegation was of the view that the second and third phases of the Brazilian proposal were of great importance to developing countries, as it represented a valuable effort to bridge the gap between existing provisions on exceptions and limitations and their actual implementation, and proposed new possible areas for transfer of technology and public policy issues. The Delegation stated that the fact that the study by external experts had not yet been submitted to the Committee should not hinder Member States from proposing a work program. In conclusion, the Delegation expressed its appreciation to the Delegation of Brazil for its valuable proposal and supported its inclusion into the work of the Committee.

58. The Delegation of Sri Lanka noted that the issue of exceptions and limitations was at the heart of the Development Agenda and that the Brazilian proposal captured that aspect. In its view, the proposal facilitated the SCP to be more supportive of development. Therefore, the Delegation supported the proposal by the Delegation of Brazil and commended the Brazilian government for its pro-active role. The Delegation hoped that the discussions would take into consideration the interests of technologically less advanced countries, like Sri Lanka, with small domestic markets, particularly in applying exceptions until they achieve the required level of technological development.

59. The Delegation of Pakistan expressed its full support to the proposal made by the Delegation of Brazil on exceptions and limitations to patent rights. It pointed out that exceptions and limitations and their correlation with the development perspective was actually inherent in nature. The Delegation further stated that the three-phase approach mentioned in the Brazilian proposal, on paragraphs 25 to 27 of document SCP/14/7, was a very systematic approach, and therefore, represented a very clear way forward.

60. The Delegation of Australia acknowledged the scale and importance of the topic on exceptions and limitations to patent rights which were at the heart of the balance inherent in the patent system. The Delegation noted that sufficient time was needed for consideration of the issue, and stated that the study by external experts would be a significant piece of work which would provide valuable information that could form the foundation of the future work on that topic. Noting that the study commissioned to external experts would not be available to Members until the next session of the SCP, the Delegation preferred discussions on the Brazilian proposal to be deferred until October 2010. The Delegation was of the opinion that that would enable the SCP to have a more complete view of the issue and to consider the proposal in detail.

61. The Delegation of Japan informed the Committee on the updates that took place in Japan since the previous session of the SCP with regard to the exclusions from patentable subject matter. Inventions related to medical activities had not been considered as patentable subject matter on humanitarian grounds in Japan. Accordingly, under the Japanese Patent Law, it had been interpreted that medical practices had not fallen under the category of industry, and thus medical method inventions had been excluded from patentable subject matter in the sense that they had been considered to be lacking industrial applicability. However, the Delegation noted that there had been some opinions that medical method inventions should be protected in order to develop medical technologies. Aiming at a further development of those technologies in the medical science, the examination standards had been revised in November 2009 by expanding the range of patentable subject matter to those inventions concerning novel dosage and administration of medicines, as well as methods of gathering data for diagnosis. While thanking the Delegation of Brazil for the efforts to submit a new document, the Delegation noted that it had received it the previous day, and therefore needed some time to study it. The Delegation was of the view that it was premature to decide on the work program based on document SCP/14/7, in view of the forthcoming study commissioned to the external experts.

62. The Delegation of Kyrgyzstan expressed its gratitude to the Delegation of Brazil for its proposal which it believed was a good basis for discussions within the framework of the Committee. However, the Delegation noted that, given the insufficient time for consideration of the document, it was unable to state its view on the proposal at that session. Therefore, the Delegation requested the discussion on the proposal to be deferred until the following session of the Committee when the study by the external experts would also be available.

63. The Delegation of the Russian Federation thanked the Delegation of Brazil for its valuable proposal on exceptions and limitations to patent rights. The Delegation stated that practical action was needed in order to achieve results in that area. Nevertheless, the Delegation was in agreement with the views expressed by the Delegation of Spain on behalf of the European Union and its 27 Member States and the Delegation of Kyrgyzstan on behalf of the Regional Group of Certain States of Eastern Europe, Caucasus and Central Asia, who stated that the consideration of that document should be made at the following session of the SCP, together with the study submitted by the external experts. In addition, the Delegation stressed the importance of the group of external experts being composed by representatives of all main regions. Further, the Delegation noted that the proposal by the Delegation of Brazil could constitute one of the new issues for analysis as the list of issues was not exhaustive and open for new topics.

64. The Delegation of Algeria supported the statement made by the Delegation of Angola on behalf of the African Group and thanked the Delegation of Brazil for its proposal on exceptions and limitations to patent rights. The Delegation was of the view that the proposal correctly analyzed the obstacles which impeded the implementation of flexibilities that were foreseen in international arrangements. Therefore, in its view, the discussions within the SCP should contribute to finding solutions for the effective realization of exceptions and limitations in the patent system in order to respond to the needs of developing countries as regards development and public policy. The Delegation expressed the wish that the work program mentioned in the proposal be taken up in the future work of the

Committee. Nevertheless, in order to avoid duplication, the Delegation expressed the view that the proposal should be discussed together with the study to be submitted by external experts at the following session. In relation to the study commissioned to external experts, the Delegation supported the proposal of the Delegation of Egypt that an expert from the Arab region should be included so as to reflect the expertise of that region.

65. The Delegation of Panama joined the other delegations who had supported the proposal put forward by the Delegation of Brazil which included a reference to the balance in the patent system. The Delegation agreed with the statement made by the Delegation of Brazil that its proposal would contribute to the review of the issue on exceptions and limitations to the rights conferred by patents. The Delegation noted that the topic was of great importance within the Committee, as it was directly related to the Development Agenda.

66. The Delegation of Indonesia recalled its statement made at the previous session of the SCP according to which the preliminary study on exclusions from patentable subject matter and exceptions and limitations to the rights had not sufficiently explored the experiences of developing countries in approaching the issue. The Delegation thus supported the Brazilian proposal, as it suggested a constructive three-phase work program on how to enrich and follow-up the preliminary study carried out by the Secretariat. While expressing its understanding that other delegations had not had sufficient time to study the proposal, the Delegation suggested to focus on the last part of the proposal which provided a simple but concise idea on the future work program for the SCP on the issue.

67. The Delegation of Norway considered the issue of exclusions from patentable subject matter and exceptions and limitations to the rights to be an important one. The Delegation looked forward to the study commissioned to external experts to be presented at the following session of the SCP. While welcoming document SCP/14/7 from the Delegation of Brazil as a contribution to the upcoming discussions, the Delegation expressed its concern about the sequence on how the different items were being handled. For instance, it would be advantageous to look at exceptions and limitations in context with the substantive standards for protection. Such substantive standards could be national, regional or international. The Delegation was of the view that without discussing those items in context, the picture would be incomplete. In conclusion, the Delegation of Norway agreed with the statement made by the Delegation of Spain on behalf of the European Union and its 27 Member States and other delegations speaking in favor of postponing the discussion on document SCP/14/7 to the following session of the SCP. The Delegation believed that the consideration of that document, together with the study provided by external experts, would provide a broader basis for discussions.

68. The Delegation of Chile stated that exclusions and limitations to patent rights should not be considered as an impediment or a barrier to innovation and to the process of creation in general. On the contrary, in its view, they were essential flexibilities in the intellectual property system in which they represented a balance in the system. The Delegation noted that there was a need to facilitate access to information and transfer of technology through those tools. In its view, that approach would make it possible to have greater innovation to invigorate the development of knowledge and access to technology which was considered as being a fundamental topic of public interest at a global scale. Along those lines, the Delegation considered the proposal submitted by the Delegation of Brazil to be a starting point for delving into that topic. The Delegation welcomed the fact that a number of countries had supported the proposal, and no one had opposed it. The Delegation stated that it was necessary to complement the existing studies with information and specific materials on the implementation of flexibilities which existed in the national and international legal systems. The Delegation further invited members of the SCP to share any relevant information on the practical national situation on exclusions, exceptions and limitations with the objective to make specific headway in that field and to improve the understanding on the worldwide application of those flexibilities. Those contributions could be shared with the external experts who would develop the study by October 2010, in order to make it as comprehensive as possible. The Delegation considered that the topic was directly linked to the strategic objectives of WIPO to develop a well-balanced agenda, and therefore, it should be given the greatest importance in the Committee.

69. The Delegation of Uruguay joined other delegations who were members of GRULAC in supporting the Brazilian proposal. It stated that the proposal should become part of the discussions in the Committee. The Delegation observed that the proposal was not incompatible with what had already been decided by the Committee, particularly with the study being carried out by the external experts. The Delegation noted that the proposal was needed in the Committee as it would give it a meaning to its future work as regards limitations and exceptions. It expressed the view that the topic on exceptions and limitations should be given intensive and extensive treatment, not only for the benefit of producers of technologies, but also for the benefit of consumers who should use those technologies to meet their basic needs. The Delegation also supported the interventions of other delegations regarding the way of moving forward and the selection of external experts. In that regard, the Delegation noted that it was informed only about the composition of the group of external experts to whom it wished to provide comments at a later stage. Further, the Delegation considered that the Committee should think about other possible contributions to the work of the external experts in drawing up the study. Along that line, the Delegation emphasized that the proposal made by the Delegation of Brazil and supported by other delegations should be an important element to be considered in the study.

70. The Delegation of Guatemala supported the proposal made by the Delegation of the Plurinational State of Bolivia that the study should look into bioethics and patentability of life forms. The Delegation recalled that those requirements had been expressed by the Delegation of the Plurinational State of Bolivia in the previous meeting and had been supported by its Delegation as recorded in paragraph 102 of the report of the 13<sup>th</sup> session of the SCP (document SCP/13/8). The Delegation also supported the proposal made by the Delegation of Sri Lanka that the study should reflect the effects of exceptions and limitations on small developing countries, so that those countries could benefit from some guidelines on those issues. The Delegation observed that exceptions and limitations were closely related to production and access to pharmaceutical products and medicines in many countries. The Delegation noted that the current mechanism did not stimulate innovation in the field of medicines in a manner that enabled developing countries to negotiate with patent holders and meet the needs of all stakeholders. The Delegation was of the view that it was necessary to add studies on the return on investment and the development of new medicines. The Delegation stated that, thus, the Committee could evaluate mechanisms in order to make better use of exceptions and limitations and safeguard access to medicines for the public. The Delegation proposed that such information be included in the third phase of the Brazilian proposal.

