



**SCP/11/6** 

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# WORLD INTELLECTUAL PROPERTY ORGANIZATION

**GENEVA** 

# STANDING COMMITTEE ON THE LAW OF PATENTS

# Eleventh Session Geneva, June 1 and 2, 2005

#### **REPORT**

adopted by the Standing Committee

#### INTRODUCTION

- 1. The Standing Committee on the Law of Patents ("the Committee" or "the SCP") held its eleventh session in Geneva on June 1 and 2, 2005.
- 2. The following States members of WIPO and/or the Paris Union were represented at the meeting: Albania, Algeria, Antigua and Barbuda, Argentina, Australia, Austria, Bangladesh, Belarus, Belgium, Benin, Brazil, Bulgaria, Cambodia, Canada, Chile, China, Colombia, Costa Rica, Côte d'Ivoire, Croatia, Czech Republic, Democratic Republic of Congo, Denmark, Dominican Republic, Ecuador, Egypt, Ethiopia, Finland, France, Georgia, Germany, Greece, Hungary, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Kenya, Kuwait, Kyrgyzstan, Latvia, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Morocco, Myanmar, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Saudi Arabia, Senegal, Serbia and Montenegro, Singapore, South Africa, Spain, Sudan, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Tunisia, Turkey, Ukraine, United Kingdom, United States of America, Uruguay, Venezuela, Viet Nam and Zambia (85).

- 3. Representatives of the World Trade Organization (WTO), the African Intellectual Property Organization (OAPI), the African Regional Intellectual Property Organization (ARIPO), the Eurasian Patent Office (EAPO), the European Commission (EC), the European Patent Office (EPO) and the South Centre (SC) took part in the meeting in an observer capacity (7).
- 4. Representatives of the following non-governmental organizations took part in the meeting in an observer capacity: Asian Patent Attorneys Association (APAA), Biotechnology Industry Organization (BIO), Brazilian Association of Intellectual Property Agents (ABAPI), Center for International Environmental Law (CIEL), Centre for International Industrial Property Studies (CEIPI), Civil Society Coalition (CSC), Exchange and Cooperation Centre for Latin America (ECCLA), Confederation of Indian Industry (CII), Consumer Project on Technology (CPTech), European Generics Medicine Association (EGA), Fridtjof Nansen Institute (FNI), Genetic Resources Action International (GRAIN), German Association for Industrial Property and Copyright Law (GRUR), Institute of Professional Representatives before the European Patent Office (EPI), International Association for the Protection of Industrial Property (AIPPI), International Chamber of Commerce (ICC), International Federation of Industrial Property Attorneys (FICPI), International Federation of Pharmaceutical Manufacturers Association (IFPMA), Japan Intellectual Property Association (JIPA), Japan Patent Attorneys Association (JPAA), Max-Planck-Institute for Intellectual Property, Competition and Tax Law (MPI), Medicins sans fontières (MSF) and Union of European Practitioners in Industrial Property (UNION) (23).
- 5. The list of participants is contained in the Annex to this report.
- 6. The following documents prepared by the International Bureau had been submitted to the SCP prior to the session: "Revised Draft Agenda" (SCP/11/1 Rev.), "Accreditation of Non-Governmental Organizations" (SCP/11/2), "Addendum to Accreditation of Non-Governmental Organizations (SCP/11/2 Add.), "Future Work Program for the Standing Committee on the Law of Patents" (SCP/11/3) and "Statement Received from Brazil" (SCP/11/4).
- 7. The Secretariat noted the interventions made and recorded them on tape. This report summarizes the discussions reflecting all the observations made.

#### **GENERAL DISCUSSION**

#### Agenda Item 1: Opening of the Session

8. The eleventh session of the SCP was opened, on behalf of the Director General, by Mr. Francis Gurry, Deputy Director General, who welcomed the participants. Mr. Philippe Baechtold (WIPO) acted as Secretary.

### Agenda Item 2: Election of a Chair and Two Vice-Chairs

9. The Standing Committee unanimously elected Mr. Boris Simonov (Russian Federation) as Chair and Mr. Yin Xintian (China) and Mr. Usman Sarki (Nigeria) as Vice-Chairs.

### Agenda Item 3: Adoption of the Agenda

- 10. The Delegation of Argentina, speaking on behalf of the "Friends of Development", expressed its readiness to contribute to a positive outcome of the meeting, its expectation that the Committee would work on the basis of the principle of consensus, as it was the tradition in WIPO, as well as its hope that all delegations would be properly heard and their views be fully reflected in the final outcome. The Delegation had no doubt that the rules of procedure would be abided by at all times. It said that, as had been done for the previous meetings of the SCP, a final report should be prepared for this eleventh session of the SCP for future adoption. For that purpose, in its view, it was important that the Summary by the Chair under item 7 of the agenda, be agreed by all.
- 11. The Chair confirmed that the Committee would strictly observe the rules of procedure and that discussions would be completely clear and understandable. In the absence of other reactions to the intervention of the Delegation of Argentina, he considered that there had been a unanimous decision that the Summary by the Chair should be discussed and agreed by consensus.
  - 12. The revised draft agenda was adopted as proposed in document SCP/11/1 Rev.

### Agenda Item 4: Accreditation of Intergovernmental and/or Non-Governmental Organizations

13. The SCP approved the accreditation of the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), the Consumer Project on Technology (CPTech), Consumers International (CI), the Fridtjof Nansen Institute (FNI), the Generic Pharmaceutical Association (GPhA) and the Mexican National Association of Pharmaceutical Manufacturers (ANAFAM) as *ad hoc* observers (documents SCP/11/2 and 2 Add.).

### Agenda Item 5: Adoption of the Draft Report of the Tenth Session

- 14. The Delegation of China proposed corrections of the fourth and fifth sentences in paragraph 24 of the draft report of the tenth session (document SCP/10/11 Prov.2) as follows: "In this regard, the Delegation noted that a recent report by the Federal Trade Commission of the United States of America published in October 2003 did not agree with the opinion that the patent applicants, rather than the general public, should be regarded as the customers of the United States Patent and Trademark Office and pointed out that this opinion was too narrow and inadequate. In this connection, it was necessary to take account of the objective under Article 7 of ...."
- 15. The International Bureau noted that it had received a request from the Representative of the EPO with respect to a correction in paragraph 125 regarding his intervention.
  - 16. The Committee adopted the draft report of its tenth session (document SCP/10/11 Prov.2) as proposed, subject to the corrections referred to in paragraphs 14 and 15, above.

### Agenda Item 6: Work program for the Standing Committee on the Law of Patents

- 17. The Secretariat introduced document SCP/11/3. It recalled that the General Assembly had, at its last meeting in September-October 2004, had difficulty in reaching a decision as to the future work program of the SCP and, in fact, had not been able to do so. The Secretariat further noted that the General Assembly had also decided that the dates of the next session of the SCP should be determined by the Director General following informal consultations that he might undertake. The Director General had duly convened informal consultations which had been held in Casablanca in the Kingdom of Morocco in February 2005. Those consultations had led to a series of recommendations by those present, which were listed in the Annex to that document, to the Director General as to how the work program of the Committee might be handled in the future. The Director General was now transmitting those recommendations to the Standing Committee for its consideration, as stated in document SCP/11/3. The recommendations and the various delegations who had participated in the informal consultations in Casablanca, as well as the position of one of those delegations, in particular, in relation to the recommendations, had all been recorded in the above-mentioned Annex.
- 18. The Delegation of Argentina, also speaking on behalf of the Delegations of Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Egypt, Iran (Islamic Republic of), Kenya, Peru, Sierra Leone, South Africa, United Republic of Tanzania and Venezuela, introduced the contents of document SCP/11/4 and expressed the importance it attached to the work of the SCP and its concern with the direction that discussions had been taking lately, particularly in the context of the negotiations on the draft Substantive Patent Law Treaty (SPLT). It noted that patent law was a very sensitive area of intellectual property law which had significant cross-cutting implications for many different areas of public policy. New norms seeking to establish more stringent international standards of patent protection, as some would like to see in the SPLT, might have a serious impact in fields as diverse as public health, the environment and nutrition. The Delegation said that the public health implications of patent law, in particular, had been brought to the attention of the international community through the adoption of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health at the fourth Ministerial Conference of the World Trade Organization (WTO) and that that crucial declaration acknowledged that the international norms on patent protection should not stand in the way of the pursuit of public health goals by developing countries and least developed countries (LDCs). The Doha Declaration therefore had encouraged all countries to make use to the full of the flexibility of the TRIPS Agreement. The Delegation noted that, more recently, developing countries and civil society had made an urgent call for the establishment of a Development Agenda for WIPO. In the light of that call, all WIPO subsidiary bodies, particularly those engaged in norm-setting, would have to properly take into account the development dimension in the pursuit of their work. It said that, in that regard, the central concern of the Development Agenda was the need to ensure that norm-setting activities in WIPO were respectful of, and did not run counter to, the policy space of developing countries and LDCs. This meant that norm-setting should safeguard the public interest flexibilities that existed in current international treaties for the pursuit of crucial public policy goals. The Delegation noted that, in the field of patent law, this meant that both pre-grant and post-grant flexibilities should be safeguarded, all of which might have serious public interest implications. One of the key concerns of the Development Agenda proposal was thus fully in line with the spirit and contents of the Doha Declaration on the TRIPS Agreement and Public Health. The Delegation recalled that negotiations on the SPLT had been taking place in WIPO since the second semester of 2000 and that some had suggested that the SPLT should

be a new treaty on the upward harmonization of patent law. These countries had proposed the SPLT as an instrument on best practices in the patent field that would add new international obligations to those already existing under the WTO TRIPS Agreement. The Delegation observed that such an approach to negotiations embodied a vision of intellectual property according to which norm-setting in WIPO should always lead to the adoption of increasingly stringent standards of protection beyond the TRIPS Agreement in all countries, irrespective of their levels of development. It noted that the consistency of such an approach with the development dimension was highly debatable and that that was the reason for the concern in respect of the manner in which the informal consultations requested by the General Assembly had been conducted. The Delegation noted that the group of participants in Casablanca was not balanced and represented a limited range of positions on the subject addressed. Moreover, while participation of Member States known to have significant views and positions on those issues had not been sought by the WIPO Secretariat, organizations that did not enjoy full WIPO membership had been included and individuals not officially representing Member States had been invited to express views in their own personal capacity. That situation had led several Member States to clarify that they did not associate themselves with the outcome of those consultations. The Delegation said that, in order to ensure that negotiations on the draft SPLT delivered a balanced instrument, developing countries had been tabling proposals for amendments to the draft treaty and that the purpose of those amendments was precisely to safeguard the flexibilities and policy space of WIPO Member States. Moreover, the Delegation noted that what developing countries had sought was essentially a balanced and inclusive approach to negotiations whereby the interests, concerns and proposals by all parties involved in the negotiations would be duly considered. It said that the program of work for the SCP adopted by some participants at the conclusion of the informal consultations in Casablanca on February 16, 2005, did not constitute a new element in the negotiation of the draft SPLT. In effect, as far as the work of the SCP was concerned, it reflected the same proposal that had been tabled by two Member States at the last WIPO General Assembly in September-October 2004, which had been rejected. It had also been rejected in the last session of the SCP in May 2004. The Delegation observed that, therefore, it was surprising that the same proposal was being submitted for consideration to the WIPO Member States for a third time, and that the proposal contained in document SCP/11/3 would fragment the negotiation on the SPLT into independent tracks dealing first only with a few issues that did not effectively address the priority concerns of developing countries, inter alia, prior art, novelty, inventive step and grace period, while leaving behind or deferring to other fora the subject matters of real interest and significance to developing countries, such as issues of public interest flexibilities, transfer of technology, competition and clauses on biodiversity, and, inter alia, disclosure of origin. Developing and least developed countries had not been demandeurs of negotiations on the substantive harmonization of the law of patents. Nevertheless, they had shown flexibility and had participated constructively in the process of negotiation by tabling suggestions and concrete proposals in the past sessions of the SCP. The Delegation said that an SPLT that limited itself to the four issues set out in the Casablanca recommendation would effectively entail considerable loss of the flexibility that developing countries currently enjoyed for the pursuit of broader goals of national policy. It noted that determination of the elements of a work program for the SCP on that matter could not be addressed as a merely procedural exercise. It said that the four issues singled out by the Casablanca recommendation as issues that should be dealt with in an accelerated manner in the SCP involved core aspects of the patent regime relating to the conditions of patentability and that, under Article 27 of the TRIPS Agreement, countries enjoyed the flexibility to establish at the national level the substantive aspects of those patentability conditions in their domestic legislation. The Delegation noted that, therefore, the negotiations of a treaty as important as the SPLT could not leave aside aspects of fundamental importance

for developing countries. Unfortunately, the fragmented approach to negotiations as suggested in document SCP/11/3 would in fact not allow all Member States to make proposals on issues that they considered to be relevant, which would be a most undesirable departure from the best practices of multilateral diplomacy. The Delegation said that, in order to strike a balance between the rigidities that would be created in the international intellectual property (IP) system by demands for upward harmonization of national patent laws and, on the other hand, for the safeguarding of existing flexibilities and national policy space, negotiations on the draft SPLT should take on board issues of concern to all Member States as a single undertaking. The Delegation said that, for those reasons, the Delegations it was representing were not in a position to accept the statement contained in document SCP/11/3 as a basis for discussion of the future work of the SCP and that, as pointed out in the statement by the "Friends of Development," negotiations should continue on the basis of the draft treaty as a whole, if one was to guarantee a final outcome that was balanced and inclusive. It said that the Delegations of the "Friends of Development" were prepared to cooperate and were open to discuss a balanced and inclusive work program for the SCP based on a systemic and inclusive discussion of the elements relevant for all delegations. The SCP would address all issues on an equal footing and with the same level of priority. The Delegations it was representing reaffirmed their commitment in ensuring that the negotiations on the draft SPLT were able to proceed in a balanced and inclusive manner. The Delegation noted that a new treaty on patent law that added new obligations without taking into account their potential impact as well as the sovereign right of States and without containing appropriate provisions to safeguard flexibilities for the pursuit of public policy goals would be at odds with the development objectives that the international community had enshrined in international fora, all of which were relevant to the realm of intellectual property. All Delegations present should understand the significance of the discussions the Committee was about to engage in. The Delegation observed that that was in effect a real practical test of WIPO's commitment to those international development goals, in particular, the establishment of a Development Agenda for the organization, especially as it should apply to international norm-setting activities. It encouraged all delegations to work together to demonstrate that it was possible to treat intellectual property issues under a broader development perspective taking into account the concerns of a majority of countries which had to deal with serious and challenging social and economic issues left unresolved in many parts of the world. The Delegation reiterated its group of Delegations' commitment to work on the basis of consensus and to duly abide by the rules of procedure.

- 19. The Delegation of Italy, speaking on behalf of Group B, said that it looked forward to a positive and constructive outcome to the meeting and that it firmly believed that harmonization would benefit all stakeholders including civil society, right holders and IP offices. Concerning the proposed work program contained in document SCP/11/3, the Delegation said that it represented an effective way of structuring and progressing the SCP's and the Intergovernmental Committeee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)'s work. Group B believed that that proposal represented a balanced work plan, which addressed the interests of all Member States. The Delegation noted that Group B looked forward to advancing the work program, both in the SCP and in the other relevant bodies of WIPO.
- 20. The Delegation of Singapore, speaking on behalf of the Association of Southeast Asian Nations (ASEAN), stated that the ASEAN countries had been following the work of the Committee with interest and that, like many Delegations, they would like to see more progress in the work of the SCP. Noting the outcome of the Director General's consultations in Casablanca undertaken in February 2005, the Delegation stated that, while it was important

for the SCP to address issues such as the definition of prior art, grace period, novelty and inventive step, it was equally important that similar progress on the sufficiency of disclosure and genetic resources be made in the IGC. The Delegation noted that the close interface between the SCP and the IGC in addressing the mandated issues in a timely and accelerated manner remained the key to those efforts. The ASEAN countries wished to underscore the salience of the SCP and IGC processes moving in tandem so that the interests of all Member States were taken fully on board in setting out the international patent agenda. The Delegation noted that, while the ASEAN countries understood the importance of developing an efficient, accessible and cost-effective international patent regime, such a patent regime had to be at the same time sensitive to and supportive of the economic, social and technological developmental needs of all WIPO Members. The Delegation stated that it was equally important that it had to preserve, safeguard and promote public interest flexibilities and policy space of Member States. Thus, the ASEAN countries supported the creation of a balanced and equitable international patent system that stroke a balance between the interests of users and rightholders, vis-à-vis consumers and society at large. In concluding, the Delegation stressed the importance of multilateralism in considering all aspects of work in WIPO and looked forward to the full engagement of members in shaping the SCP work program.

