

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

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

1. Professor Lionel Bently, Center for Intellectual Property and Information Law, Cambridge University, United Kingdom, who was the coordinator of the experts' study on exclusions, exceptions and limitations, made a presentation on the study.
2. The Delegation of Venezuela expressed the view that the issues regarding exclusions, exceptions and limitations had a philosophical, ethical or moral dimension, and that exclusions from patentable subject matter, for example, were set on a moral or an ethical basis. The Delegation noted that the only legally binding decisions in relation to exclusions, exceptions and limitations for its country had to be made by courts in Venezuela. On the issue of exclusions and exceptions, the Delegation considered that the way in which they could be applied needed to be looked at from the perspectives of human beings and human life. The Delegation considered that, in some countries, the standards of patentability set by the TRIPS Agreement had been a problem, and that private interest had been given priority over national interest. In its view, the philosophy of the patent system was the issue to be addressed.
3. In response to the question raised by the Delegation of the Plurinational State of Bolivia, the Chair stated that there would be no presentation on other Annexes of the study.
4. The Delegation of Argentina stated that, since the issue of exclusions from patentable subject matter and exceptions and limitations to patent rights were vitally relevant for developing countries in providing the necessary flexibility for public policies which enabled those countries to make progress towards effective development, it welcomed the study prepared by the experts group, coordinated by Professor Bently. With regard to the results of the study, with the objective of promoting discussion on development policy, the Delegation drew attention to the finding of the study that there was an increase in the number of international norms and standards limiting and regulating exclusions to patentability, which had led to increased cost and other effects for developing countries. The Delegation, therefore, considered that the study was very useful in showing the Committee that the exclusions, exceptions and limitations should not be applied internationally, but could be applied to adjust national policies in order to promote development.
5. The Delegation of the United Republic of Tanzania noted that it did not see in the study the possibility of reconciling the national legislature with the international legislature in relation to exclusions, exceptions and limitations. The Delegation therefore requested Professor Bently to share his view on how to move forward towards such reconciliation.
6. The Delegation of the Plurinational State of Bolivia stated that Annex III of the study did not fully fulfill the mandate, which was to analyze the issue of exclusions from patentability on life forms with a public policy and socio-economic development focus, and to analyze whether public policy, socio-economic development perspective could justify the exclusions of life forms from patentability with a view to the application of Article 27 of the TRIPS Agreement. The Delegation expressed the view that the study was not focused in that manner, and was limited to factual analysis of multilateral and bilateral agreements and certain legislations. It further noted that the study was limited to certain aspects of exclusions, exceptions and limitations. The Delegation stated that the terms of reference required the experts to analyze other aspects, such as the reflection of controversies or public policy and fundamental values of the society, which were very important for the Delegation. The Delegation expressed the view that the

study should have had provided more information with regard to policy issues relating to the exclusion of life forms from patentability. With respect to the obligations concerning patentability of life forms under multilateral treaties and trade agreements, the Delegation expressed the opinion that the values of the Delegation's country and what might be a potential danger to human life and to the planet needed to be reflected on the patent system. In its view, the analysis of the exclusions relating to biotechnology was made only from the viewpoint of incentives or other protection mechanisms rather than looking into the controversy derived from other fundamental values of the society.

7. In responding to the observation made by the Delegation of Venezuela, Professor Bently agreed with the Delegation that many of the exclusions and exceptions reflected either ethical or moral ideas about what would be good for society. He further stated that many of the exceptions and exclusions involved a balancing between the desire to provide incentives to business and to invest in research and development that led to inventions and innovations on the one hand, and the other social values on the other. Professor Bently therefore considered that the Delegation of Argentina and the members of the group who had produced the study spoke from very similar perspectives. As regards the comments made by the Delegation of the Plurinational State of Bolivia in relation to Annex III, Professor Bently was of the view that the author of Annex III had engaged with issues of public policy and socio-economic development, even if the focus had been primarily descriptive. Professor Bently explained that, in order to get a fuller picture, Annex III might be looked at together with Annexes IV and V which concerned health as well as with Annex I. He further explained that, as with any project, the study had to be cut up to make it manageable. For example, Annex IV which considered health had a lot of material on inventions that related to public policy and morality, which might be precisely a kind of information that was sought by the Delegation of the Plurinational State of Bolivia. In addition, Annex V which concerned compulsory licensing and exceptions in relation to health was clearly concerned with many of health consequences of patents. Professor Bently expressed his interest in receiving the feedback in more detail from the Delegation of the Plurinational State of Bolivia, and suggested that the Delegation submit it in writing so that it could be forwarded to Professor Barbosa. Professor Bently appreciated the comments made by the Delegation of Argentina concerning the flexibility, indicating that patent laws were applied from country to country. He emphasized that, while some of the flexibility came from exclusions, some of it also could be, or more of it could come from, exceptions. Professor Bently suggested that the delegations reflect on the question as to what more could be done with exceptions to accommodate the different social, cultural and economic priority of different countries around the world. Referring to the question raised by the Delegation of the United Republic of Tanzania concerning how the academic insight could be reconciled with the reality of the international norms, in particular Article 30 of the TRIPS Agreement, Professor Bently said that the variable use of exceptions was the reason not to interpret Article 30 narrowly. While it was not known exactly how Article 30 would be interpreted, he said that all the efforts towards taking advantage of the exceptions could be jeopardized if Article 30 turned out to be interpreted in an unfortunately narrow way. Therefore, the way he reconciled the two things was by seeing ourselves at that moment as actors in the process of forging an interpretation of Article 30 that was more positive and accommodating. He expressed his optimistic view that the experts' contribution was some parts of the background against which Article 30 would fall to be interpreted in the future, and that if countries embraced the idea of using the flexibilities in exceptions, hopefully the broad interpretation would be more likely to follow.
8. The Delegation of India sought clarification from Professor Bently regarding the possibility of substitution of exclusions with more nuanced exceptions. As Professor Bently had pointed out that one of the reasons why that could be beneficial was that many patent offices were not well equipped to detect subterfuge by patent agents and patent applicants who had sought to circumvent provisions on exclusions in national legislation, the Delegation sought clarification as to the chances that such subterfuge might be able to be detected in the area of exceptions which were even more limited, more specific and perhaps more difficult to detect. In addition,