71. The Delegation of the Bolivarian Republic of Venezuela supported the statement made by the Delegation of the Plurinational State of Bolivia, which had a strong link to human rights, such as the right to life, the right to food, the right to health, as well as to the Development Agenda. The Delegation observed that WIPO was part of the United Nations system, and therefore could not stand aside from what was agreed to in its agreements on human rights. Further, the Delegation suggested that the terms of reference of the external experts be made available to the Committee. The Delegation also welcomed the proposal made by the Delegation of Brazil as a first step in the discussion on that topic. Further, it agreed with the Delegation of Brazil regarding the TRIPS Agreement and the Declaration on the TRIPS Agreement and Public Health, contained in paragraphs 13 and 14 of document SCP/14/7. In relation to paragraph 27 on the elaboration of an exceptions and limitations manual, the Delegation stated that such an approach should not limit existing flexibilities.

72. The Delegation of the United Kingdom thanked the Delegation of Brazil for the proposal on exceptions and limitations to patent rights. The Delegation observed that it was an interesting and complex issue, and that even countries with long-standing compulsory licensing provisions in their laws might find it not really necessary or even useful to invoke them. In its view, that fact made it even more important to have the full picture of the issues which the Delegation believed would get from the external experts. The Delegation reiterated that it was willing to participate in a constructive debate on the issue. However, given the short period of time that it had had to consider the Brazilian proposal, and noting that the experts' study which had been mandated by the Committee was due in October

2010, the Delegation believed that it was premature to come to a conclusion on the issue at the current session. Therefore, it supported the statement made by the Delegation of Spain on behalf of the European Union and its 27 Member States to postpone the discussion on the document until the following session.

73. The Representative of ALIFAR noted that the proposal made by the Delegation of Brazil was clear and pragmatic, as it proposed to understand not only the national legislations, but also how they operated, in practice, in a particular country. In her view, it was a valuable contribution. The Representative stated that some academic works, including WHO documents, which provided regulations on compulsory licensing of many countries could contribute to the Brazilian proposal. The Representative observed that compulsory licenses were tools which must be at the disposal of governments to be used when they saw fit, for example, in order to meet some demands or ensure affordability. Therefore, the Representative believed that it was essential for a country to have flexibilities as provided for in Articles 30 and 31 of the TRIPS Agreement and the Doha Declaration. As regards public health and the pharmaceutical sector, she attached special importance to maintain the freedom of countries to regulate patentable subject matter as prescribed in the TRIPS Agreement and other agreements.

74. The Representative of KEI supported the proposal made by the Delegation of Brazil on a work program on limitations and exceptions to patent rights. While observing that the flexibilities found in Part 3 of the TRIPS Agreement on the enforcement of intellectual property rights were implicit in the Brazilian proposal, the Representative suggested making that explicit. He further recalled that the US Supreme Court decision *eBay v. MercExchange* had set a precedent requiring US courts to consider the grant of non-voluntary authorizations to use patents as an alternative to granting injunctive relief. In light of the flexibilities contained in Article 44 of the TRIPS Agreement and the *eBay vs. MercExchange* decision, the Representative was of the opinion that it remained to be seen how other countries would effectively rely upon limitations on damages and injunctions to address a variety of public interest and access to knowledge issues. The Representative observed that the flexibilities contained in Article 44 provided countries the policy space allowing them to set the contours for enforcing intellectual property rights tailored to their national needs. In his view, the ability of countries to employ the Article 44 flexibilities on injunctive relief might be limited by proposals in the ACTA negotiations. The Representative reported that negotiators from 38 countries were holding a closed meeting in Mexico that week to consider a new trade agreement on the enforcement of intellectual property rights. While the Representative could not confirm whether that agreement would address the issue of enforcement of patents, in case it did, he suggested that the SCP request countries involved in that negotiation to make the negotiating text of ACTA public, so that its ramifications for the patent system could be discussed at the following session of the SCP.

75. The Representative of GRUR stated that the proposal by the Delegation of Brazil represented a huge package of different subjects. In his view, the subject of compulsory licensing should be dealt with separately and should not be included in the normal limitations, because a compulsory license was a tool in itself which had a separate legal basis in Article 31 of the TRIPS Agreement and, therefore, had different ground than the use of patented subject matter for private, non-commercial use which fell under Article 30 of the Agreement. In relation to certain uses concerning foreign means of transportation temporarily entering the national territories, the Representative stated that such exception was already regulated in the Paris Convention and in the Chicago Convention on the International Civil Aviation. He therefore considered that there was no controversy, although a question of interpretation might arise. The Representative however noted that, since the *bona fide* prior use was in itself a highly controversial subject, it should also be dealt with separately and not considered together with the ordinary limitations. Therefore, the Representative suggested that paragraph 22 of the proposal be divided into sub-topics in order to separate the ordinary limitations from the right of prior use and the compulsory licensing.

76. The Representative of TWN highlighted two developments which had implications on limiting the flexibilities available in the patent regime. In relation to the first development, the Representative

stated that the European Union was negotiating or planning to negotiate with more than 80 developing countries free trade agreements in which, according to publicly available texts, it was likely to recur to limitations on exceptions for goods in transits, possible restrictions on parallel importations, possible weakening of effectiveness of compulsory licenses by data exclusivity and other provisions that would reduce remaining exceptions and limitations. The Representative further stated that the free trade agreements with the European Free Trade Association might also limit the effectiveness of exceptions and limitations, such as compulsory licenses, by recurring data exclusivity. The Representative further stated that the Free Trade Agreements of the United States of America provided limited flexibilities in the past, for example, by removing the ability to exclude plants, animals or new uses from patentable subject matter and appearing to render some exceptions and limitations less effective, limiting the grounds for compulsory licenses and restricting parallel importations. Similarly, Japan's Free Trade Agreement, in particular the investment chapter, might also significantly limit the ability to exercise exceptions and limitations to patent rights. The Representative stated that another development was the enhanced enforcement initiatives mainly from the Member States of the European Union resulting in seizure of medicines which were in transit, compromising access to medicines in various developing countries, especially in Latin America and Africa.

77. The Delegation of Angola, speaking on behalf of the African Group, thanked the Delegation of Brazil for the valuable proposal. In order to build a consensus among Member States in a constructive manner, the Delegation requested that that item be maintained on the agenda of the following session in order to be able to have further discussions and take action on the issue.

78. The Delegation of Brazil, referring to the level of support expressed by other delegations, stated that its proposal was no longer the proposal of Brazil, but of several Member States. As had been noted by the Delegation of Chile, the Delegation recalled that nobody had spoken against the proposal. The Delegation said that there were some objections to the late submission of the proposal, but no objection to the content of the document. In relation to the comments made by the Delegation of Spain on behalf of the European Union and its 27 Member States, while the Delegation understood the difficulty that Member States were experiencing in examining the document given the short period of time, the Delegation stated that the proposal had been presented on the date indicated in document SCP/14/7, and that it was detrimental to the discussions that the document had not been translated accordingly and not been ready for the discussion at the current session. Further, the Delegation informed the Committee that the proposal had been submitted for the fourteenth session of the SCP because of the expectation that the study commissioned to external experts would be available at the same session in order to be able to discuss both issues at the same time, even though they were of different nature and dealt with different aspects of the same question. The Delegation underlined that the issue, as had been seen during the discussions, was a priority for several countries. Therefore, it expressed the hope that the study commissioned to external experts would be available at the following session and that its proposal be discussed again in conjunction with that study, but at the same time, as a separate issue. The Delegation pointed out that it did not wish to link the two documents, because the external experts' study would adopt a theoretical, academic approach which could expand on the existing framework, whereas its proposal had chosen a pragmatic approach which was based on experiences of countries in accordance with their national legislations. Against this backdrop, the Delegation agreed that its proposal be taken up at the following session of the Committee.

79. The Chair, noting that there had been some delegations who had requested more time to study the proposal by the Delegation of Brazil, suggested that the discussion on that document be postponed to the following session of the Committee.

80. An information document containing the names and CVs of the external experts preparing the study, as well as their terms of reference, was made available to the Committee (document SCP/14/INF/2).

81. The Chair clarified that Member States could send comments as regards the issues dealt within the external experts' study on exceptions and limitations, and that they would be requested to take those comments into account in preparing the study. The Chair proposed to set a date to receive such comments.

**III. 13<sup>th</sup> session of the SCP, March 23-27, 2009**  
**[Excerpts from the Report (document SCP/13/8)]**

82. The Secretariat introduced document SCP/13/3.

83. The Delegation of Egypt raised a question as to whether the words "to contextualize the legal framework" in paragraph 21, meant also the inclusion of studies relating to the socio-economic conditions linked to a particular legal regime and to a particular system of protection, and whether bilateral arrangements that had an impact on patent policy had been considered.

84. Following a question by the Delegation of the United States of America, the Chair clarified that he was inviting comments on the four preliminary studies, one by one, and that delegations were free to provide any suggestions as to how to proceed on a specific subject on a specific document, which would facilitate discussions on agenda item 8, future work.

85. The Delegation of the United States of America stated that, when agreeing to the adoption of the agenda, its understanding had been that the Committee would engage in the discussion of the four topics and then proceed to a discussion of future work as a separate agenda item, which, in its view, was a more pragmatic approach to ensure a balance.