- 21. The Delegation of India, also speaking on behalf of the Delegations of Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka, assured the Chair of its readiness to contribute to a positive outcome of the meeting and associated its Delegation with the statement on procedures made by the Delegation of Argentina on behalf of the "Friends of Development".
- The Delegation of Egypt fully supported the statement made by the Delegation of Argentina on behalf of the "Friends of Development". The Delegation noted that Egypt had maintained an unambiguous position, based on the necessity to carry out the negotiations in a balanced and inclusive manner since the beginning of the SPLT negotiations, and that such manner reflected the core essence of the United Nations system, to which WIPO belonged. The Delegation observed that in that context, Egypt, among many developing countries including the countries of the African Group, had not welcomed an exclusive and unbalanced approach of the SPLT negotiations when such an approach had been raised during the previous session of the SCP as well as the previous meeting of the General Assembly. The Delegation believed that the statement adopted at the end of informal consultations among a group of participants in Casablanca had brought up the same approach again in the SCP by proposing a future work program set up on a discriminatory basis, through focusing on issues of interest to developed countries, while issues tabled by developing countries were to be tackled on a different track. Thus, the proposed work program had failed to address the legitimate concerns of a large number of countries and, therefore, could not constitute a basis for discussions on the future work of the SCP. That position of the Delegation had been clearly reflected in the statement of the "Friends of Development" in document SCP/11/4. The Delegation noted that the logic, which applied to the SPLT negotiations, should not be an exception to what applied to any other balanced, fair and transparent multilateral negotiations under the United Nations system. If the proponents of those negotiations had a genuine desire to take it forward, they should be keen on having the interests and concerns of all stakeholders on board and equally addressed in the SCP, including the issues of importance to developing countries, such as the sufficiency of disclosure, genetic resources and transfer of technology. The Delegation reaffirmed its strong determination to work constructively towards building confidence in the intellectual property system and preserving the credibility of WIPO and multilateralism. Those objectives could be realized if a balanced outcome of all intellectual property norm-setting activities was maintained, which effectively integrated the development

dimension and the aspirations of society at large and enabled the IP system to be responsive to public policy concerns.

- 23. The Delegation of Luxembourg, speaking on behalf of the European Community and its Member States, supported the work program as proposed in document SCP/11/3 and the statement made by the Delegation of Italy on behalf of Group B.
- 24. The Chair, while thanking Delegations that had explained their positions, called for constructive proposals for agreed upon action in the future.
- The Delegation of Brazil associated itself with the statement delivered by the 25. Delegation of Argentina on behalf of the "Friends of Development". It reiterated the importance Brazil attached to the work of the SCP and stated that, as highlighted by the "Friends of Development," patent law harmonization was not an issue of interest only to developed countries. The Delegation observed that patent law harmonization had many serious implications for developing countries and the LDCs in many significant areas of public policy and that harmonization could not be approached as a purely technical exercise. The Delegation noted that it wanted to share some very brief points in respect of the direction negotiations on the draft SPLT had been taking related to both substance and procedure, and expressed its full commitment to be as constructive and objective as the Chair was requesting. The Delegation emphasized the fundamental concern with the potential substantive implications of the proposed new treaty. It said that it did not see how, ultimately, the final substantive outcome of that discussion could be disassociated from the general set-up in the environment within which the negotiations took place including the underlying principles, which guided it. The Delegation noted that this was an area where substance and procedure clearly intersected and that this was the reason why there was no need to emphasize too much that the level of transparency and inclusiveness under which the discussion took place might influence considerably the level of inclusiveness and balance of the final package resulting from the negotiations. The Delegation said that, with respect to procedure, its primary concern was that the negotiations on issues such as patent law harmonization, which might have significant implications on society, should always take place in an open, transparent and member-driven manner. All parties to the negotiations should be encouraged to make proposals and to raise issues of importance to them. The Delegation noted again the concerns that had been expressed with respect to the consultations held in Casablanca. The Delegation observed that several developing countries, before the commencement of the SCP's current session, had found it necessary to clarify that they did not agree with the work plan suggested in the Casablanca statement. It noted that Brazil had had the occasion to state its position publicly as well as in consultations with other Delegations and the Secretariat, in order to make it very clear that that was a point it attached utmost importance to. On substance, the Delegation wanted to support the intervention of the Delegation of Argentina on behalf of the "Friends of Development" and to stress in particular that the four patent law provisions proposed in document SCP/11/3 as the focus of accelerated discussions in the SCP involved core aspects of the patent regime. It noted that a new SPLT which contained those four provisions, but no appropriate safeguards for the public interest, and also other issues of relevance for developing countries, would certainly compromise the policies based on the flexibilities enjoyed under the TRIPS Agreement in an undue manner. The Delegation noted that the policy space on those matters had already been considerably narrowed by the legacy of the Uruguay Round. The Delegation stated that for reasons both of substance and of procedure, it fully endorsed the view that WIPO Member States should work together to find a balanced work plan for the SCP that would be able to cover issues of interest to both

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developed and developing countries. The Delegation stated that it stood prepared to wholeheartedly contribute to that consensus exercise.

- 26. In response to a question raised by the Chair, the Delegation of Brazil clarified that, in its view, a balanced work plan was a plan that took up the concerns of both developed and developing countries.
- The Delegation of Switzerland stated that it remained convinced that the harmonization of substantive patent legislation was a key item of interest to all delegations, because that would make it possible to increase the quality of patents granted and to avoid useless duplication of work among intellectual property offices, and that harmonization had to be continued at the multilateral level, i.e. within WIPO. Harmonization of substantive patent legislation was in the interest not only of intellectual property offices but also of the users of the system and of the public at large. The Delegation noted that it was therefore important that everything be done to ensure that efforts could be unified and results reached as soon as possible. Full harmonization of basic patent law was a very comprehensive task and the way work had been organized in the SCP in the past few years had clearly shown that satisfactory progress had not been achieved on any topic. It said that, if there was a wish to achieve proper results, it was urgent to agree on a new working method in order to move forward in the SCP's work. The Delegation observed that a constructive solution, which it felt should be pragmatic and useful, was contained in document SCP/11/3. The solution was pragmatic in that it proposed to focus work in the SCP on a first list of four priority matters. But it also provided that the IGC should look at two priority matters and in doing so, it would be possible to achieve tangible results in the short term. The Delegation said that the solution offered in document SCP/11/3 was balanced, since it proposed that work be continued with the same priorities and under the same conditions, and in an accelerated manner in order to rapidly achieve results on matters of great interest to all members of the organization, whether those were matters linked to harmonization of patent law itself or questions linked to development issues relating to IP and genetic resources and disclosure thereof. The Delegation noted that that was a subject in which it had a great interest in respect of which it had submitted specific proposals. With respect to the results of the work of the two Committees, it might as well be left to the General Assembly to decide how the issues should be dealt with in order to achieve the final results leading to an international agreement. The Delegation observed that for all of those reasons, and with a view to structure the work with respect to harmonization of patent law, Switzerland would join preceding delegations in supporting the approach laid out in document SCP/11/3 with respect to the Committee's work program. A recommendation along those lines should be addressed by the SCP to the next session of the WIPO General Assembly.
- 28. The Delegation of South Africa aligned itself fully with the statement made by the Delegation of Argentina on behalf of the "Friends of Development" and recalled that an inclusive, transparent and open *modus operandi* was the core element behind the idea of making WIPO and the intellectual property system more responsive to the needs and interests of developing and least developed countries. The Delegation said that it would like to underscore the mandate of the General Assembly to the effect that the Director General should determine the date of the next SCP following informal consultation that he might undertake. The understanding of the Delegation was that those consultations should have only focused on establishing the suitable date for convening the SCP meeting and not involved matters of substance or affected decisions adopted by the General Assembly related to the SPLT negotiations. The Delegation did not agree with what the program proposed in the Casablanca recommendation. The Delegation stated that it reaffirmed the importance it

attached to multilateralism, the commitment to strengthening it within WIPO, and that the SCP should consider and endorse the continuation of negotiations of the SPLT on the basis of the draft Treaty as a whole. That should include all amendments that had been submitted by Member States to ensure a balanced treaty on the substantive harmonization of patent law that would address the concerns of all parties in the negotiations. The Delegation observed that the SPLT should focus among other things on safeguarding public interest flexibilities and not run counter to the flexibilities enshrined in the TRIPS Agreement. The Delegation noted that it was therefore important to have comprehensive negotiations which addressed the priorities of all countries and that important proposals had been made by developing countries with regard to general exceptions, patentability criteria, the protection of public health, genetic resources and traditional knowledge during the SPLT negotiations. The Delegation noted that it had been indicated at that time that those were issues of patent law and that therefore it seemed appropriate to deal with those issues in the context of the SPLT negotiations. It said that in the light of discussions around a Development Agenda for WIPO, it was imperative that the SPLT negotiations paid careful attention both to the interest of rightholders and of users, as well as that it addressed the interest of the public at large. The Delegation said it attached great importance to the preservation of flexibilities and of policy space at the international level and that the SPLT negotiations should be based on the mutual respect of interest and priorities of all countries. It noted that that would be the best way to ensure that outcomes would enjoy the necessary legitimacy and that the discussions of all elements contained in the draft SPLT would therefore pave the way to achieving balanced results that would enjoy support and adherence of all parties. The Delegation observed the present drive towards upward harmonization and the potential to undermine the effort of establishing a Development Agenda in relation to norm-setting. It noted that, in this connection, harmonized standards would close the space for developing countries to adapt their patent rules to their unique conditions and needs and that, if developing countries raised their standards to the level of developed countries, they would lose the flexibilities that currently existed in the TRIPS Agreement. The present draft SPLT provided room to advance the Development Agenda for WIPO. Therefore, the Delegation could not afford to lose that opportunity. The Delegation believed in a transparent and open-ended modus operandi as the basis on which discussions on the future negotiations of the draft SPLT should proceed. The work program proposed by the informal consultations in Casablanca did not constitute a new element in the negotiations as it contained the majority of elements in the proposal made by some developed countries in the last WIPO General Assembly, which had been overwhelmingly rejected by the majority of developing countries. The Delegation observed that, if adopted, the Casablanca statement would fragment the negotiations on the SPLT into independent tracks dealing with four issues of greatest priority to the developed countries. The Delegation observed that the SCP's outcomes would be very clear with a treaty while leaving subject matters of interest to the developing countries such as sufficiency of disclosure and genetic resources to the intergovernmental committee where the outcomes were not yet clear. The Delegation believed that international negotiations on any issue should proceed on the basis of a single undertaking as it had been the practice, and that therefore negotiations should continue on the basis of the draft SPLT as a whole.

29. The Delegation of Morocco stated that Morocco had had the honor to host a major meeting in Casablanca on informal consultations with respect to future sessions of the SCP in February 2005. It said that its Delegation had worked hard to ensure that the work went well on the basis of a constructive approach and that it welcomed the efforts undertaken by all participants in the informal consultations of the meeting so that it could be held in a positive spirit. As it had said during the Casablanca meeting, the Delegation wished to reaffirm the importance of maintaining a multilateral framework particularly within WIPO, which

represented the suitable forum for debate of intellectual property matters, particularly patents, traditional knowledge and genetic resources. The Delegation felt that the objectives and work program for the SCP contained in the recommendation of that consultation meeting should set the framework for enabling harmonization of substantive patent law. It reaffirmed its interest in harmonizing substantive patent law with the view to improving the quality of patents, reduction in the work load in patent offices and the development of a more accessible and less costly patent system for applicants. It considered that harmonization should provide the fairest and most appropriate patent system for all users of the system, particularly for developing countries. The Delegation felt that harmonization of patent law should promote economic and social development of all countries so that all the peoples of the world could enjoy better living conditions. If those objectives were not lost sight of, all obstacles could be overcome. Member States should continue to work unstintingly to seek balanced responses offering a responsible solution for all. The Delegation was convinced that multilateral work, dynamic work, could be undertaken within the IGC on intellectual property relating to genetic resources and traditional knowledge and folklore, for example with respect to moving towards the fundamental objective of protection of traditional knowledge and folklore. The Delegation stressed the importance of having a development aspect and program for intellectual property pointing to the important aspect of development for the entire international community as its priority for developing countries. That would contribute to promoting even more the use of the intellectual property system as a tool for economic, social and cultural development and thus it meant for humanity as a whole to achieve development and well being through prosperity and economic development. The Delegation hoped that all delegations would have a constructive approach in order to achieve a work program which would meet the expectations of all parties in the overall context of the use of the intellectual property system as a tool for economic, social and cultural development.

- 30. The Delegation of Sudan supported the statement by the Delegation of Morocco and expressed its understanding for the work plan as elaborated in the Casablanca consultative meeting. It looked forward to building a consensus that would enable delegations to carry on and move forward.
- The Delegation of India associated itself with the statement made by the Delegation of 31. Argentina on behalf of the "Friends of Development". The Delegation noted that the meeting took place at an important juncture in the work of the SCP. It observed that patent law was an important area of intellectual property law that had cross-cutting implications in different areas of public policy including public health, environment, health, and others, and that it was therefore important for developing countries to understand the full implications of the SPLT on their freedom to design patent laws appropriate to their circumstances and integrate them into their development policies. The Delegation stated that the General Assembly in September-October 2004 had mandated the Director General to undertake informal consultations to decide the dates of the next session of the Committee and that it had been its expectation that such consultations would be held in Geneva in an open, transparent and inclusive process. It said that the mandate did not envisage the holding of consultations on the substantive work program, matters relating to the WIPO Development Agenda or the IGC and that it did not include the time frame for the conclusion of selective issues in the SCP either. The Delegation noted that the representation at the informal meeting in Casablanca in February 2005 had been limited and that the vast majority of Member States had not been invited to those informal consultations. It said that those informal consultations should have been inclusive, transparent and open-ended and that the importance of multilateralism lay in involving and serving the interests of the entire membership of the organization, particularly those of developing and least developed countries. It noted that multilateralism should also

work towards consensus building on all issues under consideration, including all the proposals by the entire membership of WIPO. With respect to the outcome of the Casablanca consultations, the Delegation observed that India had long been on record that the de-coupling of issues and identifying some for selective fast-tracking was not acceptable to it. The Delegation noted that it was prepared to further consider discussions in the SCP provided that the issues were considered holistically, taking on board the key concerns of the entire membership including the important issues of disclosure of genetic resources and associated traditional knowledge in the SPLT.