concerning the concrete example of computer programs where Professor Bently suggested that they were one area which could be considered not in the context of exclusions but in the context of exceptions, since that would enable computer programs to be patented while also allowing incremental and formulated innovation, the Delegation asked whether the same objectives could be served by alternative models of innovation, such as open source innovation.

9. In replying to the questions raised by the Delegation of India, Professor Bently stated that the reason he thought that exceptions to patentee's rights would be preferable to exclusions from patentability was that patent offices were not necessarily reliable in enforcing those exclusions in advance. When it came to applying the exceptions to patentee's rights, in his view, that did no longer happen in the institutional environment of the patent office. He considered that pressures from applicants and their patent agents and the institutional pressure to process a certain number of patent applications in a certain length of time, made it difficult to give full examination to the patent applications and to ensure that the provisions on exclusion was properly applied. The exception to patentee's rights would not be reviewed in the patent office but in the court – in a judicial situation rather than in the situation of the bureaucracy with its own internal requirements. Because the exception was to be applied in the context of a dispute between two parties in the court, Professor Bently considered that those institutional pressures ended up quite different. Furthermore, he explained that the possibility of patent agents drafting claims and drafting patents around the exclusions did not arise, because the only question for interpretation was the statutory or legislative exception and how it applied to the circumstances. Professor Bently remarked that those points made him relatively confident that the problems with exclusions from patentable subject matter in terms of providing clarity did not arise in the context of applying exceptions to patent rights. He agreed that the judicial environment raised other questions that would need to be considered as well, such as the interpretation by the court and access to courts and access to justice that had their own dynamics. Professor Bently clarified that he was not necessarily recommending the same approach to everybody, stating that the analysis needed to be made in view of each country's own context. Responding to the question about whether systems of open innovation might constitute preferable mechanisms to either exclusions from patentability or exceptions to patentee's rights, Professor Bently noted that the study was not dealing with open innovation and with the potential use of that kind of equivalents to the creative commons on life sciences, licenses etc, the reason being that it was not within the mandate set by the SCP. Professor Bently nevertheless observed that the relation between the grant of patents or intellectual property rights and the creative commons open source style movements was not as simple as it might first had appeared. He explained that those were not alternatives, but that the enforceability of the licensing mechanisms that went with open-source software were dependent on the existence of rights in that software, and leading to a rather peculiar paradox: people who were often advocating for those positive systems that allowed widespread use of intellectual property rights and allowed for incremental development were often forced into the position that they end up being advocates for the property rights themselves. Professor Bently mentioned the example that the creative commons movement half supported for *sui generis* State-based rights because that enabled them to apply the creative commons contractual mechanisms to those property rights on stake. In his view, policy makers should consider the relative mix of those mechanisms and whether they could make open source systems workable and support open source systems.
10. The Representative of FSFE observed that the study dealt at some length with the practice of the EPO in granting software patents in Europe. However, that practice directly contravened the actual European legislation, namely, Article 52 of the EPC. He thus would be interested in knowing whether there was anything in the study or any considerations by Professor Bently on the actual court practice in Europe.
11. The Representative of TWN stated that the study was supposed to look at those issues from a public policy, socio-economic perspective bearing in mind the level of economic development and that that part of the mandate had not adequately been addressed. It had not been given

enough space, despite that there were parts in references. With regard to the conclusion that there was a shift from exclusions to exceptions, the Representative noted that, in a way, such shift was useful. He requested further information regarding resource deficiency in developing country patent offices. He observed that many countries in the past excluded pharmaceutical inventions from patent protection, and they did not end up in complex situations because pharmaceutical product inventions were completely excluded from patent protection. In comparison, regarding software exclusion, he noted that the EPO accommodated software patents through interpretation instead of excluding them. Therefore, the Representative expressed the view that exclusions were coming from the policy perspective, and they were still needed to achieve certain policy goals of a certain country. The Representative observed that it was still good for countries to have a robust set of exclusions along with exceptions. In his opinion, there should be a co-existence of both exclusions and exceptions. Further, the Representative asked whether, apart from those exceptions listed, there were possibilities of having more exceptions, taking into account Article 30 of the TRIPS Agreement.