86. In response, the Chair noted that if any delegation wished to make a point on future work during the discussions on the four subjects, he could not stop them from doing so.

87. The Delegation of Chile requested the Secretariat to elaborate the international framework that was being referred to in the preliminary study.

88. The Delegation of Costa Rica sought clarification as regards to paragraphs 23, 25 and 27. It had the impression that the Secretariat had assimilated the idea of invention to patentable subject matter which in its view could be seen in the second part of paragraph 23, and sought a specific example. As regards paragraph 24 and the following, the Delegation observed that not only the negative impact but also the benefits of exclusions should be highlighted. Further, the Delegation was of the view that paragraph 27 was not clear with regard to the function of exclusions. As regards the use of the terms "*ordre public*" and "public order", the Delegation sought clarification as to the mechanics in choosing those terms. The Delegation further observed that more detailed information could be included in paragraph 76 with inputs from NGOs.

89. The Delegation of Bulgaria requested more information regarding a quantitative and qualitative analysis of the exceptions from the Secretariat. For example, a table could be provided on the different exceptions and limitations, country by country so that it could see which exceptions and limitations were more important and commonly appeared in national legislations.

90. The Delegation of Pakistan requested some examples of the exceptions from the patentability on the grounds of public order and morality granted at the national legislation.

91. The Delegation of India supported the Delegation of Bulgaria by stating that a quantitative and a qualitative analysis would be useful to everybody. It noted that it was broadly acknowledged that the issue of exclusions from patentable subject matter was grounded in the socio-economic context of a particular country. The report devoted some attention to the exclusion of plant and animal varieties, plants and animals and essentially biological processes from patentability. It also made the point that

due to improvements in biotechnology, many inventions pertaining to plant and animal varieties had started to satisfy the criteria of patentability. The Delegation observed that it would have been relevant to also explain the impact of patenting plant variety on broader public policy issues, for instance, farmers' rights, food security, even in an academic manner, to give a broader picture. Similarly, on the issue of excluding life forms from patentability and the view that that might be relaxed in view of development in genetic technology, the Delegation noted that that had implications in terms of public policy perspective which had a much larger dimension, and suggested that those points be addressed in a subsequent study or a supplementary study on the preliminary study.

92. In response to the Delegation of Egypt, the Secretariat provided the following comments: with respect to the policy objectives and role of the exclusions from patentable subject matter, it had been highlighted that the public policy consideration was an underlying consideration with respect to exclusions and that public policy consideration might be influenced by the socio-economic conditions and the countries' different priorities in their specific conditions. However, with respect to the further analysis on the international legal framework and the national legal aspect, the preliminary study concentrated on the current *status quo* on the legal framework, both at the international level and at the national and regional levels. The Secretariat further explained that bilateral agreements had not been considered in the document. On the questions raised by the Delegation of Costa Rica, the Secretariat provided the following comments: it had been difficult to provide clear-cut characterization of the definition of the invention and the specific issues under the exclusions from patentable subject matter, since the structure of national laws were different in that regard. For example, the definition of "invention", if it is provided, were very much different from one country to the other, and some countries did not provide a definition in their national laws. Therefore, certain subject matter might be excluded from the patentability through the definition of the invention, i.e., defining the invention in such a way to exclude certain subject matter from the outset of the patent protection, or in other laws, such subject matter might be excluded by specific provisions concerning exclusions from patentable subject matter. As the Secretariat had understood the coverage of the preliminary study as the exclusions from patentable subject matter, the document in paragraph 23 touched upon what were generally considered inventions or might not be considered inventions, and the preliminary studies tried to focus more on what were normally considered as exclusions from patentable subject matter. Concerning paragraph 27 relating to the benefits of the exclusions from patentable subject matter, the Secretariat observed that while it believed that some aspects might be covered by the policy objective of exclusions which were referred to in paragraph 29 onwards, additional inputs from any delegation would be certainly welcome. On the question regarding *ordre public* and public order in paragraph 49, detailed analysis on the difference between "*ordre public*" and "public order" was not conducted, and as stated in the last sentence of paragraph 49, both terms were used as having the same meaning. The Secretariat however noted that some delegations might have a different opinion. As regards the role of exceptions and limitations in paragraph 76, the Secretariat invited any input from Member States as well as IGOs and NGOs. With respect to the intervention made by the Delegation of Bulgaria concerning the quantitative or qualitative analysis on the exceptions and limitations, the Secretariat pointed out that Annex II to document SCP/12/3 Rev.2 provided a table concerning different national laws with respect to (i) the exclusions from patentable subject matter, and (ii) exceptions and limitations to the rights. If however the delegations wished, a different type of analysis could be conducted. The Secretariat explained that, based on the information contained in Annex II of the Report on the International Patent System, document SCP/13/3 highlighted the provisions which appeared quite often in the national and regional laws. With respect to the question by the Delegation of Pakistan concerning an example of the public order and morality, the Secretariat explained that one example relating to *ordre public* and morality, and which was in some national laws specifically mentioned, was the exclusion of the human body at any stage of development from patentable subject matter. Other examples were processes for cloning human, modifying the gene line, genetic identity of human or the use of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals, which were likely to cause them suffering without any substantial medical benefit. As regards the comments by the Delegation of India, being aware of the socio-economic context referred to, the Secretariat explained that its intention was to establish as much as possible the facts that led to or influenced those exclusions, perhaps more from

a legal point of view, in order to avoid going into one direction or the other. Thus far, the mandate had been preliminary studies and the Secretariat had tried to be as factual as possible to provide a basis.

93. In response to the question raised by the Delegation of Chile, concerning the international framework on exclusions from patentable subject matter and exceptions and limitations to the rights, the Secretariat elaborated on provisions of various international treaties, namely, the Paris Convention, the Patent Cooperation Treaty (PCT), the Convention on International Civil Aviation and the TRIPS Agreement.

94. The Chair invited delegations to express their views on document SCP/13/3.

95. The Delegation of Argentina declared, as a general comment, that it should have the opportunity to make further comments on the preliminary studies in the discussions of the next session of the SCP and reserved the right to continue to make comments at the next meeting on the documents presented during the 12th and 13th sessions of the SCP. The Delegation stated that, by and large, however informative the documents were, they did not contribute to a critical analysis of the consequences and ramifications that merely strengthening IP rights' protection, in respect of the various technical aspects discussed, could have for developing countries. The Delegation declared that a more balanced and holistic view would have allowed for a more comprehensive analysis of the various issues. IP rights' protection should not be seen as an end in itself, but rather as a means of promoting public interest, innovation, access to science and technology, and for developing various national creative industries with the aim of ensuring material progress and welfare. The documentation should include that dimension in its analysis. In that sense, the Delegation shared the concerns expressed by the Delegations of Brazil and China, at the 12th session of the SCP, on aspects not included but which should be discussed in the documentation (anti-competitive practices, transfer of technology in Annex II of document SCP/12/3 and the question of exceptions and limitations in the main body of that document). The Delegation indicated that, in general terms, the documentation did not include an economic or commercial dimension, or a competition policy perspective, which would allow the benefits and drawbacks of the issues discussed for developing countries and least developed countries (LDCs) to be assessed, as those countries had low levels of national patent applications. In Argentina, for instance, they accounted for no more than 10 per cent of the total.

96. In response to a question raised by the Delegation of Sri Lanka, the Chair clarified that delegations could express their opinion on the future step of the study, if they so wish, although there was an agenda item on future work. He noted that general statements, specific statements and observations and requests for clarification by Member States would show certain indications of the next work.

97. The Delegation of Sri Lanka, speaking on behalf of the Asian Group, proposed that the second step for the preliminary study was to conduct a specific study on exceptions and limitations covering all the aspects with external experts. The Asian Group was of the view that two to three academic institutes should look into different angles of exceptions and limitations. Further, the Group suggested that regional free trade agreements and bilateral free trade agreements be also covered in the second study.

98. The Delegation of Germany, speaking on behalf of Group B, observed that the preliminary study highlighted the same general public policy objectives shared by many countries, although the concrete means as to how to reach those objectives might often vary. The Delegation noted that it was a very positive finding since policy objectives, as the study putted it, influenced by the socio-economic conditions and the countries priorities would change over time. Therefore, the statement continued, one would thus have expected difference rather than convergence. Referring to national and regional levels, the Delegation noted that study provided the significant variety in the legal frameworks. Nevertheless, the Delegation observed that certain categories of subject matter were excluded from patentability in many countries. In a similar manner, the Delegation stated that certain exceptions and

limitations to patent rights could be found in many national and regional legal frameworks. Further, Group B believed that in case of any exclusion, exception or limitation of patent rights, an appropriate balance between the interests of the right holders, other stakeholders and the general public should be struck. The Delegation suggested that the exact scope of those constraints under national or regional laws deserved more in-depth analysis, since the interpretations of the legislative provisions vary. In concluding, the Delegation expressed its anticipation of further debates on the issues at stake.