The Delegation of Pakistan stated that in deliberations on the work program of the SCP, delegations were once again confronted squarely with a critical challenge, which they had been facing for some time, as members of WIPO. That is, the delegations were called upon to demonstrate that they could formulate, and agree upon, effective intellectual property norms in response to a fast changing global environment, while ensuring that those norms fully took into account the developmental needs of the membership. The Delegation noted that that was undeniably a formidable challenge and that given the slow pace of norm-setting exercises and the fairly meager results that had been forthcoming, there were definitely grounds for some pessimism. The Delegation observed that such pessimism might, however, not be warranted, especially if the SCP embarked on norm-setting exercises with shared objectives in mind, strove for clarity and a common understanding on the implications of proposed norms, and negotiated transparently in accordance with established procedures. The Delegation noted that those principles clearly applied to present deliberations on the work program of the SCP and that for the past five years, a major component of the SCP's work had been the negotiations on the draft SPLT. The Delegation observed that some progress had been made, but much more remained to be done. That had led to a proposal by some countries for adopting an "early harvest" approach by restricting the elements to be negotiated in a first phase, to four and possibly two additional issues, which supposedly were the most urgent. The Delegation noted that that proposal had been accompanied by broad and rather unfortunate hints that if there was no quick movement on those issues, then some delegations would pursue those issues outside of WIPO. That had been countered by the position that negotiations should continue on the whole range of issues that were on the table, in order to ensure that the concerns of all Member States were addressed and that there was a balanced outcome. The Delegation observed that that was accompanied by a growing feeling of unease with the possible developmental implications of the many complex provisions of the draft SPLT, and hence, an increasing reluctance to quicken the process by picking and choosing elements for an "early harvest". There was further a sentiment that if some countries wished to proceed with that exercise elsewhere, outside WIPO, they were welcome to do so. The Delegation observed that thus, the ingredients for a deadlock appeared to be in place, but that a deadlock, a failure to progress on that important matter, should be unacceptable to all and that it would reflect badly on the delegations, on the Organization and on the collective ability to address important issues. More dangerously, it might initiate a process whereby multiple intellectual property regimes might come into existence. The Delegation said that that would complicate the lives of the users of the intellectual property system and, at the same time, impact negatively on efforts to ensure that the international intellectual property regime continued to evolve into a more development friendly system. The Delegation stated the need to bring back complete transparency and openness into that exercise and that further work could not proceed on the basis of the pronouncements of restricted conclaves such as the Casablanca meeting. In its view, a few countries could not be given the right to give directions to the entire membership on any matter, let alone one of such importance. Hence, the starting point for the SCP should be where it left off at its tenth session, and its future work should not be compromised by ill-advised initiatives such as the Casablanca event. The

Delegation noted the need to unequivocally reaffirm the objectives underpinning that exercise and that those objectives included not only the undeniably important, "efficiency" goals such as reducing the workload of patent offices and improving the quality of patents, but also the critically important goals of enhancing "balance" and "equity". That would necessitate addressing issues such as proper disclosure requirements, curbs on anti-competitive practices, and provisions that would facilitate diffusion of technology and innovation. The Delegation stated the need to take measures to clarify the many complex issues that were under discussion and that the International Bureau might be tasked to produce a comprehensive paper, on its own or jointly with the United Nations Conference on Trade and Development (UNCTAD), on the implications of the draft SPLT on public policy issues such as national capacities to innovate, access to technology, protection of national intellectual property assets, etc. The terms of reference of such a paper might be carefully elaborated in order to ensure that the varying implications for Member States at different levels of development were fully addressed. The benefits of such an exercise would be two-fold, that is, it would ally apprehensions that might exist because of incomplete understanding of the fairly complex issues that were under discussion, and it would identify areas in the draft SPLT where caution might be advisable or where additional provisions might be proposed in order to meet the large objectives of the exercise. The Delegation stated that, on the basis of the discussions on the above paper, a more informed decision might be taken on the specific negotiating approach to be pursued. The Delegation noted that the comprehensive approach of negotiating on all current elements of the draft SPLT was its preferential approach. The more limited, "early harvest" approach could be considered only if the limited package contained a balanced set of elements, which addressed the concerns of all groups of countries and were not arbitrarily selected. The Delegation noted that the proposals it was putting forward might be perceived as having the effect of further slowing down an already slow process. But that would not be the intent. A transparent approach, which sought to enhance clarity on the many complex and increasingly contentious issues, and which thereby facilitated the building of consensus, would inevitably provide a robust foundation for agreement. Clearly, that was one area where WIPO needed to adhere to the wise adage of "making haste but slowly".

The Delegation of the United States of America stated that the importance of meaningful patent law harmonization to all stakeholders of the patent system, including members of the public, highlighted the urgent and imminent need for the adoption of a sensible work plan in the Committee. To that end, it supported the statement made by the Delegation of Italy on behalf of Group B. It believed that to limit the scope of work of the SCP to discussions regarding the definition of prior art, grace period, novelty and inventive step provided the best opportunity for achieving near term agreement on core prior art related principles of patent law and thereby provided the best opportunity for meaningful results. The Delegation noted that these issues were fundamental to examination practice and patent quality throughout the world. Agreement on the four prior art related issues would promote higher patent quality, facilitate work sharing and in turn help to decrease workloads and duplication of work by national IP offices. More importantly, substantive patent law harmonization, if successful, would allow innovators, in particular, individuals and other small and medium-sized enterprises to benefit from their own innovations in a way that was not possible at the moment due to existing differences in national patent laws. It observed that in particular harmonized prior art practices would promote patent quality throughout the world, contribute to a more uniform assessment of novelty and non-obviousness and may help to address concerns that have been raised in the IGC. It firmly believed that continuing with the previous model of discussion as suggested in document SCP/11/4, i.e., discussing the entire draft treaty document as well as additional issues that had been raised, was unmanageable, inefficient and unworkable, and did not provide a viable manner in which to

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proceed. It could not support the proposal in document SCP/11/4 but could support the proposal in paragraph 3 of document SCP/11/3 to adopt the SCP workplan contained in the recommendation and urged the Committee to do so.

- The Delegation of Chile expressed its support to the point of procedure raised by the Delegation of Argentina on behalf of the "Friends of Development" and supported by the Delegations of other countries. The Delegation wished to repeat the position it had expressed on negotiations for a possible treaty on substantive patent law during the General Assembly in September 2004. On that occasion it had said that the best if not the only way of achieving a balanced result in a possible SPLT was to include and discuss all the important aspects of patents including those being worked on at the time in the draft Treaty. The Delegation observed that the unvarying position of the Chilean Government on the SPLT had been a balanced approach which would take into account the interest of all Member States and not confine itself to issues only of interest to some members. On document SCP/11/3 which suggested taking up four issues in parallel and in an accelerated way in the SCP and IGC, it said that in any negotiation the interest of all Member States should be duly taken into account. The Delegation believed that the Casablanca recommendation would be in favor of those four issues. In addition to those issues to be discussed by the IGC, it did not believe that some issues were more closely connected to patents than others. Opinions that the four issues to be examined by the SCP were more closely linked to the patent system than the others was inconsistent with an overall vision of intellectual property that recognized it as an important tool in the economic development of a country. The Delegation observed that the SCP was a Standing Committee whereas the IGC had a limited mandate that concluded in 2005 and had therefore not had a defined area of work. While the recommendation suggested that both committees should report to each other, it would be difficult to carry out the proper coordination between the two committees so as to achieve a balanced result. And the experts covering one committee weren't necessarily the same as those in the other committee. The Delegation noted that many countries were not properly represented at both meetings due to lack of resources, which exacerbated the problems of finding a solution that would be satisfactory to all Member States. The Delegation wondered about what would happen with issues not mentioned in the Secretariat's recommendations, such as objectivity, exceptions and limitations to the exclusive rights of the rights holders and other matters of public interest. Highlighting the importance of a treaty that considered the interests of all, both of the right holders and the citizens and the general public, the Delegation stated that it was not in a position to accept the proposal by the Secretariat.
- 35. The Delegation of the Philippines associated itself with the statements made by the Delegations of Argentina, India and Morocco. The Delegation stated that a balanced and inclusive approach to the issues that needed to be addressed, particularly those on prior art, grace period, novelty, inventive step, sufficiency of disclosure and genetic resources was indeed significant to the achievement of the SCP objectives of improving the quality of patents and producing benefits by making the patent system more accessible and cost-effective while at the same time taking into consideration the national patent laws, not only of the developed countries but, more importantly, of the developing as well as the least developed countries. The Delegation proposed that the impact of the obligations attached to the SPLT on those countries would have to be given a full account and that it would have to be carefully understood and considered, since the progress of the patent system should be geared not only towards the improvement of the system itself, but also towards the socio-economic and cultural development of the developing and least developed countries. The Delegation noted that an accelerated procedure would result in missing that important point.

The Delegation of Ecuador expressed its wish to achieve a positive result and outcome of the session. The Delegation noted that it had co-sponsored a program under which there was serious and in-depth consideration of the implications and impact of international measures on patent law, particularly in developing countries and those countries especially affected by poverty and economic crisis. Such an impact of the adoption of intellectual property norms, often was concentrated on patent law as in that case. As had been recognized by various international for a and in innumerable academic publications, if patent law was not correctly agreed on, it affected health, education, agriculture, biological and genetic resources, the access to knowledge, the transfer of technology and the ever greater increase in the gap between those countries that were able to invest in science and innovations and those that had quite simply not enough even to cover the basic needs of their people. The Delegation recalled the impact that the patent system had on the manufacture of medicines and pharmaceuticals which had been in such a magnitude that the WTO, during its Doha Ministerial Meeting in 2001, had had to make an explicit recognition of the close link between the production of medicines and health policies and their relationship to intellectual property, so as to effectively combat epidemics and pandemics that affected above all the poorest populations in the world, such as HIV/AIDS and tropical diseases. The Delegation observed that there had been a statement by the World Health Organization and the Pan-American Health Organization, as well as many international non-governmental organizations along the same lines. The Delegation mentioned education and agriculture, which were areas that, when affected by an inadequate and partial vision of the patent regime, did not only hold up the development of a country, but affected its very survival. The Delegation stated that what it had said did in no way imply any disregard for intellectual property rights nor did it imply that Ecuador ignored its international commitment on that subject. The Delegation noted that his country would be in a difficult position if there was an increase in obligations and a decrease in flexibilities, i.e., if there were more norms relating to patents and other areas of intellectual property. Against that background, it was clear why Ecuador, a developing country, was concerned and worried for not being invited to the consultations convened by the Director General on the basis of the mandate from the General Assembly, especially as those consultations did not follow the principles of transparency and inclusion that were required on negotiations on subjects that were extremely sensitive and that affected large groups of people. The Delegation was surprised that at those consultations, room had been given to private people and organizations who in spite of their great merits could in no way replace or express the views of the Member States of WIPO. The Delegation noted that those were procedures that should be rectified for the good of intellectual property itself and its credibility at international level and reiterated its support to what had been said by other countries about the consultations held in Casablanca. In addition, the proposal submitted in document SCP/11/3 to which the Delegation had referred to in various statements together with the "Friends of Development" did not constitute any innovation. It was nothing new, it was a proposal that had been rejected and on which there had not been consensus and which had been the subject of many questions. While the lack of novelty involved many procedural aspects that had to be resolved through the rules that did exist in WIPO for those cases, the greatest difficulty resided in its contents and the difficult nature of negotiating those important subjects and its contents. It also implied that the inclusion of main principles of many developing countries like Ecuador in their public policies, the application of the Doha Declaration of 2001 and the objectives which should be pursued when adopting any intellectual property standards internationally would be affected. The Delegation observed that it would like those concerns to be clearly enshrined in an international instrument such as the one delegations were trying to negotiate. Having such a proposal might jeopardize a full and complete instrument with full levels of participation, the

inclusion of all issues and all concerns should be fully guaranteed. The Delegation expressed its readiness to work together with the Chair and delegations in order to clearly fulfill the mandate by the General Assembly in line with all the rules of WIPO for the benefit of all.

- The Delegation of Iran associated itself with the statement of the "Friends of Development" introduced by the Delegation of Argentina, and mentioned that the developing world had a unified perception and consideration about those documents. The Delegation noted that, in order to be constructive, one had first to deconstruct the Casablanca process contained in document SCP/11/3. The Delegation considered that there were three fundamental issues to be considered: First, procedurally, the mandate which had been given and the scope of the recommendations and the discussions procedurally contradicted the WIPO regulations and laws. Second, on the psychology referring to the word "delegates". In the Delegation's view, in the document, the word "delegates," which meant something different, had been used for those persons who had been in Casablanca. Third, the Delegation noted that the substance was the most important aspect and that it contradicted the discussions that had been held. It also observed a repetitious tendency of certain interests in the discussions. The Delegation stated that, taking all that into consideration, it could not accept the recommendation contained in document SCP/11/3. It proposed three short but important concepts: first, to be inclusive and transparent; second, to take into account the interests of all Member States, as WIPO was a Member State driven entity. In its view, it was not in the interest of all countries to have harmonization. It affected security, health and public life. Delegations, as representatives of their people, had to defend their interests. Third, the Delegation stated that consensus had to be achieved and recalled that consensus building in intergovernmental organizations had its own vocabulary, culture and psychology, and that meant addressing norm-setting with care and attention in the interest of all parties.
- 38. The Chair invited delegations to react to the proposal made by the Delegation of Switzerland.
- 39. The Delegation of Algeria stated that it was fully in favor of an international instrument harmonizing patent law. The Delegation noted that it realized the magnitude of the task before the SCP in view of achieving a balanced international system, which should provide progress and well being for all. It supported the principle of multilateral discussions that were transparent, fair and took into account the interests of all parties. Since the Delegation believed that the development on substantive patent law should not lead to a two-speed system which would exclude some countries from international cooperation instead of integrating them, it was surprised by the Casablanca recommendation which did not make progress as compared to the discussion at the last WIPO General Assembly. The Delegation therefore could not support the approach set out in document SCP/11/3, and supported the statement made by the Delegation of Argentina on behalf of the "Friends of Development".
- 40. The Delegation of the United Kingdom stated that the Casablanca meeting, in which it had participated, was open and constructive, whether or not delegations agreed on every single item. The Delegation stressed the importance of making progress and getting the global intellectual property system right so that it would benefit all Member States, innovators and the public. Quoting a famous philosopher who had said that philosophers had only interpreted the world in various ways, but that the point was to change it, the Delegation considered the intellectual property system as a tool for changing the world for the better and for ensuring that human creativity was applied for the benefit of society. In its view, one of the reasons for not being able to make progress in the SCP was that too many issues of quite a different nature, and issues which were at different stages of understanding in respect of the

details involved, were addressed in the same forum. The Delegation recalled that the outcome of the Casablanca meeting was not a direction, but a recommendation to be discussed openly in the SCP and other fora, and was not an attempt to pre-empt substantive decisions. The Delegation further recalled that the recommendation by the Casablanca meeting identified six issues to be addressed in an accelerated manner, four of which in the SCP, and the other two in the IGC. The recommendation of that meeting also stated the importance of a continued active pursuit of discussions and work within WIPO on issues related to development, so that a robust, effective and actionable Development Agenda could emerge. In the light of many discussions the Delegation had had with other delegations since the Casablanca meeting, it believed that the best way for making progress was to address those limited substantive issues, which concerned issues that affected developed, developing and least developed countries alike. The Delegation expressed the belief that a clarification of the notion of prior art would ensure that encroachments on the public domain would be contained. A grace period would provide a safety net for those who inadvertently, or because of commercial necessity, disclosed their invention to the public, and the novelty definition would ensure that patent rights, which were powerful rights, could only be obtained for genuine additions to knowledge. In its view, such a detailed agenda should be addressed in the SCP. The Delegation further noted that there was also an agenda for the IGC that required the same level of commitment. It believed that separating issues at this stage was wise with a view to clearly focus the attention. Equally, the Delegation recalled that the Inter-sessional Intergovernmental Meeting on a Development Agenda for WIPO (IIM) had already started its work on the basis of a significant number of proposals. The Delegation stressed the importance of addressing the development implications of any proposal for norm-setting, taking account of not only how intellectual property affected technology transfer, but also other issues. The Delegation understood that the outcome of those different bodies would have to be brought together as had been suggested by the Delegation of Switzerland so that the outcomes could be examined in a balanced manner by holding a truly comprehensive Diplomatic Conference. In its view, the above mechanism had more chances of success than a mechanism that had manifestly failed in the past.