12. The Representative of ITSSD emphasized a point that was, in his opinion, lost in the discussion, namely, the role of government in setting the right policy framework to promote so-called balanced interests. Much of innovation and inventions were performed by individuals, and individuals had to incur costs as well as time and effort in order to develop certain inventions in high technology. He questioned whether the role that those incentives play in creating private investments to bring those inventions and innovations to the public for the public good had been adequately addressed and needed to be addressed more thoroughly in the future.
13. Referring to the question raised by the Representative of the FSFE concerning the reconciliation of patent granting practices at the EPO and the full terms of Article 52 of the EPC, Professor Bently stated that he'd rather not comment in the SCP on specific issues relating to the EPC, but reiterated the point drawn out in the introduction that exclusions were prone to the pressures exerted on patent offices. In his view, the pressures exerted on the EPO did lead it to take a particular root to the interpretation of exceptions and then to change that root sometime 10 years ago, which facilitated the granting of patents for computer-implemented inventions. In his opinion, that showed that exclusions were not necessarily a good way to go, and that was one of the reasons why he had been suggesting that there were benefits to thinking in some areas of patent law about exceptions rather than about exclusions. In relation to computer-implemented inventions, he noted that the kinds of exceptions such as the experimental use exception, possibilities for cross-licensing and the compilation exception for interoperability which was in the draft Community Patent Convention (CPC) might be relevant. Professor Bently appreciated valuable observation made by the Representative of TWN, and clarified that, although there was value in thinking of replacing exclusions with exceptions where those exceptions could more productively achieve the same policy goal, a room was left for exclusions to continue to exist where they were aimed at achieving a different policy goal which could not be achieved by exceptions. In some circumstances, it would be useful to have both an exclusion and an exception, and it did not necessarily have to be an either/or. He reiterated that, in so far as the problem with exclusions had to do with issues of claim drafting, while a patent office might extend applying exclusions, exceptions could reassure users that their activities were free from liability. Professor Bently expressed his wish to further reflect on an example of a situation where the exclusion had not proved that problematic for patent offices to operate in the area of pharmaceutical inventions. With respect to the possibilities for more exceptions, he noted that, for example, scholars in the United States of America suggested new types of exceptions building on the concept of fair use in copyright. He was of the view that more debates would have to occur before taking the new ideas forward, since whether they could possibly pass the test under Article 30 of the TRIPS Agreement was not known. In his opinion, there was plenty of room for thinking about new exceptions to accommodate the legitimate interest in countervailing values that had ceased to exist. In replying to the Representative of ITSSD, Professor Bently clarified that he had not suggested that patent systems were not a good thing and that incentives to invest in research and development were

not important. He explained that the study tried to address the best way to accommodate different kinds of values within the patent system. It was not intended to be a study advocating bringing the patent system to an end. Professor Bently noted that the traditional view of patents in economic terms had been incentives to research and development and incentives to disclose. However, there was a third stream of economic thinking which viewed patents in terms of incentives to exploit inventions. It was not concerned with how the invention came into existence at all, but it concerned maximizing the exploitation of it. He explained that such thinking by the school of neoliberal economics tended to view patents as invaluable property right with very few exceptions, and tended to see the best way to facilitate exploitation was to promote contractual transactions. Professor Bently remarked that within that very logic, it assumed a ready capacity for transactions between a willing buyer and a willing seller who could locate one another readily and strike a deal. It also assumed that they had enough understanding of each other's economic, social and technical environment to forge that deal. In his opinion, while it could work in terms of a transaction between two US companies that knew about the law and that understood each other's relative bargaining power and were able to form a reasonable transaction, in many other circumstances, that presumption was not realistic. He explained that neoliberal economists would argue that if there was market failure as a result of the unwillingness or inability of two willing parties to enter transaction because of the information asymmetry about each other's situation, then the law should intervene and provide an exception. Therefore, those economists would actually provide for exceptions and limitations in some circumstances. Professor Bently observed that, in general, he found neoliberal economic arguments for intellectual property rights unpersuasive. In his view, the idea that everything should be turned into a property right and subject to transaction would naturally lead to the conclusion, for example, that the patent should last perpetually, the copyright should last perpetually, etc., so that somebody was in a position to optimize the exploitation. He referred to such an argument made supporting perpetually renewable copyright by Landes and Posner and a critique of that argument by Mark Lemley in the *Chicago Law Review*. He shared the views of the latter, although that did not mean that he was not interested in the position of exploiters, and in his view, the patent system was primarily there to incentivize research and development and it played a very important role in doing that.

14. The Representative of ITSSD observed that, in addition to market failure, there was also government failure. In his view, although the perfect and most beautiful framework in a regulatory sense might be idealized, that did not assure that incentives would not be dampened to the point of inactivity.

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

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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 14th 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 Bentley'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 Bentley, 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 13th 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.

45. 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.

46. 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.

47. 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*.

48. 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.

49. 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.

50. 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.

51. 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.

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