99. The Delegation of the Plurinational State of Bolivia stated that the preliminary study on exclusions made it possible to see the situation especially from a legal point of view, internationally. The Delegation noted that no analysis had been made on bilateral agreements. Further, the Delegation pointed out that the preliminary study mentioned the possibility of patentability of life forms being something that was related to the advances in science, and the patent system being analyzed in the light of recent technological advances especially as concerns the patentability of life. The Delegation nevertheless felt that there was also a need to take into account recent advances made in international law, specifically, international law relating to the rights of indigenous people, for instance the Declaration of the United Nations on the Rights of Indigenous People adopted in 2007. The Declaration stated that governments must take measures in order to protect the rights of the indigenous peoples especially those which were tied to their genetic resources, their seeds, medicines and knowledge of the nature of the flora and fauna amongst other things. The Delegation stressed the importance of verification and coordination of work with other fora such as the Food and Agriculture Organization of the United Nations (FAO), the CBD and in the United Nations on Human Rights. The Delegation considered that the possibility of patenting forms of life was one of the basic elements that the patent system was based on and substances and processes which existed in nature were discoveries and not inventions. Although in its view, those subject matters should not be subject to appropriation under the patent system, the multilateral situation had provided the possibility of patenting some forms of life as microorganisms, and a high increase in patenting genetic resources was observed. The Delegation further noted that, as a consequence, there were some social, economic and ethical consequences that might arise from such patenting in developed countries. It stated that, since many of those patents were in violation of the legislation in developing countries, there was a concentration of patents in very few institutions or people mostly in developed countries. According to the view of the Delegation, that situation led to a prejudice against developing countries in general, but specifically against those indigenous people who lived in those countries. The Delegation expressed its concern that indigenous people were threatened in their life styles and in their food security. It considered that there were ways of looking at exclusions with regard to the environment and health, and that patent offices should not be dealing with those matters. Patent offices must interpret legislation and see how it should be applied. Further, the Delegation continued that if it was up to the governments to decide what could and could not be patented, then ethical considerations had to be taken into account along with the legal considerations. The Delegation was of the view that exclusions were tied to a question of urgency. For example, in order to mitigate the consequences of climate change, the relevant technologies should be excluded from the system as well, and it was hoped that all of those comments would be taken into account and would provide with food for thoughts for a following revision of the preliminary study.

100. The Delegation of the Russian Federation pointed out that the Russian Federation had adopted the codified legislation in the field of intellectual property. The said legislation had expanded the number of subject matters to be excluded from patentability. According to that legislation, the following matters were excluded from patentability: processes of human cloning, modifying the germ line genetic identity of humans, uses of human embryos for industrial or commercial purposes. In that line, the Delegation intended to send the International Bureau the referred modifications to be added to the Annex II of document SCP/12/3 Rev.2. Regarding document SCP/13/3, the Delegation noted that paragraph 29 provided that, under many national laws, non-technical creations were not considered to be "inventions" within the meaning of the patent law. In that regard, the Delegation found it useful if the Secretariat could add the information on the main criteria as to how technical creations differ from non-technical. As regards the issue of compulsory licensing as an instrument to

prevent abuses in cases of non-working or insufficient working of an invention protected by a patent, the Delegation pointed out that its legislation was in compliance with international laws, in particular with Article 5 of the Paris Convention. The Delegation stressed that the provision was an important tool for excluding abuse of non-use of a patent. As the issue of compulsory licenses in the Russian Federation was subject to decisions by a court, the Delegation explained that the process was considered to be very expensive and time consuming, which influenced the effectiveness of the application of the provision. In addition, the Delegation informed the members of the Committee that, under the legislation of the Russian Federation, the grant of voluntary licenses were possible. The information on applications in which a patentee expressed his wish to grant the right to use the invention to any person was published on an annual basis. In conclusion, the Delegation suggested to the Committee continuation of its work on document SCP/13/3, since it raised some problems which were of great interest to the Russian Federation.

101. The Delegation of the Czech Republic, speaking on behalf of the European Community and its 27 Member States, recognized the importance attached to the issues covered by document SCP/13/3. As regard the exclusion from patentable subject matter and subjects not considered to be inventions, the Delegation observed that the international legal framework was given directly by the TRIPS Agreement. The Paris Convention and the regulations under the Patent Cooperation Treaty touch upon those issues indirectly. It was stated that, in Europe, a considerable level of harmonization had been achieved in the area concerned, through the Community Law and the European Patent Convention. As regards exceptions and limitations to patent rights, the Delegation mentioned that the following international documents were relevant: the Paris Convention, the Convention on International Civil Aviation, the Chicago Convention and the TRIPS Agreement, the Declaration on a TRIPS Agreement and Public Health and the Doha Ministerial Declaration. The Delegation noted that within the framework of the European Community, the important issues relating to compulsory licensing for pharmaceuticals, experimental use in the context of pharmaceuticals and biomedical research, farmers privilege and breeder's exceptions had been harmonized. The European Community and its 27 Member States believed that an appropriate balance between the right holders and the interest of the general public should be maintained.

102. The Delegation of Morocco observed that the TRIPS Agreement defined exceptions to patent rights and exclusions from patentable subject matter. It was noted that the national legislation provided for exclusions from patentable subject matter in accordance with international agreements, in particular, taking into account the interest of the public in general. Further, the Delegation suggested that it would be appropriate that work on those issues continued within the Committee and the document remained open for further comments.

103. The Delegation of Egypt stated that it had four comments of a methodological nature on the preliminary study. Supporting the suggestion of the previous speakers, the Delegation requested that the study remained open for comments and for further elaboration during the forthcoming session of the Committee. In connection with a response provided by the Secretariat on the question raised by the Delegation of India, the Delegation was of the view that the mandate did not particularly specify that the preliminary study to be of a legal nature; therefore the Delegation suggested that there was no need for a new mandate. As regards paragraph 32 of the preliminary study which mentioned that countries shared similar aims related to the patent system, that is, the need to protect innovation, promote development, etc., according to the Delegation's view, the term "socio-economic conditions" used in that paragraph was not accurate. The Delegation argued that the socio-economic conditions in Switzerland were different from the socio-economic conditions in Sweden, but, generally, there were of the same level of economic development. The Delegation continued that, while the use of the term "socio-economic conditions" might be politically correct, it needed to be replaced by the level of economic development. In its view, it was the level of economic development which was a determining factor. The Delegation was concerned that the preliminary study did not mention the level of economic development and how that would impact on the patent system. Further, it was stated that the preliminary study made references only to market power without referring to monopolies and anti-competitive practices. While agreeing that the politically correct language was important as well,

the Delegation stated that it should not obviate the need to refer to issues and the problems as they really were. In connection with the proposal made by the Delegation of Bulgaria on a quantitative approach, the Delegation suggested adding tables and statistics on the use of exceptions and limitations. The Delegation specified that, for example, a table could display the information on the use of compulsory licensing such as which members used it and how often it was used. According to the Delegation, such approach would be instructive and would show the patterns of use of exceptions and limitations in the various national legal systems. The Delegation agreed with the Delegation of Sri Lanka on behalf of the Asian Group which underlined the importance of including bilateral and plurilateral arrangements in the international aspects of the patent system and of conducting a study by an external group of experts in the fields, noting the development aspect. Recalling an excellent study commissioned by the government of the United Kingdom, which was renowned for its objectivity and balance, the Delegation concluded that such a properly commissioned study from a highly renowned group of experts was a positive way forward.

104. The Delegation of China underlined that the issues in document SCP/13/3 were the most important issues in all the countries. The Delegation explained that any country had relevant provisions on that subject in their patent law compared to the three other issues on the table. For instance, in its view, the issue of standards related to the process and provisions of standard making, and they were not the issues to be included in the patent laws but rather in other relevant laws. Whereas the issues dealt with in document SCP/13/3 were not avoidable. Therefore, the Delegation considered that it was worthwhile to give more consideration and more exploration on the issues described in document SCP/13/3. While the Delegation appreciated the content of the document, it identified some shortcomings. As an example, the Delegation referred to paragraph 43 of document SCP/13/3, which listed subject matters that no International Preliminary Examining Authority was required to conduct a preliminary examination, such as scientific and mathematical theories, performing purely mental acts or playing games, the mere presentation of information and computer program. The Delegation noted that those issues actually were subject of exclusions in the laws of most countries, including China. Therefore, the Delegation suggested that the Secretariat provide more summary of different practices in different countries and give more explanation as to the reasons of exclusion and comparison of different countries' practices. That type of study, in its view, would be conducive for the future harmonization of the patent law. Further, it was stated that the Chinese Congress had adopted a revision of the Patent Law on December 27, 2008. The revised legislation contained two points relevant to the discussion on the table, i.e., exclusions from patentable subject matter and exceptions to patent rights. As regards the exclusions, the Delegation informed the Committee that, after the revision, the Chinese Patent Law newly stipulated that using of genetic resources illegally and inventions thereof were not patentable. As for the exceptions and limitations to patent rights, the revised Patent Law allowed the parallel importation. The Delegation noted that the exhaustion of rights was an important part of the exceptions and limitations, while the TRIPS Agreement was silent on that matter. The Delegation suggested that the exhaustion of rights be added in the document. In conclusion, the Delegation expressed its willingness to provide more information on the revised Patent Law.

105. The Delegation of Ecuador stated that the document did not cover a number of points, in particular, the issue of exhaustion of patent rights. In its view, the issue of exhaustion was related to the exclusion from patentability. The Delegation continued that the issue of exclusion was crucial due to its impact on the economic development of countries. The Delegation was of the view that developing countries should use the patent system focusing on issues which were of specific interest to them. The Delegation observed that, while there were exceptions for second use in the Andean region, they were not used because of its development conditions. Further, the Delegation noted that some countries, for example, the Andean region, had adopted provisions on exclusions from patentability specifically related to some technological advances. In that line, it was stated that there were discussions held within their Constitution on the misappropriation of the genetic resources. In conclusion, the Delegation requested that the document remain open for further discussions.