The Delegation of Australia, supporting the statement made by the Delegation of Italy on behalf of Group B, believed that the current discussion was about the substantive matters before the Committee. Although the Delegation had not been invited and had not attended the Casablanca meeting which led to document SCP/11/3, it had no comment on that process. The Delegation endorsed the proposed work program in that document, as it was broader than the work program originally put to this Committee and subsequently to the 2004 WIPO General Assembly. The new work program included two additional patent law issues, sufficiency of disclosure and disclosure of genetic resources. That new work program also included progressing the creation of an international Development Agenda through initially the IIM meetings and ultimately the General Assembly later this year. Furthermore, in the view of the Delegation, that new work program was explicitly proposed in the context of meeting a key need of civil society by avoiding unwarranted encroachments on the public domain through the patent system, and also of the users of the system through reducing unnecessary and costly duplication of work in IP offices. Nonetheless, the Delegation considered that the proposed work program might require some refinement to ensure that it would benefit all Member States, especially on how the issues raised by the Delegation of Argentina on behalf of the "Friends of Development" would be dealt with under the proposed patent law changes. Therefore, with respect to the proposal made by the Delegation of Pakistan concerning a study on the implications of the proposed changes on patent law on development, the Delegation found that it was a sensible suggestion. Thus, the Delegation suggested that the SCP build on the procedure that had been used in its country to assess the

impact of legislative changes of particular interest or sensitivity. The Delegation explained that, in its country, when the Office proposed a change to the Patent Act, it had to also prepare a regulatory impact statement which analyzed what impact the legislative change would have on a range of particular interests, for example, small businesses. Such an impact statement was separately examined for its adequacy by a separate agency before it was submitted to the government for consideration. The Delegation considered that the most fundamental role of WIPO had been and was the role of creating and managing international law relating to intellectual property, and that it was a willing participant in WIPO processes which it believed would lead to new types of intellectual property law. Stressing the term "law" in that context, the Delegation believed that the SCP should maintain its technical focus on and confidence in the law of patents, and should not transform itself into an agency that was responsible for the law of all subjects merely because patents touched upon many other important issues, such as public health. Instead, the Delegation believed that the SCP should focus on its role of improving the law of patents based on its technical expertise and competence. The Delegation also believed that the SCP should adopt appropriate processes which analyzed the impact of changes to patent law not only on the users of the system, IP offices or developing countries, but on civil society in all Member States. The Delegation called on the adoption of not only the work program proposed in document SCP/11/3, which focused on key changes on the law of patents, but also the development of procedures that properly assessed and took into account the impact of any proposed changes.

- 42. The Delegation of Japan, supporting the statement made by the Delegation of Italy on behalf of Group B, stated that harmonization of the four issues (novelty, prior art, grace period and inventive step) contained in document SCP/11/3 would benefit all WIPO Member States. The Delegation also supported the accelerated and concurrent process of discussing those four issues and the two other issues contained in that document, which would lead to obtaining an early result in the SCP. The Delegation believed that the recommendation contained in document SCP/11/3 was a good basis for further progress in the SCP.
- 43. Responding to the invitation by the Chair to react to the proposal made by the Delegation of Switzerland, the Delegation of Argentina stated that all proposals made were constructive, and that the proposal made by its Delegation on behalf of the "Friends of Development" could also be accepted as a basis for the negotiation. In its view, a number of delegations spoke in favor of the proposal made by its Delegation, since it showed a constructive and balanced way defending the interests of all. The Delegation stated that the work plan of the SCP was not a mathematical question, such as four plus two or six minus four, but that many delegations had expressed their interest in negotiating many other topics. The Delegation therefore felt that the deadlock would not be resolved if the discussion focused on, or took as a basis, the recommendation by the Casablanca meeting.
- 44. The Chair stated that all the proposals made were indeed constructive, and explained that he had concentrated his attention on the approach which appeared to cover different views. The Chair noted that a solution that resulted in a win-win situation should be sought.
- 45. The Delegation of China noted that, during the Casablanca informal consultations, in view of the difficulties which the SCP had been confronted with at the previous sessions, it did not oppose the suggestion to concentrate the initial discussion on certain topics. However, the Delegation emphasized that the selected topics should not cover only the issues of concern of developed countries, but also the issues which were important to developing countries, particularly the issue concerning the disclosure of the source of genetic resources and relevant traditional knowledge in patent applications. Noting the earlier suggestion by the Delegation

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that the final text of the draft Treaty formulated by the SCP should reflect the results of the discussions on both kinds of issues, the Delegation regretted to see its view not captured by the recommendation of the Casablanca meeting. Associating itself with many other delegations, the Delegation of China reiterated that the issue concerning the disclosure of the source of genetic resources in patent applications was of paramount importance to it. The protection of genetic resources, which was not only discussed in the SCP, but also in other for a such as the IGC, PCT Reform and the TRIPS Council, had drawn broad attention at the international level. The Delegation considered that WIPO was competent to settle the problem, since that issue related to the requirements of patent applications. The Delegation therefore wished that WIPO coordinate and integrate those efforts by taking more effective measures and a more active attitude to expedite the establishment of an internationally acceptable norm on that issue. The Delegation strongly encouraged the inclusion of such issue into the final text of the SPLT, and stated that a treaty text excluding the issue of the disclosure of the source of genetic resources was not desirable. In that connection, the Delegation suggested that the SCP should include that issue in the agenda of the SCP. Further, the Delegation stated that, since issues such as the facilitation of technology transfer, prevention of the abuse of patent rights and policy spaces for public interest were important for the effective operation of the patent system, it supported broad and extensive discussions on those issues within WIPO so as to establish international rules which were supported by both patentees and the public in general.

- 46. The Delegation of Colombia expressed its concern about the Casablanca meeting which had held unofficial discussions without the presence of its country and many other developing countries which were members of WIPO. The Delegation considered that the participation to such a procedure chosen by the Director General was restricted to a limited number of countries on subjects which were of interest for many other developing countries. Noting the importance of the subject of patents and the work of this Committee for the Delegation, it hoped that the consultative process in the future would be open and inclusive. The Delegation did not share the recommendation by the Casablanca meeting which excluded the equally important topics of sufficiency of disclosure and genetic resources, among others, from the work of the SCP. The Delegation believed that those last two were subjects directly concerned with the patent system, and should be included in any future treaty which would be developed within the framework of the SCP. Finally, the Delegation felt that the terms of reference given by the General Assembly in September 2004 to the Director General were directed to determining the dates of the next meeting of the SCP and not defining questions of substance about the future work of the Committee. With respect to other elements of a possible treaty, the Delegation expressed its support for the delegations which had stated the need to include, in the SPLT, issues such as anti-competitive measures, safeguard of the public domain and principles and objectives.
- 47. The Delegation of Bolivia stated that it fully acknowledged the Development Agenda. The Delegation expressed its concerns with the procedure that had been used on other occasions, and noted that strict obedience to the rules of procedure would give credibility to WIPO and its practices. It reiterated that the negotiations and a possible outcome should fully include the interests of all Member States. The Delegation stated that it could therefore not accept the proposal contained in document SCP/11/3, since it had doubts about its basis and legitimacy in terms of procedure as well as in terms of its contents. Specifically, the Delegation was concerned with the reference being made to the processes to be completed in the SCP and the IGC on an equal footing, the latter Committee having a limited mandate that might or might not be renewed. Supporting the "Friends of Development," the Delegation said that there were common subjects in both fora and that a single undertaking was desired.

It further stressed the importance of the concept of consensus and noted that this was an opportunity for all the delegations to show their good intentions as it had heard in the previous sessions.

- 48. The Delegation of Germany, supporting the statements made by the Delegation of Italy on behalf Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States, believed that the work plan set out in document SCP/11/3 was a practical and balanced proposal that also included development issues. It considered that a limited package approach was the only way to reach concrete results in the future, since the broad approach that had been pursued in the past had proven to be ineffective.
- 49. The Delegation of Canada supported the statement made by the Delegation of Italy on behalf of Group B. The Delegation noted that two principles had emerged so far. The first related to a balanced approach and the second point was that some emergency should characterize the way by which the issues were dealt with. The Delegation fully supported those two concepts, and although it did not participate in the Casablanca meeting, considered that the SCP should concentrate on the substantive outcome of the meeting rather than on the process. The Delegation believed that document SCP/11/3 outlined the process for a balanced and accelerated discussion of issues, and called for not only the SCP but also other WIPO bodies to get on with the work, which had the potential to respond to all Member States' concerns and needs. The Delegation urged the SCP and other WIPO bodies to continue the discussions on those important issues to achieve balanced and tangible results, and to avoid any further deadlock. The Delegation believed that document SCP/11/3 allowed for advancing the discussions and hoped that it would be supported as a manageable approach keeping in mind the interests and needs of all parties.
- 50. The Delegation of Italy stated that it had participated in the Casablanca meeting in a constructive manner in view of the impact that this work would have on all WIPO members. Noting that the interests of all, not just of some, should be safeguarded, the Delegation explained that the recommendation of the Casablanca meeting reaffirmed the importance of carrying on discussions in WIPO on the development dimension and emphasized the need to carry on, in parallel discussions in the relevant Committees concerned, with the highlighted six major issues. The Delegation further expressed its support to the proposal made by the Delegation of Switzerland.
- 51. The Delegation of the Republic of Korea fully supported the recommendation by the Casablanca meeting. Stressing the importance of transparency and inclusiveness, the Delegation believed that the concept of consensus constituted the cornerstone of the United Nations system and that it should therefore be the basis of discussions at the SCP. With a view to working in an inclusive and transparent manner, the Delegation believed that informal consultations should be open-ended. The Delegation further emphasized the importance of the need to strike a balance between the concerns of developing and developed countries. It considered that harmonization of patent law would make the system more convenient and less costly and reduce unnecessary duplication of work among patent offices. The Delegation was therefore of the view that the sooner an agreement on the SPLT could be reached, the better for all Member States of WIPO. The Delegation, however, also stressed the need to avoid unnecessary burden on developing countries.
- 52. The Delegation of Peru supported the statement made by the Delegation of Argentina on behalf of the "Friends of Development" and the interventions made by the members of that group. In its view, it was clear that the SCP could not adopt all recommendations contained

in document SCP/11/3 because one of them suggested that the disclosure of the origin of genetic resources should be discussed in the IGC. The last session of the IGC under its present mandate, would be held next week and it was still unclear what the future of that Committee would be. The Delegation considered that, since the issue of disclosure of genetic resources was related to the discussions on the patent system, it should remain in the SCP. The Delegation noted that the issues included in document SCP/11/3 were all important, but that the disclosure of origin of genetic resources was the most important issue that should be addressed in the SCP. The Delegation also pointed out that, apart from the six issues contained in document SCP/11/3, other issues that had been discussed in the SCP were also important, and that different delegations had different priorities. The Delegation suggested that the SCP might have made more progress if the negotiation had been based on the draft SPLT that had been tabled in that Committee.

- 53. The Delegation of France supported the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States. The Delegation clarified that the outcome of the Casablanca meeting was a recommendation, which did not prejudge the result of the discussion at the SCP, and that it was up to the SCP to discuss that recommendation. The Delegation considered that that recommendation was the way by which the Member States could achieve progress and obtain tangible and well-balanced results in various areas. Further, the Delegation was in favor of the proposal relating to an impact study of the SPLT on developing countries. It believed that such a study would make it possible to clarify the situation as regards the possibilities, the challenges and perhaps even the threats that had been mentioned by other delegations.
- 54. The Delegation of New Zealand supported consideration of issues such as the disclosure of origin of genetic resources in the IGC because of its expertise, although it did not exclude consideration of those issues in the SCP, since they had a direct bearing on the negotiations of the SPLT. In the Delegation's view, proceeding on two parallel courses did not mean that these courses would permanently remain separate, since they could converge at some point.
- 55. The Delegation of Brazil pointed out that the position stated in document SCP/11/4 was to continue the negotiations on the basis of all issues on the table as a single undertaking, without precluding any issues and without fragmenting the process. The Delegation stated, however, that it was willing to establish a manageable and effective work program on the basis of this understanding.
- 56. The Delegation of Sweden, supporting the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States, stated that the recommended work program in document SCP/11/3 contained important issues that required an accelerate process and a near-term agreement. Bearing in mind the lack of progress on the draft SPLT, the Delegation was of the view that a step-by-step approach should be adopted. The Delegation considered that the four issues, i.e., harmonization on prior art, novelty, grace period and inventive step, were most important in order to improve patent quality and reduce duplication of work, which was in the interest of all Members of the SCP. The Delegation further stressed that the other two issues contained in the recommended work program, which were proposed to be dealt with in the IGC, that is, sufficiency of disclosure and genetic resources, were of equal importance in terms of requiring a near-term agreement and results. In that context, the Delegation referred to a proposal by the European Union, which had been tabled in the context of the Ad Hoc Intergovernmental Meeting on Genetic Resources and Disclosure

Requirements. The Delegation further supported the statements made by the Delegations of Switzerland and the United Kingdom regarding the interface for the work in the different committees. The Delegation concluded its intervention by expressing its commitment to constructive efforts in order to reach a balanced agreement and to continue a successful work in WIPO on patent law harmonization.

- 57. The Delegation of Ireland, supporting the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States, reaffirmed its commitment to the patent law harmonization process and also to make progress on issues such as sufficiency of disclosure and genetic resources. The Delegation endorsed the Casablanca recommendation, which dealt with not only the four prior art related issues but also issues relating to genetic resources and the proposal on the international Development Agenda being discussed at the IIM. As regards the disclosure of the origin of genetic resources in patent applications, recalling that the European Community had submitted a proposal on that matter to WIPO in December 2004, the Delegation believed that the IGC was the most appropriate forum to discuss such an issue.
- 58. In response to the Chair's invitation to react to the proposal made by the Delegation of Switzerland, the Delegation of the United States of America stated that it could not support such a proposal, because it would prejudge a possible outcome concerning issues, including issues relating to genetic resources, on which there was little agreement at the international level. Referring to the various proposals regarding genetic resources, including its own, the Delegation expressed the view that the issue was far too immature to be dealt with in the SCP or to be submitted to a Diplomatic Conference along with the four issues in the reduced package.
- 59. The Delegation of Spain, supporting the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States, expressed its support to the work program set out in document SCP/11/3, which, in its view, provided a constructive solution that allowed continuing the work on substantive harmonization and achieving results in the short term.
- 60. The Delegation of Ecuador reiterated its concerns about dealing only with a few specific aspects of patent law. Although there was a reference to issues relating to genetic resources and to traditional knowledge, the Delegation considered that all issues coming under the heading of patents should be covered in order to balance the contents of the discussion. In its view, since there were issues that had impacts on development, a broad open discussion that covered all those aspects was necessary to properly focus on the concerns of all parties who were interested in working on an agreement. The Delegation believed that a comprehensive negotiation, which covered not only the aspects that were important to certain parties but the full range of issues including those aspects of concern for developing countries, was precisely what the majority of delegations had been supporting.
- 61. The Delegation of Hungary supported the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States. The Delegation hoped that proposals submitted to the IGC might be able to contribute to adequately address and to solve the issue of genetic resources and the disclosure requirement. The Delegation also supported the Delegations of Australia and Pakistan concerning the establishment of an impact study.

- 62. The Representative of the EPO associated himself with the statements made by the Delegation of Italy on behalf of Group B and by the Delegation of Luxembourg on behalf of the European Community and its Member States. In connection with the concerns raised by some delegations regarding the impact on development of the limited package, the Representative supported the suggestion to prepare studies with respect to the actual impact of harmonization on those issues, which could help to bring the discussion forward.
- 63. The Representative of EGA explained that the objective of his association was to assist the right of people for access to medicines at an affordable price. The Representative noted that patents were of great importance for his association because firstly, bigger parts of international patent litigation involved pharmaceutical patents, and secondly, malaria, which was the most sensitive issue, also related to the pharmaceutical field. In the view of the Representative, a patent was neither a piece of paper, nor a document, nor a stamp. It was a very important tool in market competition. It could be a very useful tool that promoted innovation, but could also be dangerous if it started blocking competition in an illegal way or if patent rights were abused. The Representative was of the view that, although the suggested six issues were important, they should not be addressed out of context because patent life had two parts: the grant of the patent and the enforcement of patent rights. He considered that those two should be discussed in full. The Representative was interested in strong and well-examined patents, but was of the opinion that the patent system should keep its original objective and should not become a bar to competition or a source of abuse.
- 64. With respect to the proposal made by the Delegation of Pakistan regarding an impact assessment, the Delegation of India noted that it had spoken in the past on the need for WIPO undertaking a proper impact assessment of the various norms and standards that had been developed in the field of intellectual property. The Delegation, however, considered that the question of impact assessment was different from the one the SCP was currently addressing, i.e., discussing a choice to be made between various proposals. In the Delegation's view, the question of impact assessment rightly seated when delegations were discussing the Development Agenda in the context of which Member States would have an opportunity to discuss the question of impact assessment in detail. In the context of the Development Agenda, the Delegation believed that confusion should be avoided between the impact assessment and attempts which would make the Casablanca outcome more palatable to the developing countries. The Delegation clarified that that was not an issue that could make the Casablanca proposal acceptable to developing countries.
- 65. In response to a question by the Chair as to the modalities of the impact study, the Delegation of India explained that, in the context of the work undertaken by the Secretariat, the question of an impact assessment of the various norms and standards and laws that had been formulated on intellectual property could be undertaken with the assistance of WIPO. The Delegation, however, further explained that, since the SCP was currently discussing a very limited question, i.e., choosing between different packages, the impact assessment was not directly relevant here, however important the question of impact assessment as such might be.
- 66. The Delegation of Pakistan clarified that its proposal was to produce a comprehensive paper which could be prepared jointly with UNCTAD on the implications of the draft SPLT on public policy issues, such as national capacities to innovate, protection of national intellectual property etc., and that the terms of reference of such a paper might be carefully elaborated so that it fully addressed implications for Member States at different levels of development. The Delegation explained that the paper would lay the apprehensions that

might exist because of the incomplete understanding of the fairly complex issues under discussion. And secondly, it would identify the areas in the draft SPLT where caution might be advisable or where additional provisions might be proposed in order to meet the larger objective of the whole exercise. The Delegation considered that the utility of such an exercise would be that it would provide a more complete information with regard to the substance, namely, the SPLT, in terms of how it was likely to impact countries that were at various levels of development, and would help the countries move forward on taking the decision as to whether it was important to retain the draft SPLT's integrity in terms of all the issues that were on the table, or whether they could be fragmented.

- 67. In response to a question by the Chair as to the time necessary to prepare the impact assessment, the Delegation of Pakistan explained that the time frame should be agreed by the SCP taking into account the comprehensiveness of the study examining the implications of all the issues involved.
- 68. The Delegation of India stated that the point made by the Delegation of Pakistan captured its basic concern and demanded that, before proceeding with further harmonization at an increasingly higher level, Member States should establish a comprehensive study of the impact of the existing international laws and conventions on intellectual property and the likely impact of the laws that were being considered. The Delegation considered that it would have to be a comprehensive process because, at the end of it, many of the doubts and misgivings by developing countries, which had beset the work of the SCP, would probably be removed and they would then be assured that the proposals that were being made to them were indeed beneficial. The Delegation therefore supported the proposal by the Delegation of Pakistan.
- In view of trying to formulate some possible middle ground way forward which ultimately could hopefully be of benefit to all, the Delegation of Switzerland explained that, since November 2000, the SCP had held six sessions to discuss the scope and contents of the draft SPLT. While that work had led to many useful results, recent discussions in the SCP suggested that the current pace of discussion might not be as productive as it could and should be. According to the Delegation, there were several reasons for this lack of progress. One shortcoming was the sheer volume and complexity of issues to be covered at each SCP session with regard to the establishment of the SPLT. This led to inadequate discussions of certain issues and continuous postponement of others. Moreover, several provisions included in the draft Treaty had been extremely controversial in the SCP and were of a high political sensitivity to many of the delegations, especially to the ones from developing countries and least developed countries. Discussions on those divisive issues had therefore been the focus of many debates within the SCP and had, as a result, cut off and hampered the desired progress. The same, however, was true for several of the proposals tabled so far to the newly established IIM in the various papers. An expansive SPLT including all issues currently in the draft SPLT document and in the various papers in the IIM might therefore not be achievable in the near future. In order not to overload the boat, in view of the Delegation, all stakeholders should agree to a reduced package. A reduced package did not mean a "no" to other issues. It meant that the SCP tried to get the possible harvest, followed by the next harvest. The Delegation explained that that was why it was proposing a pragmatic approach aiming at an early and realistic result through a feasible package without adherence to a rigid framework, and why it considered that the package in document SCP/11/3, containing four technical patent law issues, namely, prior art, grace period, novelty and inventive step, should be dealt with in the SCP as a priority, and two issues, namely, sufficiency of disclosure and genetic resources, should be dealt with as a priority in the IGC. The Delegation stated that it

was willing to renew the mandate of the IGC which would end this year. Therefore, in its view, there should be no negative impact on any issue of interest for any delegation. The Delegation considered that nobody would lose anything following a procedure according to which the SCP as well as the IGC should make recommendations to the General Assembly as soon as they finished the discussion on the issues concerned. Every delegation would then have the possibility to decide in the General Assembly in the light of the outcome of both Committees whether they would ultimately benefit from the outcome and would therefore be willing to proceed to a Diplomatic Conference on the six issues. If the package was not interesting enough to proceed to a Diplomatic Conference, there would be no Diplomatic Conference. The Delegation noted that such a pragmatic approach would not be an obstacle for a comprehensive long-term study on the likely benefits of patent harmonization. However, the Delegation believed that it would guarantee that work in the SCP and the IGC would continue with a clear focus, and that a result which was for the benefit of all would be achieved in the near future.

- 70. In connection with the proposal by the Delegation of Pakistan concerning an impact assessment, the Delegation of the United States of America stated that it would have some serious misgivings about adopting such an approach. While it might disagree with other delegations on substantive questions and certain issues that had arisen, the Delegation shared the view expressed by the Delegations of Argentina, Brazil and others that transparency and inclusiveness in any process were indeed paramount. In that light, the Delegation was troubled by the proposal that the impact assessment would involve a body potentially involving a subset of the Secretariat in combination with another secretariat. Since no suggestion had been made regarding involvement by any Member State, the Delegation was concerned about the discussion in the light of transparency and inclusiveness. In its view, Member States would likely be better situated to determine impacts of particular suggestions and provisions, and in that light, the Delegation would have serious misgivings about such an impact assessment proposal.
- The Representative of the EAPO noted that practically all the delegations had spoken in favor of the continuation of the harmonization process of patent law. The Representative considered that the harmonization of patent law norms was only possible for such norms which existed in the legislation of the States, and where the consequences of applying those norms were known. Since norms such as prior art, grace period, novelty and inventive step all existed in the laws of the States, they could be successfully harmonized. The Representative, however, noted that national experiences and legislation to date varied with respect to genetic resources and traditional knowledge. The Representative also pointed out that, during earlier sessions of the SCP, clear information about how genetic resources and traditional knowledge could be applied in order to assess prior art and novelty had not been submitted in any clear form. Consequently, the Representative supported the contents of document SCP/11/3 so that the process of harmonization could be implemented in a package form. On the other hand, the Representative was of the view that it was important to look at questions such as how to define the source of genetic resources, how inventions should be disclosed and under what situation the disclosure of the source of genetic resources and traditional knowledge was required. It considered that accumulated experiences on those questions would objectively prove whether any change in the patent system was required.
- 72. The Representative of AIPPI noted that, although the work on the draft SPLT did not look too difficult when discussions started in November 2000, it became obvious that the problems were getting more and more complex to the extent that the SCP got into a dead-end and since the technical matters discussed should have been carefully set aside because they

were source of great divergences of opinion. The Representative explained that that was why AIPPI, concerned about efficiency and pragmatism, had voted the resolution limiting the SPLT to a certain number of issues, specifically on questions arising before the granting of a patent. AIPPI did not wish to discuss post-grant questions, such as counterfeiting, on which the SCP would still be discussing at the end of the third millennium. The Representative further explained that the resolution contained a limited number of points obviously concerning genetic resources, while feeling that this subject ought to be addressed by the IGC. The Representative pointed out that the AIPPI resolution had been unanimously adopted by the national groups, some 60 countries representing all stages of development: industrialized, developing and least developed countries. The aim of the resolution was to submit a proposal which, in his opinion, would make it possible within a short period of time to achieve a first treaty on harmonization, while other points would be dealt with in another treaty, i.e., step-by-step harmonization. Although AIPPI was not present in Casablanca, the Representative gave his strong support to the contents of document SCP/11/3, which, in his view, represented a good balance, fulfilled different conditions and safeguarded the interests of all countries. The Representative also considered that it provided a valid support of the interests of patent holders, since it made it possible to reduce the cost for obtaining a patent while avoiding national offices having to repeat certain tasks which were being done by others. In the Representative's view, the reduction of cost would be significant particularly for small enterprises and universities. Further, the Representative stressed the importance of an increased quality of granted patents, which was a matter of interest of patent holders as well as third parties.

- The Representative of MSF advocated a balanced intellectual property system that had the public interest at large as its main focus, while stating that he was not against patents. In his view, WIPO being a United Nations agency should include the public interest approach in its work. The Representative considered that, since intellectual property provisions affected prices and availability of medicines that were often priced out of the reach of the poor people who desperately needed them, he could not accept a world in which medical innovation could only be enjoyed by the wealthy. The Representative noted that such a principle had been acknowledged in the WTO's Doha Declaration on the TRIPS Agreement and Public Health, and that the consequences of the implementation of the TRIPS Agreement for public health only started being recognized. The Representative feared the emerging of new patent standards through WIPO's work before the consequences of the current global patent system were fully understood. He therefore recommended WIPO to cease its pursuit of higher levels of intellectual property protection through the SPLT process that would close off the flexibilities that were available under the TRIPS Agreement and confirmed in the Doha Declaration on the TRIPS Agreement and Public Health. He also expressed the fear of the birth of a "TRIPS II" agreement even before the beginning of the evaluation of the effect of the full implementation of the TRIPS Agreement. The Representative stated that, therefore, the SPLT process should be guided by the outcome of the debates on the WIPO Development Agenda, rather than moving ahead disconnected from that process.
- 74. The Representative of ABAPI said that, long before the submission of a proposal of the Development Agenda, his organization had supported a broad harmonization, because it believed that harmonization brought predictability and created an additional incentive for foreign direct investment in developing countries. The Representative recognized that the harmonization process was in a deadlock and, if such a deadlock persisted, there was a risk of losing the multilateral aspect of the current negotiations. He believed that compromise was the only way out. The Representative recalled that the Delegation of Pakistan suggested that the reduced package, not necessarily the Casablanca recommendation, would be acceptable if

it was a balanced one. Although the Representative would prefer a more complete harmonization, he also believed that a reduced package could be of benefit for developing countries from a development perspective. From the same perspective and according to the conclusion of the Roundtable of NGOs in London in 2003, the Representative suggested that the current proposal for a reduced package be supplemented by the provision of a first-to-file system. The Representative considered that that was a fundamental issue that should not be left outside the first package, and that such an inclusion seemed opportune in view of the recent submission of a bill in the US Congress to amend the United States' patent law. In order to address some of the concerns of developing countries, the Representative also suggested a provision to the effect that nothing in the treaty derogated from the objectives and principles of Articles 7 and 8 of the TRIPS Agreement. The Representative did not see how that could harm the harmonization effort. Further, the Representative noted that it might be worthwhile discussing conditional provisions similar to those of the TRIPS Agreement providing more time for harmonization for developing and least developed countries. In conclusion, the Representative also informed the Committee that his written submission included further comments about the negative impact of a possible system of international examination having binding effect and about the fact that developing countries should not be compelled, in bilateral trade agreements, to ratify a first substantive harmonization treaty before the harmonization process was concluded by the adoption of another treaty based on a second package.

The Representative of CPTech stated that the objectives in paragraph 3 of document SCP/11/3 did not match up with the work program contained in paragraph 4 of that document. The Representative explained that, in the United States of America, there was a growing dissatisfaction with the current state of the patent system in that country and a concern that the patent system in that country was out of control and had become harmful to the innovation process. The Representative considered that, not because the patent system itself was not playing an important role in promoting innovation, a bad implementation of the patent system could cause some damage. In that respect, the Representative referred to a proposal by the Business Software Alliance and Microsoft who had essentially imposed a system of compulsory licensing on the patent system of the United States of America because there was so much unhappiness with the low standard of patent quality in that country, with the consequence of constant litigation with those who had low-quality patents. In his view, the problem with the work program was that the issues that were driving the debate in the United States of America about low patent quality and low standards for patentability were not addressed in the patent harmonization agenda, and that this forced developing countries to adopt standards on inventive step moving more in the direction of a patent policy that would drive patents further and further into their economy, particularly in areas of concern, such as pharmaceuticals. In order to build confidence that there was a balanced agenda, and in view of the statement made by the "Friends of Development" and other documents such as the Doha Declaration on TRIPS Agreement and Public Health and the Geneva Declaration on the Future of WIPO, the latter of which was a large civil society experts and NGO statement, the Representative considered that it might be wise to think about a role for the SCP to address those areas that had to deal with the problems in the patent system before harmonizing the patent system. In other words, rather than focusing on how to drive the patent system further and further into society, it might be better to address the problems more directly, for example, addressing the problem of high cost of litigation to invalidate granted patents. The Representative considered that the Patent Cooperation Treaty (PCT) could deal with cooperation on issues of challenges of patentability. The Representative further considered that addressing anti-competitive practices was another area which would build confidence in developing countries. The Representative supported the statement by the Representative of

MSF that the SCP should focus on the implementation of the Doha Declaration to ensure the countries' follow-up with paragraph 4 of the Doha Declaration. He called upon the SCP to look at the implementation of Article 40 of the TRIPS Agreement concerning the control of anti-competitive practices in contractual licenses, in particular, to review how such a provision had been implemented in Member States, so that developing countries could fully understand how such a provision worked and what type of international cooperation was required. The Representative further stated that, in the area of standards and open-standards, particularly the development of technologies such as the Internet, there had been problems identifying submarine patents. He had proposed in the past that the PCT develop a facility or a separate instrument designed to deal with the issue of standards whereby a person who wanted to develop a standard could, through WIPO, advertise standards and then invite patentes to disclose whether the implemented standard would involve infringement of their patents.

- The Representative of APAA supported the Casablanca recommendation according to which four issues, namely prior art, grace period, novelty and inventive step, should be addressed in an accelerated process in the SCP, since such harmonization of prior art-related issues would improve the quality of patents, which would be beneficial for users and practitioners in Asian countries. The Representative explained that the discrepancy in the prior art standard needed to be solved in the near term because the Asian countries had some diversity with respect to the nations' capacity. In her view, if a universal prior art standard applied, offices with small capacity could better utilize prior art search results from other offices with bigger examination capacity, which would expedite the process of examination and secure the quality of patents. In addition, since there was an inter-Asian market, patent protection at least in other Asian countries and also in other countries was needed. In such a situation, the Representative noted that the universal prior art standard would increase the predictability of obtaining patents in foreign countries, thus it would bring cost effectiveness in seeking for global patent protection. She further noted that well-examined patents would be free from being revoked on the basis of hidden prior art and would not take away the public domain from third parties. The Representative drew the attention of the Committee to the Resolution adopted last year in Fukuoka, Japan, in which support for making progress in the discussion of SPLT was expressed. She concluded by saying that near-term solution in pre-grant issues, in particular prior art-related issues, was needed.
- The Representative of BIO noted that a vast majority of her organization's members, 77. more than 90%, were small companies that did not yet have any products in the market. They were approximately five to ten years away from producing innovative products in the area of health care, agriculture and environmental remediation. She stated that, while her members had ideas with great promise which were protected by patents, they needed efficient and cost-effective patent protection to turn their ideas into innovative biotechnology products and processes. In her view, without effective patent protection, they would not be able to entice investors to support expensive research and development that was required to develop those promising products. Their dependency on effective patent protection gave the Representative's organization an important stake in the discussion at the SCP. The Representative was of the view that, although a comprehensive treaty was many years away, members of her organization were anxious for a more efficient international patent protection system. She considered that reduced cost from an improved patent system would lead to more and better products. The Representative therefore supported the adoption of a work program that included the accelerated consideration of the provisions of the draft SPLT relating to prior art, grace period, novelty and inventive step.