106. The Delegation of Pakistan clarified its question by stating that it had sought cases where inventions contained in patent applications had been refused on the ground of public order and morality under the national patent system. In its view, the main shortcoming of the document was that it did not explain the rationale of exclusion but provided the rationale of IP system. Further, it was stated that the preliminary study devoted substantial attention to the issues of exclusions of plant, animal varieties and essentially biological processes from patentability. Referring to paragraph 60 of the preliminary study, the Delegation noted that due to the advances in biotechnology, many inventions pertaining to plant and animal varieties had started to satisfy the criteria of patentability. However, in the view of the Delegation, that deduction in the study was made without explaining the impact of patenting of plant varieties on the farmer rights and food security, which were considered to be important public policy issues. Referring to the European Directive 98/44 on the Legal Protection of Biotechnological Inventions, the Delegation observed that the traditional limits to patentability had been newly defined in Europe by the Directive, which circumvented the prohibitions to patentability as defined in the European Patent Convention (EPC). The Delegation stated that according to the Directive, patents on plants and animals, on parts of human body and on genes were explicitly allowed. In its view, the Directive not only expanded existing patent laws and corroded some of the fundamental principles of the system of intellectual property rights, but also led to a serious violation of essential ethical principles. Further, the Delegation argued that the Directive violated the EPC and went far beyond on what was required by the WTO. It was further stated that the preliminary study did not focus on the adverse implications of broadening the scope of patentability modeled on the EU Directive. In addition, the Delegation highlighted that the case studies and national laws quoted in the document were mostly from the developed countries. Therefore, the Delegation expressed its anticipation that the case studies from the developing countries on the issue of exceptions and limitations would also be quoted. Regarding the Article 30 of the TRIPS Agreement, in its view, a broad interpretation of Article 30 on exceptions was necessary for the developing countries. The Delegation understood that it was not a closed list of exceptions and new exceptions could be included from which the developing countries should benefit.

107. The Delegation of the Republic of Korea stated that the preliminary study reflected the objective and clear rules on the exclusions, exceptions and limitations. Regarding the suggestion made by the Asian Group, the Delegation welcomed the further study on the subject matter, assuming that the same opportunity would be given to the other agenda items to be discussed in the future. Further, the Delegation emphasized the importance of including the diverse and different views on the issue of exclusions, exceptions and limitations. It was observed that the document included only the legal standards of exclusions and exceptions, and in that way it was fairly objective. However, the Delegation considered that when there was a discussion on the detailed criteria on the exceptions and limitations, reflecting the social and economic needs of various countries, there could be many different views on that point. Therefore, the Delegation suggested including various views on the exclusions, exceptions and limitations. In conclusion, the Delegation requested that the detailed presentation on the preliminary studies, which could enhance the understanding of the issues at stake, be done by the Secretariat at the following sessions of the SCP.

108. The Delegation of Colombia referred to the legal framework in which the exceptions operated under its patent law. Citing Articles 53 and 56 of the Andean Agreement as well as the TRIPS Agreement, the Delegation stated that it was important to maintain existing flexibilities. It further underlined that the flexibilities should be given priority when considering the possible harmonization efforts. The Delegation noted that more time was needed to explore the issues of concern. In concluding, the Delegation emphasized the importance of maintaining the flexibilities and the freedom of national governments to shape the rules according to their own needs.

109. The Delegation of Islamic Republic of Iran associated itself with the statement made by the Delegation of Sri Lanka on behalf of the Asian Group, and supported the statement made by the Delegation of Pakistan. The Delegation stated that the exceptions and limitations were the key issues in the patent system, which had enormous implications on different parts of the society in developing countries. In the global sophisticated technological environment, the Delegation observed that the

laws and regulations in patent system could deeply impact on public policy objectives on one side, and the extent of presence of the States in international trade, on the other. Therefore, the extent of exceptions and limitations might promote or prohibit the innovation in a particular country. The Delegation said that, in the context of the work of SCP, the exceptions and limitations in the patent system should be viewed in a way that kept the balance between elements of the patent system itself, namely the right of patent holders and the public interest to the exceptions and limitations, and keeping the balance between the interests of Member States as a whole. It was further stated that the industrial infrastructure and public policy in different countries defined the assumption of each country to its patent system or elements of eligibility for protection, namely, novelty, inventive steps and industrial applicability, and that shaped the views of countries to look at exceptions and limitations to balance the system. In that context, the Delegation believed that, for example, public health, food security, the environment and other socio-economic considerations for developing countries made sense. In relation to the preliminary study, referring to paragraph 23 concerning non-patentable subject matter and paragraph 27 concerning patentable subject matter excluded from patentability, the Delegation observed that the idea was to include such excluded matters within the patentable subject matter with justifications, such as emergence of new technologies. Referring to paragraph 32, the Delegation observed that, even public policy considerations evolved, certain subject matter was by nature not patentable. Further, as regards paragraph 34, the Delegation sought clarification as to whether the investor was a private entity and whether he was going to invest into technologies needed by the State concerned. The Delegation was of the opinion that there was a misinterpretation of the term “public order and morality” and its interrelation with the phrase “restricted by law” described in paragraphs 39 to 42 and 51 of the preliminary study. In its view, “restricted by law” referred to trade, while the “public order” was a concept which associated with the historical, cultural and social considerations of a nation which could not be affected by the technological developments. The Delegation considered that the exceptions and limitations were integral part of the IP system which worked to balance the IP system. The Delegation, however, was of the view that the preliminary study, in paragraph 74, referred to them as infringement. In the view of the Delegation, the same approach was taken in paragraph 76, which introduced the exceptions and limitations as impediments of innovative activities. The Delegation considered that a research exemption, which was recognized in any IP system was interpreted in a low-profile manner in paragraph 102. The Delegation further stressed that there was a need for a broad interpretation of compulsory licenses in the Paris Convention, the Chicago Convention and in the TRIPS Agreement. It was underlined that the issue of exceptions and limitations in the patent system was a major concern of the Delegation. In conclusion, the Delegation suggested that the preliminary study remain open for further comments and that the work on the document be continued, focusing on the implication of exceptions and limitations on countries with various levels of industrial and economic development.

110. The Delegation of Chile stated that the issue of exclusions from patentable subject matter and exceptions and limitations to the rights was an aspect of high relevance for developing countries, but also for the intellectual property system as a whole, given the state of development of the system. The Delegation observed that the exclusions, exceptions and limitations could be looked as hindering innovations or access. It was further stated that exclusions and limitations could actually constitute an essential element to the patent system representing a balance: the system which protected the rights of inventors and facilitated access to innovation and technology transfer. Referring to the exclusions from patentability provided by the TRIPS Agreement, the Delegation stated that there were no standards which referred to the matter in a substantive way. As regards exceptions, the Delegation cited the Paris Convention and the Chicago Convention, which covered to some extent the scope of application of those exceptions and limitations. Further, in relation to national legislations, it was noted that there was a great divergence in the standards in the different legal systems of the members, as provided in Annex II of document SCP/12/3 Rev.2, but also diverging views relating to public order and morality in different countries. The Delegation considered that it was important to take into account in which legal system, common law or civil law, the exceptions were dealt with. The differences, as well as convergences, regarding the concept “*ordre public*” or public order or civil protection in common law, could be identified among various systems. The Delegation believed that studying the different legal systems of various countries could facilitate an understanding of the issues

and could move forward to creating a common vision on the need to harmonize the patent system. As there was a greater trend towards standardizing the patent registries, the Delegation believed that, there was a need to better explore the international context of exceptions and limitations on patents. It was suggested that a study could, for example, focus on which limitations and exceptions were most frequently accepted and what their use was in the international arena. Observing that Annex II of document SCP/12/3 Rev.2 provided rich information on limitations and exceptions with regard to the national legislation of different members, the Delegation suggested that members needed to provide more information in order to update it. The Delegation assumed that, in order to analyze in-depth the way limitations and exceptions were applied by different countries, the study needed to look at the interpretation of exceptions and limitations by the tribunal and the courts. The Delegation underlined that, when conducting such study, it should be kept in mind that it was the justice system which interpreted the legislation in place, and which created complexity with regard to the patent system. The Delegation reiterated that information contained in Annex II of document SCP/12/3 Rev.2 could be broadened by requesting Member States to provide relevant jurisprudence and the way national legislation dealt with the issue of limitations and exceptions.

111. The Delegation of Brazil stated that the exceptions and limitations were part of the checks and balances of the IP system as they ensured the transfer and dissemination of a technology incorporated in the invention. The Delegation was of the view that a stronger IP system meant a balanced IP system, and a balanced IP system was one which contained substantive provisions on exceptions and limitations. It was stated that the issue of exceptions and limitations played a central role in the debate held at the World Health Organization (WHO) and in other international fora on the issue of access to health and access to medicines. The Delegation further noted that exceptions and limitations were equally central to the national policies of developing countries as they provided a leeway for developing countries to pursue their own technological and innovation goals. In its view, exclusions from patentable subject matter and exceptions and limitations to patent rights were viewed of utmost importance for reviewing the agenda of the SCP as it was closely related to fundamental development concerns. The Delegation observed that a number of recommendations of the Development Agenda addressed directly the issue in connection with norm-setting, public policy, technology transfer, access to knowledge and impact aspects. For instance, recommendation 17 of the WIPO Development Agenda stated that WIPO should take into account in its activities, the flexibilities existing in international IP agreements. In addition, recommendation 22 provided that WIPO should address in its working documents for norm-setting activities, issues such as potential flexibility, exceptions and limitations for Member States. As regards the preliminary study, in its view, while the document identified and described a wide circle of exclusions from patentability and exceptions and limitations to patent rights, it depicted a negative portrayal of exceptions and limitations. The Delegation was of the view that the study, to a certain degree, depicted the exceptions and limitation as a hurdle to technological advancements, or they were presented as a disincentive for investment. The Delegation was of the view that the preliminary study stated that considerations of ethical, health and environmental nature should be regulated by other laws than the patent law. The Delegation, however, believed that exceptions and limitations were an extricable part of the IP system. Therefore, patent law should not disregard ethical, health or environmental principles. Moreover, in its view, the preliminary study attempted to construe a relationship or connection between exclusions from patentability on the one hand, and patentability criteria on the other. The Delegation observed that, while the exclusions from patentability were the subject of the study, the substantive patentability criteria fell out of the scope of the study. Further, the Delegation was of the opinion that exclusions from patentability were aimed at different and, in general, specific policy objectives, while the patentability criteria related to the patent examination and the quality of patents granted. Therefore, the Delegation thought that such criteria should not be considered as an equivalent to exclusions. Referring to paragraph 76, the Delegation did not agree with the notion that exceptions and limitations might lead to reducing the incentive for investors to invest in innovative activities. In opposite, it was observed that exceptions and limitations had brought competition into many economic fields. In considering the distinction made between disclosure and know-how, the Delegation advised that the distinction required caution. It was underlined that the concepts should not be construed as an excuse for inventors not to reveal the full content of the invention. It was said