- 78. The Delegation of Denmark fully supported the Casablanca recommendation, although it did not participate in the Casablanca Meeting.
- The Representative of FICPI, supporting document SCP/11/3, stated that FICPI had always supported, and continued to support, all the efforts towards international harmonization of substantive patent law. The Representative introduced its Resolution adopted unanimously last month in Seoul. The Resolution urged the members of the SCP to work quickly towards the conclusion of an agreement of such a harmonization, at least initially, on the basis of a reduced package of measures. The Resolution also noted with approval recent initiatives to introduce a first-to-file system in the United States of America and hoped that that could simplify some definition of novelty or perhaps a grace period, or even extend the reduced package to a first-to-file system. The Representative invited developing and least developed countries to appreciate that, if no progress was made in the SCP, the governments of the Trilateral Patent Offices would independently work on a reduced package. The Representative considered that, in such a case, developing countries would lose the opportunity to pursue their interests in or express their concerns about the harmonization process. The Representative further stated that its Resolution set out a tentative of establishing a minimum framework for the definition of the declaration of the origin of genetic resources.
- 80. The Representative of JIPA expressed the belief that the main objective of patent law itself was to develop industry in the country. As for users from industries, the Representative noted that business activities had become more global and there was no border that restricted the technical development in the territory. However, substantive patent law had not been harmonized for many years, and the Representative found that many difficulties existed due to the differences of national patent law. Hoping that harmonization of substantive patent law and rules would be realized as soon as possible, the Representative was of the opinion that the most important issue was an acceleration of the discussion on the SPLT. In that light, he supported the recommendation adopted in Casablanca.
- The Representative of CSC noted that many of the organization's members were at the moment involved in a campaign called "Make poverty history". He believed that the world had enough resources to feed and to house everyone, but that humankind had not yet managed to make social arrangements at the global or national level to fulfill such a goal of getting rid of hunger, making sure that every child was healthy, and that every man and woman, who so wanted, had a job. The Representative said that it was from that concern and perspective that he addressed the issue of harmonization and of intellectual property. His experience on harmonization had been to look at the effects that the TRIPS Agreement had had. The Representative said that there was a broad feeling among many members of his organization that the minimum standard of the TRIPS Agreement, though minimum, was already too high for many developing countries from the point of view of food security, provision of jobs, industrial development, and most important of all, the provision of medicines and essential products. He noted that although the TRIPS Agreement had many flexibilities, it had already removed flexibilities, for example, the TRIPS Agreement had removed the flexibility of allowing countries to examine patents in some sensitive areas, such as medicines, imposing a range of obligations that many countries were not yet in a position to undertake. He further noted that, as regards flexibilities such as compulsory licenses, in many countries, putting into effect such flexibilities firstly into the national law, and secondly into practice, was a very complex and difficult exercise. The Representative considered that that was why most developing countries had not yet mastered the art of making use of those flexibilities or even including them in their national law. Thus, in view of those problems of implementing a

harmonized international law, the Representative was very concerned about negotiations of the SPLT in the SCP to further harmonize those laws upward. The first problem that he had was access to medicines and limited access to information. Secondly, in relation to development, the Representative was of the view that there was evidence that too high a patent standard could hinder the development of technology and the adoption of technology of many local firms in developing countries. In his view, their access to inputs and technology were hindered by higher cost or by not being allowed to make use of those inputs. In relation to farmers and food security, the Representative noted that there was a concern about whether the trend of tightening intellectual property in the area of seeds due to both the International Union for the Protection of New Varieties of Plants (UPOV) as well as the TRIPS Agreement might make concerned people susceptible in the future to insecurity in relation to the cost of seeds and the availability and access of seeds. In that connection, the Representative noted that there was a heated debate in the TRIPS Council in relation to what could constitute a sui generis system for protection of seeds. The Representative considered that developing countries and consumers in those countries were rightfully and justifiably concerned that development principles had to be included, since there were special characteristics of developing countries that made them require special attention and special treatment. Firstly, developing countries were at the lower end of the development scale. In his view, it would take them a long time before they could compete. Secondly, most patents in developing countries were owned by foreign institutions and companies, due to the national treatment principle. As a consequence, firstly, if the material was patented, it would be very difficult for local people to make use of the material as an input into their own production, whereby too high a patent standard, especially if the patents were owned by foreigners, could hinder research and innovation and the production process by local firms in developing countries. Secondly, it became worse if, for example, foreigners were allowed to patent genetic materials and traditional knowledge belonging to a developing country. The farmers, researchers and enterprises in those developing countries might find it difficult to make use of their own indigenous knowledge or their own genetic materials, either as consumer products or as inputs or as technology in the production process. Referring to the case of the Neem patent at the European Patent Office, the Representative said that there were thousands of other examples of wrong patents. Finally, the Representative noted that, because of the foreign ownership of most of the patents, there was not only an imbalance within the TRIPS Agreement, which had been pointed out by Professor Bagwati from Columbia University and also by World Bank economists. According to the Representative, the World Bank estimated that developing countries were losing foreign exchange as a result of the foreign patenting within their countries. One estimate by Michael Finger, who was the founder of the World Bank Research Program, was that the increased obligation to developing countries as a result of the TRIPS Agreement had resulted in a loss to them of foreign exchange per year of 60 billion dollars which would more than offset the gains that they would get in other areas in the Uruguay Round. Therefore, the Representative was of the view that, if upward harmonization was continued according to the same principle as in the TRIPS Agreement, developing countries would lose out more in terms of foreign exchange, in terms of their ability to have food security or medical health security in relation to control biopiracy. Given that situation, the Representative stated that it was urgent that WIPO established a Development Agenda, but not only in rhetoric terms. If it was only established in rhetoric terms, but was not enforced, the Representative considered that it was better not to have a Development Agenda at all, because that would give the false impression of taking care of development. For the Development Agenda to really take root, the Representative stressed the importance of infusing the principles of development guided by the kinds of concerns in the negotiations in all the Committees of WIPO, particularly the SCP, which was perhaps the most important Committee because negotiations were now heading towards a new treaty. In

that context, the Representative viewed with extreme concern any proposal that only focused on issues that would lead to upward harmonization, but which would ignore issues that could balance the present patent system with policy flexibilities and public interest. As regards the Casablanca recommendation, the Representative was worried that the first stage would be the one and only stage, and the SPLT would contain only those four issues. The Representative was also concerned that focusing on those issues would remove existing flexibilities in the TRIPS Agreement, since the TRIPS Agreement provided flexibility to countries to determine what an invention was. For example, the Representative was concerned about the removal of flexibility wanting to institute the tenet of the patent system that living organism, at least naturally living organisms, could not and should not be patented because they were not an invention. There was a trend towards the patenting, for example, of human genes or even of animals, even if they were naturally occurring on the ground that the function of the gene sequence was discovered. In his view, it was up to countries to decide on the patentability of naturally occurring microorganisms and gene sequences. The Representative was afraid that, through the SPLT process, that flexibility would be removed and it would lead to further inappropriate upward harmonization of patent law. The Representative said that recent studies had shown that there were many deficiencies in the patent system of developed countries, such as the United States of America, pointing out that too many patents were inappropriately granted. He recommended to the Committee a book called "Innovation and its Discontents". In conclusion, the Representative stated that he could not support the Casablanca recommendation. The Representative felt that it was too biased on one side. He proposed that the SCP consider development issues and public interest issues at the top of its agenda, and unless and until this was guaranteed, negotiations towards patent harmonization should not continue. The Representative endorsed the proposal made by the Delegation of Pakistan regarding an impact assessment on the possible implications of the harmonization process on developing countries and the tools they needed for development before following the path of harmonization. Finally, the Representative said that the foundations for development had to be built in WIPO and in the SCP and that such a foundation was essential before proceeding to construct the building of that foundation. Only if there was a good foundation would the building be strong and withstand the test of time and would contribute to the millennium development goal.

- 82. The Delegation of Turkey stated that, as regards paragraph 4 of the Casablanca recommendation, not only the issues relating to prior art, grace period, novelty and inventive step, but also sufficiency of disclosure and genetic resources were important. The Delegation therefore considered that those six issues should be addressed together in the SCP for harmonization of patent law.
- 83. The Delegation of Pakistan clarified that its proposal on impact assessment would not just ensure transparency through an intergovernmental process to agree on the terms of reference of the study, but would ensure elements of equity, since implications of the SPLT provisions on the whole range of issues would be covered, and would gain efficiency, since the study would help countries taking informed decisions on how to proceed in the negotiations. The Delegation also clarified that it was of the view that a comprehensive approach of negotiating all current elements of the draft SPLT was the preferable approach, and that a more limited early harvest approach could be considered only if the limited package contained a balanced set of elements which addressed the concerns of all groups of countries and were not arbitrarily selected as in the case of the four issues of the Casablanca process.
- 84. The Chair noted that everybody had been looking for a worthy solution and a promising future workplan of the SCP, had emphasized the need to harmonize the process and had

aspired to find a balance of interests in a positive and constructive manner. The Chair further noted that it was also important to emphasize the role and participation of the non-governmental organizations which represented the interests of the business community. In substance, the Chair summarized the discussion by saying that the SCP had discussed two proposals on the future work program, and that most of the industrialized countries supported the workplan contained in document SCP/11/3, while the positions of developing countries had been confined in document SCP/11/4. A proposal by the Delegation of Switzerland in view of finding a way to ensure the further development of this process had been supported by many countries, but opposed by others.

- 85. The Chair expressed the hope that the SCP might formulate a recommendation that could be submitted to the forty-first session of the General Assembly, which would be a move forward. He considered that if the delegations simply expressed their views without making clear recommendations to the General Assembly, then inevitably, they would once again have to repeat different positions and concerns and call for the establishment of a constructive approach. The Chair recognized that the process was not only technical, but also involved political aspects, and that the SCP had limited time for the discussion. The Chair further said that, although it might be possible to find a solution for the technical aspects, today, the process of globalization was creating new challenges for the SCP, which should take into account the interests of all countries in a balanced way. In his view, if the SCP could not find a solution to those questions, ultimately, it would not be answering the challenge of addressing the development of society as a whole, because intellectual property related to legal issues as well as to political issues.
- 86. The Delegation of Argentina reserved its position regarding the option of a recommendation to the General Assembly. The Delegation said that, as it had already stated, it had to examine the timeliness, the possibility and the need to put a resolution before the General Assembly.

#### CONCLUSION OF THE MEETING

### Agenda Item 7: Summary by the Chair

- 87. The draft Summary by the Chair (document SCP/11/5 Prov.) was noted with certain amendments which were included in the final version (document SCP/11/5).
- 88. The SCP noted the Summary by the Chair, which was agreed by all, and further noted that the official record of the session would be contained in the report of the session. The report would reflect all the interventions made during the meeting, and would be adopted in accordance with the procedure agreed by the SCP at its fourth session (see document SCP/4/6, paragraph 11), which provided for the members of the SCP to comment on the draft report made available on the SCP Electronic Forum. The Committee would then be invited to adopt the draft report, including the comments received, at its following session.

### Agenda Item 8: Closing of the Session

89. The Chair closed the session.

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90. In accordance with the procedure previously adopted by the Committee (see paragraph 88, above), Committee members and observers are invited to comment on this draft report, which is being made available on the SCP Electronic Forum. The Committee will be invited to adopt the report at its twelfth session.

[Annex follows]

#### ANNEXE/ANNEX

#### LISTE DES PARTICIPANTS/LIST OF PARTICIPANTS

### I. ÉTATS MEMBRES/MEMBER STATES

(dans l'ordre alphabétique des noms français des États) (in the alphabetical order of the names in French of the States)

### AFRIQUE DU SUD/SOUTH AFRICA

Nakedi Desmond MARUMO, Registrar of Patents, Trade Marks, Designs and Copyrights, Companies and Intellectual Property Registration Office, Department of Trade and Industry, Pretoria

<dmarumo@cipro.gov.za>

Elena ZDRAVKOVA (Ms.), Deputy Registrar of Patents and Designs, Companies and Intellectual Property Registration Office, Department of Trade and Industry, Pretoria <ezdravkova@cipro.gov.za>

Simon Z. QOBO, First Secretary, Permanent Mission, Geneva

### ALBANIE/ALBANIA

Diana SINOJMERI (Mrs.), Director in Charge, General Directorate of Patents and Trademarks, Tirana <dsinojmeri@alpto.gov.al>

### ALGÉRIE/ALGERIA

Mourad SADOU, directeur des brevets, Institut national algerien de la propriété industrielle, Algiers

<sadou@inapi.org>

Leila BOUDINA (Mme), assistante du Directeur général, Institut national algerien de la propriété industrielle, Algiers <br/> <br/>boudina@inapi.org>

#### ALLEMAGNE/GERMANY

Tammo ROHLACK, Counsellor, Patent Law Division, Federal Ministry of Justice, Berlin <rohlack-ta@bmj.bund.de>

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### ANTIGUA-ET-BARBUDA/ANTIGUA AND BARBUDA

Laurie FREELAND-ROBERTS (Mrs.), Registrar of Intellectual Property and Commerce, Registrar's Office, St. John's <a href="mailto:kibrogeneous.com/"><a href="mailto:kibrogeneous.com/">kibrogeneous.com/<a href="mailto:kibrogeneou

### ARABIE SAOUDITE/SAUDI ARABIA

Fahd ALAJLAN, Director, Technical Services, General Directorate of Patents, King Abdul-Aziz City for Science and Technology (KACST), Riyadh <fajlan@kacst.edu.sa>

### ARGENTINE/ARGENTINA

Alberto J. DUMONT, Embajador, Representante Permanente, Misión Permanente, Ginebra

Marta GABRIELONI (Sra.), Consejera, Misión Permanente, Ginebra

Eduardo Ricardo ARIAS, Comisario, Administracion Nacional de Patentes, Instituto Nacional de la Propiedad Industrial, Buenos Aires <earias@inpi.gov.ar>

### AUSTRALIE/AUSTRALIA

Ian HEATH, Director General, IP Australia, Phillip ACT <ian.heath@ipaustralia.gov.au>

Dave HERALD, Deputy Commissioner of Patents, Deputy Registrar of Designs, IP Australia, Phillip ACT <Dherald@ipaustralia.gov.au>

### AUTRICHE/AUSTRIA

Johannes WERNER, International Relations, Austrian Patent Office, Vienna <johannes.werner@patentamt.at>

### **BANGLADESH**

Mahbub ZAMAN, Minister (Political), Permanent Mission, Geneva <zaman-mahbub@hotmail.com>

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# BÉLARUS/BELARUS

Natallia SUKHANAVA (Mrs.), Head, Substantive Examination Department, National Center of Intellectual Property, Minsk

#### **BELGIQUE/BELGIUM**

Katrien VAN WOUWE (Mme), conseiller adjoint du Service public fédéral économie, petites et moyennes entreprises (PME), classes moyennes et énergie, Direction générale de la régulation et de l'organisation du marché, Office de la propriété intellectuelle, Bruxelles <katrien.vanwouwe@mineco.fgov.be>

# BÉNIN/BENIN

Juliette AYITE (Mme), directrice du Centre national de la propriété industrielle (CENAPI), Ministère de l'industrie, du commerce et de la promotion de l'emploi, Cotonou <a y ijuliette @yahoo.fr>

## BRÉSIL/BRAZIL

Luiz Felipe DE SEIXAS CORRÊA, ambassadeur, représentant permanent, Mission permanente, Genève

Henrique CHOER MORAES, Ministère des relations extérieures, Brasilia <a href="mailto:hcmoraes@mre.gov.br">hcmoraes@mre.gov.br</a>

Maria Celi S. MOREIRA DE PAULA (Mme), directrice adjointe des brevets, Institut national de la propriété industrielle, Ministère du développement, de l'industrie et du commerce extérieur, Rio de Janeiro <celi@inpi.gov.br>

José Carlos ARANJO FILHO, analyste, Commerce extérieur, Brasilia <jose.filho@desenvolvimento.gov.br>

#### **BULGARIE/BULGARIA**

Svelta YORDANOVA (Mrs.), State Examiner, Bulgarian Patent Office, Sofia <siordanova@bpo.bg>

#### CAMBODGE/CAMBODIA

NHEM Phally (Miss), Chief, Patent Office, Department of Industrial Property, Ministry of Industry, Mines and Energy, Phnom Penh <nhemphally@yahoo.com>

TITH Rithipol, First Secretary, Permanent Mission, Geneva <rithipol6@hotmail.com> <cambodge@bluewin.ch>

# **CANADA**

David TOBIN, Commissioner of Patents, Registrar of Trademarks and Chief Executive Officer, Canadian Intellectual Property Office, Gatineau, Quebec <tobin.david@ic.gc.ca>

Alan TROICUK, Senior Counsel, Legal Services, Industry Canada, Department of Justice, Gatineau, Quebec <troicuk.alan@ic.gc.ca>

W.B. (Barney) DE SCHNEIDER, Director, Patent Branch, Canadian Intellectual Property Office, Gatineau, Quebec <deSchneider.Barney@ic.gc.ca>

J. Scott VASUDEV, Project Officer, Patent Branch, Canadian Intellectual Property Office, Gatineau, Quebec <vasudev.scott@ic.gc.ca>

Sanjay VENUGOPAL, Acting Chief, International Affairs, Canadian Intellectual Property Office, Gatineau, Quebec <venugopal.sanjay@ic.gc.ca>