that the Committee should deal with the analysis of the benefits of exceptions and limitations, as well as with issue of the flexibility of the IP system. Regarding the future work, the Delegation requested that the preliminary study remain open for comments and contributions from delegations, especially focusing on how the study portrayed the national legislation of Member States. Further, it was advised that technical activities carried out by the Secretariat should encourage Member States, recipients of such technical assistance, to make full use of exclusions from patentability as well as of exceptions and limitations in a manner conducive to their own goals in the field of education, health, agriculture and technology fields. The Delegation stressed the importance of those issues in the context of the Development Agenda. In that regard, the Delegation supported the proposal put forward by the Asian and African Groups that the Secretariat prepare a study about the development and implications of the erosion of exceptions and limitations generated by the dissemination of TRIPS plus standards in bilateral agreements. Finally, the Delegation suggested that the exceptions and limitations be part of the permanent agenda of the SCP, as it was viewed to be a matter that deserved attention and deeper analysis in upcoming meetings.

112. The Delegation of Tunisia stated that the preliminary study was built upon a postulate according to which the patent system intended to promote innovation and to improve social benefits resulting from the innovation. In its view, the expression “social benefits” was apprehended from the broader sense of society and would not necessarily entail direct benefits that might be enjoyed by all individuals or groups of people in a given society, since IP rights were primarily private rights. It was observed that public policy objectives played a major role in crafting national IP systems, setting the patentability criteria and drawing the margin of exceptions and limitations. It was stated that the Committee should keep in mind that exceptions and limitations were intended to safeguard social and economic priorities of countries. The Delegation observed that paragraphs 77 to 94 of the preliminary study clearly demonstrated how existing international rules addressed issues relating to exceptions and limitations. While noting that those important provisions were often hard to put into real practice, the Delegation observed that they constituted a minimum that should be safeguarded. The Delegation further noted that despite the normative nature of the work of the Committee, the preliminary study had omitted to refer to the work achieved in the CDIP and, particularly, the relevant recommendations regarding the norm-setting activities. In its view, the preliminary study should be complemented by due reference to and inspiration from the Development Agenda. Finally, the Delegation joined the previous delegations which had requested complementing the study with tables and statistics, as well as a reference to bilateral and plurilateral agreements, and had asked the study to be open for further comments at the next sessions.

113. The Delegation of Indonesia stated that the preliminary study presented the fact that the nature and scope of exclusions of certain subjects from patentability and exceptions and limitations to patent rights were relative to the public policy objectives of a country. The Delegation associated itself with the statement made by the Delegation of Sri Lanka on behalf of the Asian Group. Concerning the preliminary study, the Delegation was of the view that it did not explore the experiences of developing countries in approaching the issues, for example, the experience relating to compulsory licenses. According to the Delegation, the preliminary study also fell short in describing the impact of the socio-economic development of those countries. Therefore, the Delegation echoed the voice of the Asian Group that there should be further studies on the exceptions and limitations and most importantly it should take into account the development dimension. In conclusion, the Delegation stated that it would also be beneficial if the study could further illustrate the implementation of the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health, in particular, focusing on how countries could apply that subject for their respective public interest.

114. The Delegation of Switzerland associated itself with the statement made by the Delegation of Germany on behalf of Group B. As to the content of the preliminary study, the Delegation was of the opinion that it was balanced in two respects: it had neither too little nor too much information. It supported the statement of the Delegation of China that the study contained very rich information. Therefore, while noting that any report could be always more detailed, the Delegation thought that comprehensiveness was not necessary useful. Furthermore, the Delegation was of the view that it

was very wise of the International Bureau to have presented a factual report, leaving the interpretation to the Committee. The Delegation stated that it could not subscribe to all interpretations that had been put forward in the Committee. The Delegation explained that the social and economic rationales for some limitations might vary; therefore it was not possible to give one solution that would be right for all national legislation. Concerning future work, the Delegation preferred a coherent discussion on the corresponding agenda item. Nevertheless, the Delegation expressed its objection to the proposal to establish an expert report. In its view, the International Bureau should be refrained from being unduly burdened with further studies. Therefore, the Delegation joined the proposals of the Delegations of Chile and China that Member States should provide more details to the International Bureau by responding to questionnaires to be sent by the Secretariat and to be further assembled in a table. According to the Delegation, that type of exercise would provide the requested details on the issues discussed.

115. The Delegation of India wished to place on record its appreciation to the Secretariat for putting together useful and factual studies. The Delegation stated that it was aware of many constraints and limitations faced by the Secretariat in preparing the studies. The Delegation felt that the preliminary studies had served the desired objective of initiating discussions on those important issues. The Delegation further continued that the next logical steps would be, as proposed by the Delegation of Sri Lanka on behalf of the Asian Group, to take the preliminary studies further to a group of experts, a panel, or academics who could put the issues in a broader public policy context reflecting the reality. In that context, the Delegation made a reference to paragraphs 34 to 37 on the role of exclusions, noting that they gave a general account that the exclusions have a positive or negative impact on the patent system. The Delegation stated that the focus on those paragraphs was on the impact of exclusions on the patent system rather than addressing the impact of exclusion from a public policy perspective, with reference to issues like public health, technology transfer, etc., which had a direct and undeniable bearing on the issue of exclusion. Referring to paragraph 32 of the preliminary study, the Delegation agreed that the public policy considerations were never static but would change over time, reflecting the needs and realities of countries. In its view, it would be useful if the paragraph could be complemented with country studies or concrete examples of how a different patent system had existed in developed countries when they had been at the stage of development where many developing countries were at present, and the role of that patent system in driving the development, particularly focusing on what exclusion and exemption had been employed during their stage of development. According to the Delegation, that type of study would be useful and instructive for many countries.

116. As regards substantive patent law harmonization, the Delegation of Argentina believed that there had still not been sufficient evidence to conclude that there would be benefits for developing countries. Greater harmonization would entail, conversely, a significant reduction and even the loss of the flexibilities available to national jurisdictions as regards patents. It would compromise the scope available for public policy formulation and the economic, commercial, social and cultural development of developing countries.

117. The Delegation of Bulgaria supported the statement made by the Delegation of India that it would be useful to know how the exceptions and limitations had developed in developed countries over the years. The Delegation recalled that there were several countries which did not have a patent until after the World War II. It was reiterated that it might be useful to see how the patent laws evolved to reach the contemporary stage. The Delegation further proposed that the exceptions and limitations be presented in a table so that it was possible to see which countries apply how. Referring to Annex II of document SCP/12/3 Rev.2, the Delegation noted that it would be useful if the information could be organized by subject matter under the limitations and exceptions, as provided by paragraphs 23 and 43 of document SCP/13/3, rather than by countries. In conclusion, the Delegation noted that computer-related inventions should also have a separate heading, like biotechnology inventions, because how to protect software was always a question.

118. The Delegation of Kuwait thanked the Delegation of Sri Lanka for its statement on behalf of the Asian Group with regard to the exclusions, exceptions and limitations. The Delegation hoped that further studies would be based on scientific methodology. It noted that a great number of Delegations had expressed their opinions on economic and social considerations of the issues and their value for developing countries. In that light, the Delegation wondered whether a change in economic and social criteria in the future according to the economic conditions would have an effect on the exclusions and exceptions.

119. The Delegation of Guatemala shared concerns expressed by other Delegations, including the Delegations of the Plurinational State of Bolivia and China, regarding the genetic resources. The Delegation noted that there was no specific legislation on that issue in Guatemala. Nevertheless, Chapter 4 of the Examining Procedures specified clearly that, for example, an identification of a substance, a plant extract, and a chemical compound in a natural environment were not inventions but were discoveries. Furthermore, in relation to paragraph 51, the Delegation expressed its concern about bioethics. The Delegation requested more information with regard to protecting life, in view of uncertainty in that area. Concerning the protection of plants and animals, and specifically in relation to plants, the Delegation noted that its country was a member of the International Plant Protection Convention of the FAO and requested the Secretariat to provide more information on that matter.

120. The Delegation of China observed that paragraph 45 of document SCP/13/3 touched upon Articles 27.2 and 27.3 of the TRIPS Agreement. In its view, Article 27.1 was also relevant to the issue of exclusion, since the paragraph requested that all WTO Members should provide patents to any invention without discrimination as to the field of technology. In its view, according to Article 27.1, WTO Members did not have an obligation to protect creations of non-technical character. The Delegation noted that in many countries that issue was a very important and delicate one, and that numerous cases had been heard on that matter. Therefore, the Delegation suggested that the Secretariat conduct deep studies on the issue.

121. The Delegation of Kenya believed that the exclusions and limitations in the patent system should be viewed in the way that it provided a balance between the interests of the patentee and the public. The Delegation viewed that the exceptions and limitations were ways to deal with the malpractice in the patent system. In its view, the limitations and exclusions should be left as flexible as possible in each country. The Delegation observed that most of the patents protected in developing countries were from developed countries, and some of those patents were considered to be unethical under the national law. In addition, the Delegation stated that each country had a leeway of interpreting what could be listed within the exceptions and the limitations, especially in relation to inventions of unethical character or posing security threats. In conclusion, the Delegation requested the Secretariat to examine the case laws of various countries on exceptions and limitations.

122. The Delegation of El Salvador considered that document SCP/13/3 was a good basis for the work of the Committee, and expressed its interest in having the document continued to be enriched with contributions. The Delegation was, in particular, interested in the issues such as compulsory licensing and amendments to the TRIPS Agreement on public health, etc. The Delegation stated that the document could be extended by using practical cases and looking at examples.

123. The Delegation of Thailand, associating itself with the statement made by the Delegation of Sri Lanka on behalf of the Asian Group, stated that WIPO should carry on further studies on exceptions and limitations to patent rights. Since the Delegation was aware that it might be too much time consuming for WIPO Secretariat and it might not essentially produce any solid outcome if WIPO was going to carry out further studies on all the issues, it proposed that the focus of those studies be on the development aspects of IP on certain issues which were of particular interest to several delegations, for example, on public health and genetic resources.

124. The Delegation of the Czech Republic, speaking on behalf of the European Community and its 27 Member States, made a statement regarding inventions in the field of biotechnology under the

European law as follows: first, genetic sequences are not patentable in their natural state, and an invention relating to a gene sequence is only patentable under certain conditions, for example, if the gene has been isolated by means of a technical process and if the invention meets the normal patentability requirements of novelty, inventive step and industrial applicability; second, the EC Directive 98/44 is fully compatible with the EPC, and has been incorporated in the EPC through the Implementing Regulations; third, the EC Directive takes into account ethical concerns in at least two respects. The Delegation explained that the Directive established a European Group of Advisors on Ethics, which could provide advice on request, and that it also contained specific exclusions on the grounds of morality and *order public* with particular examples. Finally, the Delegation stated that the Directive was adopted after inputs from various stakeholders, including representatives of patients who were keen to benefit from advances in biotechnology.

125. The Delegation of Indonesia supported a proposal to prepare a further study on computer-related inventions. The Delegation suggested other important topics, namely, a second medical use and methods of doing business, for further studies. The Delegation appreciated the preliminary study, since its country was in the process of revising the patent law and looked forward to having further studies as requested by Member States.

126. The Representative of the EPO noted that the study on exclusions from patentable subject matter and exceptions and limitations to the rights clearly outlined international legal framework and the underlying policy objectives for the exceptions and limitations which were regarded as essential elements of any patent system. The Representative, supporting the Delegations of the Czech Republic on behalf of the European Community and its 27 Member States and Germany on behalf of Group B, expressed its willingness to assist the work of the Committee and to provide additional inputs to the study regarding the treatment of the issue within the framework of the EPC, which had achieved a considerable level of harmonization also in the area of exclusions from patentable subject matter at the regional European level. The Representative expressed his support to the latest statement made by the Delegation of the Czech Republic on behalf of the European Community and its 27 Member States regarding the inventions in the field of biotechnology and the implementation of the EC Directive on the legal protection of biotechnological inventions. The Representative stated that the EPO held no political views of its own on biotechnology patents, and as the executive organ of the European Patent Organisation, it examined patent applications on the basis of the EPC. The Representative explained that the essence of the Directive was incorporated into the Implementing Regulations to the EPC, which provided the ground rules for considering the patentability of biotechnology inventions together with the other principle criteria valid for all patents.

127. The Representative of KEI noted that one area where the preliminary study could be strengthened related to goods in transit because of the recent news about the seizure of generic drugs which were manufactured in India and were sent to destinations in Africa and South America. The Representative considered that a study on goods in transit would help better understanding on the role of limitations and exceptions regarding a shipment of generic drugs which were temporarily at an airport or in a warehouse in Europe, but were not destined for the European market, but rather for the markets in developing countries, and suggested that the SCP focus its work in that area. The Representative further noted that the document did not include the so-called Part III of the TRIPS flexibilities, although it contained flexibilities that were set out in Part II of the TRIPS Agreement. The Representative explained that Article 44 in Part III of the TRIPS Agreement contained an important provision that allowed countries to forgo the enforcement of the exclusive rights in cases where compensation was given to patentees, and that it had been the primary area where the government of the United States of America issued compulsory licenses in the last three years, particularly after the decision of the *e bay v. MercExchange* in 2006. The Representative further noted that the study did not discuss the role of bilateral, regional and plurilateral trade agreements in limited injunctions or the relationship to the norm-setting about injunctions. The Representative was of the view that the TRIPS flexibilities were affected by the bilateral, regional and plurilateral agreements as well as by unilateral trade policies such as the Special 301 list of the United States of America, and that the issue be discussed in a global norm-setting. Further, the Representative noted that many examples on

limitations and exceptions in the document were sector specific, for example, the United States of America provided a special prior use exception for business method patents and France had a special exception in the area of genetic testing. The Representative wondered how far could countries single out certain sectors for special limitations and exceptions with a view to the non-discrimination provision in Article 27 of the TRIPS Agreement, and questioned compliance with their obligations under the WTO rules.

128. The Representative of GRUR, referring to paragraph 109 of the document, was of the view that the background of the decisions of the Federal High Court of Justice was broader than it appeared in the document. The legal provision on the research exemptions was newly introduced into the German Patent Law in 1980, which read: the rights conferred by a patent shall not extend to acts done for experiment purposes relating to the subject matter of the patented invention. The Representative explained that that text could not be construed in isolation, since it was taken over from Article 27 of the Community Patent Convention as established in 1975 and confirmed again by the second version in 1989. The Representative noted that the provision had been adopted by the other Member States of the European Communities due to the political commitment of those Member States to harmonize their national laws on the basis of the European Patent Convention and the Community Patent Convention. Since the case law before 1980 had given the exemption of a very limited and narrow scope, the decision by the Federal High Court of Justice in the case *Clinical Trial I* had received criticisms from various interested circles. The plaintiff submitted the decision of the Supreme Court of Justice to the Federal Constitutional Court. That Court however had confirmed the decision of the Federal High Court of Justice, and had rejected the constitutional complaint. The Representative further noted that the decision *Clinical Trial II* was generally considered as the act of the Federal High Court of Justice to draw a distinctive boarder line against any attempt to extend the research exemption too much into the direction of a hidden commercial exploitation of the protected invention. He explained that such slippery ground was caused by the wording, namely, whether the clinical trials were employed for wider purposes such as commercial interest.

129. In response to the statement made by the Representative of KEI, the Delegation of Brazil stated that, although it shared, to a large extent, the same concerns as expressed by the Representative of KEI, deciding on detaining or seizing goods in transits was neither a matter of exclusions from patentability nor exceptions and limitations to patent rights. In its view, the issue was more straight forward: goods in transit did not enjoy patent protection and the compatibility of the goods in transit with the law of the country in transit should not be assessed, since the goods in transit were not destined for the market in transit, but were destined for a third market. Therefore, the Delegation was of the opinion that the issue was a violation of the principle of territoriality, which fell outside the scope of the preliminary study. It considered that the issue under consideration was in a situation where no patent rights were granted in the manufacturing country as well as destination countries.

130. The Representative of ICTSD pointed out two studies produced in conjunction with the UNCTAD/ICTSD project on IP and sustainable development, which could be of relevance for the work of the Committee. The first work was the resource book on TRIPS Agreement and development that comprehensively looks at the TRIPS Agreement from a developing perspective and highlighted the implications of issues and options on development objectives, in particular, areas where developing countries could benefit from broad interpretation of the TRIPS Agreement in consistent with their development needs and development levels. The second study was entitled "Exceptions to Patent Rights in Developing Countries", issued in October 2006. That study looked exhaustively at exceptions and limitations which developing countries could use and could benefit from in the context of a broad development oriented interpretation of relevant international standards. The Representative further noted that, in other committees of WIPO, particularly in the context of the SCCR, studies on exceptions and limitations had been commissioned to external experts, and that there had been a useful study on, for example, exceptions and limitations for libraries that looked comprehensively at almost all the laws and practices of the WIPO Member States.

131. The Representative of EAPO associated itself with the statement made by the Delegation of Germany on behalf of Group B. The Representative also agreed with the Delegation of China on the point that exceptions and limitations were the key to all the matters concerning the subsequent decisions. As regard the development of the international patent system, the Representative shared the view expressed by the Representative of EPO, since it appeared unacceptable to have flexibility as regards the decisions taken with respect to exceptions and limitations. The Representative explained that, under the Eurasian Patent Convention, a single patent prevailed on the territory of nine Member States. These were States where it was established on the basis of constitutional priority for standards of international law, which went above the standards of national rights. The Eurasian patents could face limitations in the framework of the Eurasian Patent Convention, and could come against limitations which were applied in relation to national patents issued by each of those States. Taking into account the convention approach and the constitutional standards of international law as compared to those of national legislation, the Eurasian patent could not be cancelled or challenged in any of those States, if it came under limitations provided for exclusively by national legislation and not by the Eurasian Patent Convention. The Representative stated that, if an adoption of a given doctrine as regards the exclusions or the exceptions and limitations was failed, an application submitted in accordance with the PCT could face exclusions under the national laws and could turn the patents useless if the flexibility in the national laws allowed the introduction of various limitations.