#### CHILI/CHILE

Bernardita ESCOBAR (Mrs.), Minister's Advisor, Santiago <a href="mailto:seecobar@economia.cl">bescobar@economia.cl</a>

Maximiliano SANTA CRUZ, First Secretary, Permanent Mission, Geneva

#### CHINE/CHINA

YIN Xintian, Director General, Legal Affairs Department, State Intellectual Property Office, Beijing

<yinxintian@sipo.gov.cn>

HE Yuefeng, Director of Division II, Legal Affairs Department, State Intellectual Property Office, Beijing

<heyuefeng@sipo.gov.cn>

HU Yuzhang, Program Officer, International Cooperation Department, State Intellectual Property Office, Beijing

<huyuzhang@sipo.gov.cn>

#### COLOMBIE/COLOMBIA

Ricardo VELEZ BENEDETTI, Ministro Consejero, Misión Permanente, Ginebra

# **COSTA RICA**

Vanessa COHEN (Sra.), Directora, Registro Nacional de la Propiedad Intelectual, Zapote, San Jose

<vcohen@rnp.go.cr>

Alejandro SOLANO-ORTIZ, Ministro Consejero, Misión Permanente, Ginebra <alejandro.solano@ties.itu.int>

# CÔTE D'IVOIRE

Sidibe DAOUDA, chef du Service des brevets et signes distinctifs, Office ivoirien de la propriété intellectuelle (OIPI), Abidjan

<tienkolemane@yahoo.fr>

Désiré BOSSON-ASSAMOI, conseiller, Mission permanente, Genève <cotedivoire@bluewin.ch>

#### CROATIE/CROATIA

Jasminka ADAMOVIĆ (Mrs.), Head, Administration-Legal Section, Patent Department, State Intellectual Property Office, Zagreb <jasminka.adamovic@dziv.hr>

Zlata SLADIĆ (Mrs.), Head, Patent Examining Department, State Intellectual Property Office, Zagreb <zlata.sladic@patent.htnet.hr>

#### DANEMARK/DENMARK

Jesper KONGSTAD, Director General, Danish Patent and Trademark Office, Ministry of Economic and Business Affairs, Taastrup <jko@dkpto.dk>

Anne REJNHOLD JØRGENSEN (Mrs.), Director, International Affairs, Danish Patent and Trademark Office, Ministry of Economic and Business Affairs, Taastrup <arj@dkpto.dk>

# ÉGYPTE/EGYPT

Naéla GABR (Mrs.), Ambassador, Permanent Representative, Permanent Mission, Geneva

Amin MELEIKA, Deputy Permanent Representative, Permanent Mission, Geneva

Nival M. NABIL (Mrs.), Head, Legal Department, Patent Office, Ministry of Scientific Research, Academy of Scientific Research and Technology, Cairo <nivalpat@hotmail.com>

Hammad Sudeek Hassan MURAD, Head, Legal Department, Patent Office, Ministry of Scientific Research, Academy of Scientific Research and Technology, Cairo

Ragui EL-ETREBY, First Secretary, Permanent Mission, Geneva

#### ÉOUATEUR/ECUADOR

Rafael PAREDES PROAÑO, Ministro, Representante Permanente Adjunto, Misión Permanente, Ginebra <mission.ecuador@ties.itu.int>

#### ESPAGNE/SPAIN

Javier COLLAR, Ministro, Misión Permanente, Ginebra

David GARCÍA LÓPEZ, Jefe, Servicio de Relaciones Internacionales UE-OEP, Departamento de Coordinación Jurídica y Relaciones Internacionales, Oficina Española de Patentes y Marcas, Madrid <david.garcia@oepm.es>

Carmen LENCE REIJA (Sra.), Técnico Superior Jurista, Departamento de Patentes e Información Tecnológica, Oficina Española de Patentes y Marcas, Madrid <carmen.lence@oepm.es>

# ÉTATS-UNIS D'AMÉRIQUE/UNITED STATES OF AMERICA

Lois E. BOLAND (Ms.), Director, Office of International Relations, Patent and Trademark Office, Department of Commerce, Alexandria, Virginia <lois.boland@uspto.gov>

Charles A. PEARSON, Director, PCT Legal Administration, Patent and Trademark Office, Department of Commerce, Alexandria, Virginia <cpearson@uspto.gov>

Charles R. ELOSHWAY, Patent Attorney, Office of International Relations, Patent and Trademark Office, Department of Commerce, Alexandria, Virginia <charles.eloshway@uspto.gov>

Lisa M. CARLE (Mrs.), Counsellor for Economic and Science Affairs, Permanent Mission, Geneva <carleLM@state.gov>

Jon P. SANTAMAURO, Intellectual Property Attaché, Permanent Mission, Geneva <jon\_santamauro@ustr.eop.gov>

# ÉTHIOPIE/ETHIOPIA

Eftihia MARIO (Miss), Team Leader, Ethiopian Intellectual Property Office, Addis Ababa <eftihiamr@yahoo.com>

# EX-RÉPUBLIQUE YOUGOSLAVE DE MACÉDOINE/THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Irena JAKIMOVSKA (Ms.), Head, Patents and Technology Watch Department, State Office of Industrial Property, Skopje <irenaj@ippo.gov.mk>

#### FÉDÉRATION DE RUSSIE/RUSSIAN FEDERATION

Boris SIMONOV, Director General, Federal Service for Intellectual Property, Patents and Trademarks, Moscow <simonov@rupto.ru>

Evgeny ZAGAYNOV, Counsellor, Permanent Mission, Geneva <evgeny.zagaynov@ties.itu.int> <mission.russian@ties.itu.int>

Llya GRIBKOV, Third Secretary, Permanent Mission, Geneva

#### FINLANDE/FINLAND

Maarit LÖYTÖMÄKI (Ms.), Deputy Director, National Board of Patents and Registration, Helsinki

<maarit.loytomaki@prh.fi>

Riitta LARJA (Ms.), Coordinator, International and Legal Affairs, National Board of Patents and Registration, Helsinki <riitta.larja@prh.fi>

Heli SIUKONEN (Ms.), Senior Adviser, Ministry of Trade and Industry, Helsinki <heli.siukonen@ktm.fi>

#### **FRANCE**

Martine HIANCE (Mme), directrice générale adjointe de l'Institut national de la propriété industrielle (INPI), Paris <mhiance@inpi.fr>

Gilles REQUENA, chef de service, affaires européennes et internationales, Institut national de la propriété industrielle (INPI), Paris <grequena@inpi.fr>

Gilles BARRIER, premier secrétaire, Mission permanente, Genève

# GÉORGIE/GEORGIA

David DZAMUKASHVILI, Deputy Director General, National Intellectual Property Center, Tbilisi <dzdato@yahoo.com>

#### GRÈCE/GREECE

Theodora SIMITSI (Mrs.), Attorney-at-Law, International Affairs and Legal Matters, Industrial Property Organisation, Athens <a href="mailto:dsim@obi.gr">dsim@obi.gr</a>

#### HONGRIE/HUNGARY

Krisztina KOVA'CS (Ms.), Deputy Head, Industrial Property Law Section, Hungarian Patent Office, Budapest <a href="mailto:krisztina.kovacs@hpo.hu">krisztina.kovacs@hpo.hu</a>

Veronika CSERBA, First Secretary, Permanent Mission, Geneva <veronika.cserba@ties.itu.int>

#### INDE/INDIA

Naresh Nandan PRASAD, Joint Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce and Industry, New Delhi <nareshnp@nic.in>

C. BALAKRISHNAN, Joint Secretary, Department of Secondary and Higher Education, Ministry of Human Resource Development, New Delhi <a href="mailto:kondary.com/character/"><cbalakrishnan.edu@sb.nic.in></a>

Debabrata SAHA (Mrs.), Deputy Permanent Representative, Permanent Mission, Geneva

#### INDONÉSIE/INDONESIA

Azmi DAHLAN, Government Official, Tangerang

Dewi Ratih KARTONEGORO, Second Secretary, Permanent Mission, Geneva

# IRAN (RÉPUBLIQUE ISLAMIQUE D')/IRAN (REPUBLIC ISLAMIC OF)

Seyed Kazem SAJJADPOUR, Ambassador, Deputy Permanent Representative, Permanent Mission, Geneva

Hekmatollah GHORBANI, Legal Counsellor, Permanent Mission, Geneva

Hamid AZIZI MORAD POUR, Patent Expert, Registration of Deeds and Properties Organization, Tehran <a href="mailto:kamidazizimp@yahoo.com">kamidazizimp@yahoo.com</a>

#### IRLANDE/IRELAND

Jacob RAJAN, Head, Patents Section, Intellectual Property Unit, Department of Enterprise, Trade and Employment, Dublin <jacob\_rajan@entemp.ie>

#### ITALIE/ITALY

Maria Ludovica AGRO (Mme), directrice, Office italien des brevets et des marques, Rome <ludovica.agro@attivitaproduttive.gov.it>

#### JAMAHIRIYA ARABE LIBYENNE/LIBYAN ARAB JAMAHIRIYA

Khamees M. IHDAYB, Head, Intellectual Property Division, National Bureau for Research and Development, Tripoli <kihdayb@yahoo.com>

Hassan HABIBI, Head, Industrial Property Section, Industrial Research Center, Tripoli

Esounni ABDALLAH, General Committee of Industry and Commerce, Trade Marks Office, Tripoli

<esouni2003@yahoo.co.uk>

Hanan Bahgat ALTURGMAN, Researcher, Trade Marks Unit, IP Office, Tripoli <a href="mailto:rhanan\_alturgman@hotmail.com">hotmail.com</a>

Nasser ALZAROUG, First Secretary, Permanent Mission, Geneva

#### JAPON/JAPAN

Shinjiro ONO, Deputy Commissioner, Japan Patent Office, Tokyo

Satoshi MORIYASU, Director, International Cooperation Office, International Affairs Division, Japan Patent Office, Tokyo

Hiroki KITAMURA, Deputy Director, International Affairs Division, Japan Patent Office, Tokyo

Shintaro TAKAHARA, First Secretary, Permanent Mission, Geneva

#### **KENYA**

Jean W. KIMANI, First Counsellor, Permanent Mission, Geneva <jeankimani@hotmail.com>

#### KIRGHIZISTAN/KYRGYZSTAN

Jenish SARGALDAKOVA (Mrs.), Director of Examination Center, State Agency of Science and Intellectual Property under the Government of the Kyrgyz Republic, Bishkek <kygyzpatent@infotel.kg>

# KOWEÏT/KUWAIT

Ali AL HAJERI, Assistant Manager, Patent and Trade Marks Department, Ministry of Commerce and Industry, Safat <al\_hajeri666@yahoo.com>

Fahed BAGER, Head, Section of Intellectual Property, Ministry of Commerce and Industry, Safat

<fahadbager64@hotmail.com>

#### **LETTONIE/LATVIA**

Guntis RAMANS, Deputy Director, Patent Office of the Republic of Latvia, Riga <gr@lrpv.lv>

#### LITUANIE/LITHUANIA

Žilvinas DANYS, Deputy Head, Division of Law and International Affairs, State Patent Bureau of the Republic of Lithuania, Vilnius <z.danys@vpb.lt>

#### **LUXEMBOURG**

Khalid LARGET, chargé de mission, Direction de la propriété intellectuelle, Ministère de l'économie et du commerce extérieur, Luxembourg <khalid.larget@eco.etat.lu>

Claude SAHL, Direction de la propriété industrielle et des droits intellectuels, Ministère de l'économie, Luxembourg <claude.sahl@eco.etat.lu>

Christiane DALEIDEN-DISTEFANO (Mme), représentante permanente adjointe, Mission permanente, Genève

#### MALAISIE/MALAYSIA

WAN A. YUSRI Wan Abdul Rashid, Second Secretary, Permanent Mission, Geneva

#### MALTE/MALTA

Tony BONNICI, First Secretary, Permanent Mission, Geneva <a href="mailto:konnici@gov.mt">konnici@gov.mt</a>

#### MAROC/MOROCCO

Nafissa BELCAID (Mme), chef du Département des brevets et des dessins et modèles industriels, Office marocain de la propriété industrielle et commerciale, Casablanca <nafissa.belcaid@ompic.org.ma> <nbelcaid@hotmail.com>

Mhamed SIDI EL KHIR, conseiller, Mission permanente, Genève

#### MEXIQUE/MEXICO

Fabián R. SALAZAR GARCIA, Director Divisional de Patentes, Instituto Mexicano de la Propiedad Industrial, Mexico <rsalazar@impi.gob.mx>

Andrea LARRONDO-SCHOELLY (Sra.), Coordinadora Departamental de Negociaciones Internacionales, Instituto Mexicano de la Propiedad Industrial, Mexico <alarrondo@impi.gov.mx>

#### **MYANMAR**

Khin Oo HLAING, Second Secretary, Permanent Mission, Geneva <a href="mailto:klingkhinoo@yahoo.com">khin Oo HLAING, Second Secretary, Permanent Mission, Geneva</a>

# NIGÉRIA/NIGERIA

Usman SARKI, Minister Counsellor, Permanent Mission, Geneva <usmansarki1959@yahoo.com>

Maigari BUBA, First Secretary, Permanent Mission, Geneva <maigaribuba@yahoo.co.uk>

# NORVÈGE/NORWAY

Lisbeth WOLTHER (Mrs.), Director, Legal and Political Affairs, Norwegian Patent Office, Oslo

<lwo@patentstyret.no>

Eirik RØDSAND, Acting Head, Law Section, Norwegian Patent Office, Oslo <eir@patentstyret.no>

#### NOUVELLE-ZÉLANDE/NEW ZEALAND

Warren HASSETT, Senior Analyst, Regulatory and Competition Policy Branch, Ministry of Economic Development, Wellington <a href="mailto:kwarren.hassett@med.govt.nz">kwarren.hassett@med.govt.nz</a>

#### **OMAN**

Amina Blint Salim AL-JELANI (Mrs.), Head, Copyright Section, Ministry of Commerce and Industry, Muscat <umm-Fahad2000@yahoo.co.uk>

Fatima AL-GHAZALI (Mrs.), Economic Counsellor, Permanent Mission, Geneva

#### **PAKISTAN**

Masood KHAN, Ambassador, Permanent Representative, Permanent Mission, Geneva

Rizwan Saeed SHEIKH, First Secretary, Pemanent Mission, Geneva <rizsheikh@hotmail.com>

#### PAYS-BAS/NETHERLANDS

Albert SNETHLAGE, Legal Adviser on Industrial Property, Innovation Directorate, Ministry of Economic Affairs, The Hague <a.snethlage@minez.nl>

N.O.M. (Nikki) RETHMEIER, Patent Examiner Biotechnology, Netherlands Patent Office, Rijswijk

<n.rethmeier@octrooicentrum.nl>

#### PÉROU/PERU

Alejandro NEYRA, Second Secretary, Permanent Mission, Geneva

#### **PHILIPPINES**

Enrique A. MANALO, Ambassador, Permanent Representative, Permanent Mission, Geneva

Nevah D. VELASCO (Ms.), Assistant Division Chief, International Patent System Division, Bureau of Patents, Intellectual Property Office, Makati City <nevah.velasco@ipophil.gov.ph>

Raly L. TEJADA, Second Secretary, Permanent Mission, Geneva

#### POLOGNE/POLAND

Grazyna LACHOWICZ, Head, International Cooperation Unit, Patent Office of the Republic of Poland, Warsaw <glachowicz@uprp.pl>

#### **PORTUGAL**

Isabel AFONSO, Director of Patents, National Institute of Industrial Property, Ministry of Economy, Lisbon <imafonso@inpi.pt>

José Sergio de CALHEIROS DA GAMA, Legal Counsellor, Permanent Mission, Geneva <mjgama@freesurf.ch>

# RÉPUBLIQUE DE CORÉE/REPUBLIC OF KOREA

Dae-kyo JANG, Deputy Director, Patent Examination Policy Division, Korean Intellectual Property Office, Taejon <a href="mailto:cyber4you@kipo.go.kr">cyber4you@kipo.go.kr</a>

Hoi-kee LEE, Judge, Patent Court, Taejon <jdhklee@scourt.go.kr>

Jooik PARK, Intellectual Property Attaché, Permanent Mission, Geneva <a href="mailto:kang7200@dreamwiz.com">kang7200@dreamwiz.com</a>

# RÉPUBLIQUE DÉMOCRATIQUE DU CONGO/DEMOCRATIC REPUBLIC OF THE CONGO

Fidèle SAMBASSI KHAKESSA, ministre conseiller, Mission permanente, Genève <missionrdc@bluewin.ch>

#### RÉPUBLIQUE DE MOLDOVA/REPUBLIC OF MOLDOVA

Ion DANILIUC, Deputy Director General, State Agency on Intellectual Property, Kishinev <office@agepi.md>

Eugen REVENCO, Deputy Permanent Representative, Permanent Mission, Geneva <eugen.revenco@bluewin.ch>

#### RÉPUBLIQUE DOMINICAINE/DOMINICAN REPUBLIC

Gladys Josefina AQUINO (Srta.), Consejera, Misión Permanente, Ginebra

#### RÉPUBLIQUE TCHÈQUE/CZECH REPUBLIC

Eva SCHNEIDEROVÁ (Mrs.), Deputy Director, Patent Department, Industrial Property Office, Prague <eschneiderova@upv.cz>

#### ROUMANIE/ROMANIA

Liviu BULGĂR, Director, Legal and International Cooperation Department, State Office for Inventions and Trademarks, Bucharest liviu.bulgar@osim.ro>

Ion VASILESCU, Director, Patents Directorate, State Office for Inventions and Trademarks, Bucharest

<ion.vasilescu@osim.ro>

Viorel PORDEA, Head, Regular National Filing, Preliminary Examination, National Registers, Fees Division, State Office for Inventions and Trademarks, Bucharest <office@osim.ro>

Livia PUSCARAGIU (Miss), Third Secretary, Permanent Mission, Geneva <a href="mailto:slivia.puscaragiu@romaniaunog.org">slivia.puscaragiu@romaniaunog.org</a>

#### ROYAUME-UNI/UNITED KINGDOM

Ronald John MARCHANT, Chief Executive and Comptroller-General, The Patent Office, Newport

<ron.marchant@patent.gov.uk>

Roger WALKER, Divisional Director, The Patent Office, Newport <roger.walker@patent.gov.uk>

Hugh EDWARDS, Legal Section, The Patent Office, Newport <a href="https://www.newport.gov.uk">hugh.edwards@patent.gov.uk</a>

Pierre OLIVIERE, Policy Advisor, The Patent Office, Newport pierre.oliviere@patent.gov.uk>

#### SÉNÉGAL/SENEGAL

André BASSE, premier secrétaire, Mission permanente, Genève <andrebasse814@hotmail.com>

#### SERBIE ET MONTÉNÉGRO/SERBIA AND MONTENEGRO

Ivana MILOVANOVIĆ (Mrs.), Third Secretary, Permanent Mission, Geneva <ivana.milovanovic@ties.itu.int>

#### SINGAPOUR/SINGAPORE

Simon SEOW, Deputy Director (Patents) and Legal Counsel, Intellectual Property Office, Singapore <simon seow@ipos.gov.sg>

#### SOUDAN/SUDAN

Farida Abdalla RAIHAN (Ms.), Senior Legal Adviser and Head, Patent Division, Ministry of Justice, Khartoum

# SUÈDE/SWEDEN

Carl JOSEFSSON, Deputy Director, Division for Intellectual Property and Transport Law, Ministry of Justice, Stockholm <carl.josefsson@justice.ministry.se>

Marie ERIKSSON (Ms.), Head, Legal Affairs, Patent Department, Swedish Patent and Registration Office, Stockholm <marie.eriksson@prv.se>

#### SUISSE/SWITZERLAND

Felix ADDOR, directeur général adjoint et chef, Division juridique et affaires internationales, Institut fédéral de la propriété intellectuelle, Berne <felix.addor@ipi.ch>

Alexandra GRAZIOLI (Mme), conseillère juridique, Relations commerciales internationales, Institut fédéral de la propriété intellectuelle, Berne <alexandra.grazioli@ipi.ch>

Christine VETTER (Mme), Service juridique, brevets et designs, Institut fédéral de la propriété intellectuelle, Berne <christine.vetter@ipi.ch>

#### THAÏLANDE/THAILAND

Panisa SUWANMATAJARN (Miss), Department of Intellectual Property, Ministry of Commerce, Bangkok <panisas@moc.go.th>

Supavadee CHOTIKAJAN, Second Secretary, Permanent Mission, Geneva <supac@mfa.go.th>

#### TUNISIE/TUNISIA

Hamadi FERJANI, chargé du dépôt des brevets, Institut national de la normalisation et de la propriété industrielle, Tunis <inorpi@email.ati.tn>

Elyes LAKHAL, conseiller, Mission permanente, Genève <elakhal@bluewin.ch> <mission.tunisia@ties.itu.int>

# TURQUIE/TURKEY

Ayse Giil ULUÇAY (Ms.), Engineer, Turkish Patent Institute, Ankara <aysegul.ulucay@tpe.gov.tr>

Yaşar ÖZBEK, Legal Counsellor, Permanent Mission, Geneva <yozbek@yahoo.fr>

#### **UKRAINE**

Inna ZAVALNA (Ms.), Director, Department of Civil Law and Entrepreneurship, Ministry of Justice, Kyiv <zavalna@minjust.gov.ua>

Anatoliy GORNISEVYCH, Deputy Director, Ukrainian Industrial Property Institute, State Department of Intellectual Property, Ministry of Education and Science, Kyiv <gornisevych@ukrpatent.org>

Larysa AKSONOVA (Ms.), Senior Specialist, Law Division, Ukrainian Industrial Property Institute, State Department of Intellectual Property, Ministry of Education and Science, Kyiv <l.aksionova@ukrpatent.org>

Tamara SHEVELEVA (Ms.), Assistant of the Director, Ukrainian Industrial Property Institute, State Department of Intellectual Property, Ministry of Education and Science, Kyiv <sheveleva@stip.gov.ua>

#### **URUGUAY**

Alejandra de BELLIS (Ms.), First Secretary, Permanent Mission, Geneva <mission.uruguay@urugi.ch>

#### **VENEZUELA**

Eduardo SAMÁN NAMEL, Director General, Servicio Autónomo de la Propiedad Intelectual, Caracas <samanedu@sapi.gob.ve>

Alessandro PINTO DAMIANI, Secundo Secretario, Misión Permanente, Ginebra <damiani24@hotmail.com>

# **VIET NAM**

LE Huu Hung, First Secretary, Permanent Mission, Geneva <lehhng@yahoo.com>

#### ZAMBIE/ZAMIBIA

Mathias DAKA, Deputy Permanent Representative, Permanent Mission, Geneva <mdaka53876@aol.com>

# II. ORGANISATIONS INTERGOUVERNEMENTALES/ INTERGOVERNMENTAL ORGANIZATIONS

# ORGANISATION MONDIALE DU COMMERCE (OMC)/WORLD TRADE ORGANIZATION (WTO)

Jayashree WATAL (Mrs.), Counsellor, Intellectual Property Division, Geneva <jayashree.watal@wto.org>

Wolf MEIER-EWERT, Legal Affairs Officer, Intellectual Property Division, Geneva <wolf.meier.ewert@wto.org>

# OFFICE EUROPÉEN DES BREVETS (OEB)/EUROPEAN PATENT OFFICE (EPO)

Wim VAN DER EIJK, Principal Director, International Affairs and Patent Law, Munich <wvdeijk@epo.org>

Panagiotis RIGOPOULOS, Lawyer, International Legal Affairs, Munich gopoulos@epo.org>

# ORGANISATION AFRICAINE DE LA PROPRIÉTÉ INTELLECTUELLE (OAPI)/ AFRICAN INTELLECTUAL PROPERTY ORGANISATION (OAPI)

Wéré Régine GAZARO, chef du Service des brevets, Yaoundé <were\_regine@yahoo.fr> <wereregine@hotmail.com>

# ORGANISATION EURASIENNE DES BREVETS (OEAB)/EURASIAN PATENT ORGANIZATION (EAPO)

Victor B. TALIANSKY, Director, Examination Division, Moscow <ira><info@eapo.org>

Ancetoly PAVLOVSKY, Eurasian Patent Attorney, Moscow <pat@gorodissky.ru>

# ORGANISATION RÉGIONALE AFRICAINE DE LA PROPRIÉTÉ INTELLECTUELLE (ARIPO)/AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

John N. KABARE, Examiner, Harare <aripo@ecoweb.co.zw> <info@aripo.wipo.net>

# COMMISSION EUROPÉENNE (CE)/EUROPEAN COMMISSION (EC)

Mirjam SÖDERHOLM (Mrs.), Deputy Head of Unit, Industrial Property, Internal Market Directorate-General, Brussels <mirjam.soderholm@cec.eu.int>

Alfonso CALLES SANCHEZ, Seconded National Expert, Industrial Property, Internal Market Directorate-General, Brussels <alfonso.calles-sanchez@cec.eu.int>

#### SOUTH CENTRE (SC)

Sisule F. MUSUNGU, Team Leader, Intellectual Property, Investment and Technology Transfer, Geneva <a href="mailto:southcentre.org">musungu@southcentre.org</a>

Lingawako KALINDE (Miss), Intellectual Property Intern, Geneva <a href="mailto:kalinde@southcentre.org">kalinde@southcentre.org</a>

# III. ORGANISATIONS INTERNATIONALES NON GOUVERNEMENTALES/ INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS

<u>Action internationale pour les ressources génétiques (GRAIN)/Genetic Resources Action</u> <u>International (GRAIN)</u>: Peter EINARSSON (Consultant, Stockholm) peter@einarsson.net>

Association allemande pour la propriété industrielle et le droit d'auteur (GRUR)/German Association for Industrial Property and Copyright Law (GRUR): Alfons SCHÄFERS (Attorney, Bonn) <office@grur.de>

Association asiatique d'experts juridiques en brevets (APAA)/Asian Patent Attorneys Association (APAA): Kay KONISHI (Ms.) (Patent Attorney, Tokyo) <konishi@miyoshipat.co.jp>; Casey Kook-Chan AN (Patent Attorney, Seoul) <kcan@ip.kimchang.com>

Association brésilienne des agents de propriété industrielle (ABAPI)/Brazilian Association of Industrial Property Agents (ABAPI): Ivan BACELLAR AHLERT (Industrial Property Agent, Rio de Janeiro) <a href="mailto:kalantenancom.br"><a href="mailto:kalantenancom.br">kalantenancom.br</a>

Association internationale pour la protection de la propriété intellectuelle (AIPPI)/ International Association for the Protection of Intellectual Property (AIPPI): Alain GALLOCHAT (Chairman Q170: Substantive Patent Law Treaty, Deuil-la-Barre) <alain.gallochat@wanadoo.fr>

Association japonaise des conseils en brevets (JPAA)/Japan Patent Attorneys Association (JPAA): Kay KONISHI (Ms.) (Patent Attorney, Tokyo) <konishi@miyoshipat.co.jp>

<u>Biotechnology Industry Organization (BIO)</u>: Lila FEISEE (Ms.) (Director, Intellectual Property, Washington, D.C.) <lfeisee@bio.org>; Carl-Michael SIMON <csimon@sidley.com>

<u>Center for International Environmental Law (CIEL)</u>: Linsey SHERMAN (Ms.) (Fellow, Geneva) <lsher102@uottawa.ca>; Jessica BOLANOS (Ms.) (Intern, Bari) <jessibolanos@yahoo.es>

<u>Centre d'échanges et coopération pour l'Amérique Latine (CECAL)/ Exchange and Cooperation Centre for Latin America (ECCLA)</u>: Lydia GARCETE-AQUINO (Ms.) <garcete@yahoo.com>; Géraldine SUIRE (Ms.) (Consultant, Valence) <g\_suire@yahoo.fr>

<u>Centre d'études internationales de la propriété industrielle (CEIPI)/Centre for International Industrial Property Studies (CEIPI)</u>: François CURCHOD (professeur associé, Université Robert Schuman de Strasbourg, Genolier) < françois.curchod@vtxnet.ch>

<u>Chambre de commerce internationale (CCI)/International Chamber of Commerce (ICC)</u>: Ivan HJERTMAN (European Patent Attorney, IP Interface AB, Stockholm) <ivan.hjertman@ipinterface.se>; Thaddeus J. BURNS (Counsel, Akin Gump Strauss Hauer & Feld, Brussels) <tburns@akingump.com>

<u>Civil Society Coalition (CSC)</u>: Martin KHOR (Representative, Penang)
<twnet@po.jaring.my>; Sangeeta SHASHIKANT (Steering Committee Member, Geneva)
<ssangeeta@myjaring.net>; Marina KUKSO (Ms.) (Delegate, Geneva)
<marina.kukso@cptech.org>; Thiru BALASUBRAMANIAM (Representative, Geneva)
<thiru@cptech.org>

<u>Confédération des industries indiennes (CII)/Confederation of Indian Industry (CII)</u>: T.S. VISHWANATH (Head, Geneva Office, Geneva) <t.s.vishwanath@ciionline.org>

<u>Consumer Project on Technology (CPTech)</u>: James LOVE (Director, Arlington, Virginia); Eleonore DAILLY (Advisor/Attorney, Arlington, Virginia); Thiru BALASUBRAMANIAM (Representative, Geneva) <thiru@cptech.org>

<u>Fédération internationale de l'industrie du médicament (FIIM)/International Federation of Pharmaceutical Manufacturers Associations (IFPMA)</u>: Manisha DESAI (Eli Lilly and Co., Indianapolis) <madesai@lilly.com>

<u>Fédération internationale des conseils en propriété industrielle (FICPI)/International</u>
<u>Federation of Industrial Property Attorneys (FICPI)</u>: Francis AHNER (President, Paris) <a href="mailto:<a href="mailto:regimbeau.fr"><a href="mailto:regimbe

Fridtjof Nansen Institute (FNI): Morten TVEDT (Research Fellow, Oslo) <mwt@fni.no>

<u>Institut des mandataires agréés près l'Office européen des brevets (EPI)/Institute of Professional Representatives Before the European Patent Office (EPI)</u>: Francis LEYDER (Chairman, Harmonization Committee, Brussels) <info@patentepi.com>

<u>Japan Intellectual Property Association (JIPA)</u>: Hiroki NAITO (Chairperson, International Committee, Tokyo) <naito.hiroki@jp.panasonic.com>

Max-Planck-Institute for Intellectual Property, Competition and Tax Law (MPI): Wolrad PRINZ ZU WALDECK UND PYRMONT (Member, Research Staff and Program Director, Munich Intellectual Property Law Center, Munich) <w.waldeck@ip.mpg.de>

<u>Médecins sans frontières (MSF)</u>: Cailin MORRISON (Ms.) (Legal Advisor, Access to Essential Medicines Campaign, Paris) <cailin.morrison@london.msf.org>; Victor VAN SPENGLER (Legal Consultant, Phnom Penh) <esthervictor@online.com.kh>

<u>Union des praticiens européens en propriété industrielle (UNION)/Union of European Practitioners in Industrial Property (UNION)</u>: François POCHART (Chair, Patents Commission, Paris) <fp@cabinet-hirsch.com>

#### IV. BUREAU/OFFICERS

Président/Chair: Boris SIMONOV (Fédération de Russie/

Russian Federation)

Vice-présidents/Vice-Chairs: YIN Xintian (Chine/China)

Usman SARKI (Nigéria/Nigeria)

Secrétaire/Secretary: Philippe BAECHTOLD (OMPI/WIPO)

# V. <u>SECRÉTARIAT DE L'ORGANISATION MONDIALE</u> <u>DE LA PROPRIÉTÉ INTELLECTUELLE (OMPI)/SECRETARIAT OF THE</u> WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

Secteur PCT et brevets, Centre d'arbitrage et de médiation et questions mondiales de propriété intellectuelle/Sector of PCT and Patents, Arbitration and Mediation Center and Global Intellectual Property Issues:

Francis GURRY, vice-directeur général/Deputy Director General

Philippe BAECHTOLD, chef de la Section du droit des brevets/Head, Patent Law Section

Ewald GLANTSCHNIG, conseiller principal, Section du droit des brevets/Senior Counsellor, Patent Law Section

Tomoko MIYAMOTO (Mme/Mrs.), conseillère principale, Section du droit des brevets/Senior Counsellor, Patent Law Section

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