132. The Representative of TWN stated that, as regards paragraph 13 of document SCP/13/3, the list of exceptions allowed by Article 30 of TRIPS Agreement was not a closed list, as mentioned in the UNCTAD/ICTSD 2006 study. With respect to paragraph 69, the Representative stated that, according to a study by Alston and Venner, the result for introducing plant variety protection in the United States of America was that there was an increase in public expenditure on plant variety improvement but private sector's investment in plant breeding did not appear to have increased. Given the concerns raised by Member States on the impact of patents and plant variety protection on farmer's rights and food security, the Representative suggested looking at the justification for patents on plants and plant variety protection. For example, one justification for it might be that there would be an increase in agricultural product activity or increased yields. In that context, she referred to a literature survey by two American economics professors in a 2008 book published by Cambridge University Press, according to which total factor productivity in the agriculture in the United States of America had not accelerated after the introduction of patents on plants, yields did not increase faster after patents on plant variety had been allowed, and the economic analysis indicated that plant variety protection in the United States of America had not caused any increase in experimental or commercial activities. As regards paragraph 76, the Representative pointed out that a study by Scherer found that issuing compulsory licenses did not lead to reduction of investment in research and development in 70 companies which were studied. It was found that those whose patents had been compulsory licensed actually significantly increased their research and development compared to companies of comparable size who had not been subject to compulsory licenses. Concerning paragraph 142, the Representative was of the view that the conditions for granting compulsory licenses were not largely harmonized due to the TRIPS Agreement, since, for example, a period of 30 days was considered as a reasonable period to fulfill the requirement to negotiate a voluntary license in circumstances in the European Union and in Canada, as opposed to Argentina's requirement for 150 days. The Representative further noted that in some countries, compulsory licenses could be very broad, for example, for any medicine used in the treatment of people suffering from HIV/AIDS, without identifying and listing all the patents involved. She added that compulsory licenses could be chosen to last until the end of the patent period in some States, but in other States, the compulsory license had to be renewed, and that who could apply for a compulsory license and how quickly compulsory license could be granted differed widely from country to country. On remuneration, the Representative stated that there was wide variety of practices, and referred to the United Nations Development Programme (UNDP) and WHO remuneration guidelines for medical technology. She explained that, in the United States of America, it was a 0% royalty for anticompetitive compulsory licenses and less than 0.1% of the value of the total product in a number of recent compulsory licenses even when it was not the remedy to anticompetitive conduct. She further noted that, in California, there was a mandatory license in air pollution prevention inventions under the Clean Air Act. With respect to the history of

developed countries using exceptions and limitations, the Representative noted that Spain had not allowed patents on chemicals or medicines until 1992 because they had not been able to afford the high prices. The Representative also suggested including in the study the extension that least developed WTO Members had received under the TRIPS. With respect to the concerns about the current crisis, the Representative stated that Member States might use the California example of mandatory compulsory licensing on the technology needed to deal with the climate change crisis. Similarly, with the financial crisis, the Representative noted that the heads of States of a number of countries, such as Ethiopia and Liberia, had said that the financial crisis was big enough to cause violence and chaos. The World Bank said it was unprecedented, and the IMF predicted pressure on balance of payments, for example, in Africa due to commodity exports and in Asia due to manufacturing exports. The Representative noted that, according to government statistics, there was a net outflow of royalty payments of 1.7 billion US dollars in 2005 alone in Malaysia. Given the fact that 98% of patents granted in Malaysia were to foreigners, in her view, more money flew overseas. She considered that, in the time of the balance of payment crisis, exclusions from patentability might be able to help the economic position. Given the importance of these exclusions and limitations to development in achieving public policy objectives and the need to preserve the adequate policy space to face the current crisis whether it is finance, climate or food, the Representative was of the opinion that the effect of bilateral and regional trade agreements on the ability to use the exclusions and limitations should be looked at. She referred to free trade agreements with the European Union and the European Free Trade Association, which might limit the effectiveness of some of the limitations such as compulsory licenses via requiring data exclusivity. She also noted that the US free trade agreements in the past had limited flexibility, for example, by removing plants, animals and new uses from exclusions, and might have rendered some exceptions and limitations less effective by the data exclusivity linkage, limiting compulsory licensing grants and restricting parallel importation. In her view, the Japanese free trade agreement, especially the investment chapter, also significantly limited the available exceptions and limitations.

133. The Delegation of Guatemala sought clarification regarding plant varieties. As regards its country, in Chapter 5 of the Agreement 15/1, each party should ratify the Convention of 1991 by January 1, 2006. Countries which had signed the free trade area agreement such as Central America had already ratified the treaty or were about to do so. In its view, there was a common objective both for the holders and the patent system: innovations should be encouraged and all inventions in all technical areas had to be protected. As regards plant variety protection based on UPOV, a system had been set up to protect plant varieties. The Delegation observed that there should be no dual protection in relation to the patent system, but innovative biological inventions should be encouraged. It explained that the patents referred only to new genes, or new nucleotides, of plants and also of new procedures, but not to new plant variety. Therefore, a bill to implement the UPOV Convention had been examined by the Parliament of its country.

134. The Representative of ALIFAR stated that the exceptions and limitations for industrial property were governed by the TRIPS Agreement. In the light of the Doha Declaration on Intellectual Property and Public Health, States might develop their public policy in various areas such as access to food, health, etc. As regards exclusions and limitations, the Representative stressed the importance of the ability of the countries to regulate what was patentable under the TRIPS Agreement as well as encouraging innovation, access to technology and access to medicaments at the lowest possible price. Referring to Article 30 of the TRIPS Agreement, the Representative pointed out that the use of an invention in order to obtain the registration of a generic product before the expiry of the patent concerned would enable the countries to have rapid marketing of the generic version after the expiry of the patent. The Representative stated that many countries applied such exception, which was in accordance with the TRIPS Agreement. The Representative further suggested that the Secretariat's study also deal with the rights to industrial property in bilateral treaties.

135. The Representative of FSFE believed that the preliminary studies provided an excellent starting point for the discussion, and should be maintained as living documents that could accompany the debates and act as backdrop for the future work discussion. Referring to document SCP/12/3 Rev.2,

the Report on the International Patent System, the Representative believed that the preliminary studies should take into account the systematic considerations in the Report. In particular, the economic rationale for the patent system should be taken into account and reflected for the considerations of document SCP/13/3. In his view, the rationale for exceptions and limitations should loosely be based on the ancient wisdom of "*primum non nocere*", i.e., the knowledge that actions could be more harmful than inaction, that is, inclusion of an area in the patent system could result in less innovation than its exclusion. He considered that the overarching principle for this SCP should be to maximize innovation, and that the economic rationale for patenting provided a background to understand when to avoid regulation through patents. As highlighted in document SCP/12/3 Rev.2, the economic rationale for patents was based on providing incentives in cases of market failure, disclosure of knowledge in the public domain, as well as technology transfer, commercialization, and diffusion of knowledge. The Representative therefore considered that the "three step test for inclusion in the patent system" should be based on demonstrated market failure to provide innovation, demonstrated positive disclosure from patenting, and effectiveness of the patent system in the area to disseminate knowledge. In his view, software failed all three tests. For instance, innovation in the IT industry had been dramatic before the introduction of patents, there was no disclosure value in software patents, and patents played no role in the diffusion of knowledge about software development. The Representative regretted that where the exceptions from the patent system were based on different views on patentable subject matter, such as software under Article 52 of the European Patent Convention, such exceptions were not covered by the study. Consequently, in order to provide an overview of the area covered by patents and the exceptions to that coverage, the Representative suggested that Member States mandate the Secretariat to provide an overview over the differences in patentable subject matter and reasons therefore.

136. The Representative of FFII noted that one of its main objectives was to fight software patents. While the European Parliament had given a strong signal in 2005 by rejecting the software patent directive proposal with an overwhelming majority, software patents were still being granted on a massive scale in Europe. He considered that it was a priority for the SCP to address software patentability in the framework of "subject matter exclusions", since new rules for software patents were being developed both by the EPO and by the courts in the United States of America, among others. The Representative observed that the economic benefit of software patents was very controversial, as economists had found that increased software patenting actually coincided with decreased R&D activity, a strong example of the well-known "patent paradox". He noted that even software patent proponents were worried about the legal uncertainty caused by complicated and inconsistent rules, which caused excessive transaction costs due to litigation and litigation prevention, and SMEs in the software realm could not afford the tremendous administrative burden of patents. In sum, the Representative believed that the exceptions in Article 52 EPC, Section 101 of the US Patent Act and associated case law needed due attention of the SCP and that the issue, which was not even on the non-exhaustive list of 18 issues agreed last year by the SCP, required priority.

137. The Representative of GCC stated that, according to the GCC rules, a patent application should not contradict the Islamic sharia, or what was called the Islamic jurisprudence. The Representative explained that that law was not in contradiction with exclusions regarding public order and morality in other regional and national patent systems. The Representative further clarified that patents issued by the GCC office were valid in all six Member States.

138. The Representative of MPI stated that, while recognizing the objective of the preliminary study and the intention of not deriving policy recommendations at that stage, from a technical point, it was helpful to start with a positive analysis describing the facts and then as a second step, drawing normative conclusions from the findings. He noted that, from the description of the different exclusions and exceptions, the importance of such exclusions and exceptions for the respective patent regime could not be assessed. Furthermore, he noted that a comparative analysis was difficult when the respective law regime as a whole was not taken into account. For example, if a national law did not provide exclusions from patentable subject matter, it might be due to the fact that the subject matter in question was not regarded as an invention. To avoid this problem, he considered that the

document could be structured in a different way by organizing it as a country-by-country analysis than arranging it by the nature of the respective provisions. The Representative further observed that it was unclear what impact the exceptions and limitations actually had in practice, where a statute did not play any role in practice or it was not enforced. As an example, he noted that, although a compulsory licensing provision was provided for in the German patent law, in the last decades, only very few of such licenses had been actually granted. Compared to the amount of patents, it was a number that could be neglected. Even with the assumption that the threat of compulsory licensing induced voluntary licensing, he was of the view that the overall importance of that provision in Germany was low, while, on the other hand, compulsory licensing might play a great role in some other Member States. Although it might be difficult to assess whether the exclusions, exceptions or limitations presented in the preliminary study were of great or limited importance in practice, the Representative believed that that would be the best way to go in order to make further progress.

[End of document]