



Lack of Progress at the Twenty-Second Session of the WIPO SCP for a Balanced and Development-Oriented Work Programme on Patent Law Related Issues

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Introduction

The twenty-second session of the WIPO Standing Committee on the Law of Patents (SCP) was held in Geneva from 27 to 31 July 2015. About seven years since the Standing Committee on the Law of Patents (SCP) of the World Intellectual Property Organization (WIPO) had reconvened in June 2008 with a focus on developing a balanced work programme on issues relating to the law of patents that would also address development and public policy issues that arise in the context of the patent system, the SCP has been unable to agree on a work programme on any issue related to patents and development. Since the nineteenth session of the SCP there has been no conclusion of any of the items on the agenda. Indeed, discussions on future work in the SCP have focused on how to ensure that diverse issues and proposals that are on the agenda are sustained on the agenda without any substantive progress. Member States have agreed to limit the work in the SCP to fact finding. This has essentially limited the scope of discussions in the SCP to a review of existing challenges in relation to the patents system, but has restrained the SCP from venturing forward to seek solutions to these challenges. The stalemate continued at the twenty-second session of the SCP which was held in Geneva from 27 to 31 July 2015. This policy brief summarizes the discussions in the SCP and recommends that the WIPO Secretariat should provide appropriate guidance to the member States in accordance with the WIPO Development Agenda recommendations, particularly recommendation 22, in order focus discussions in the SCP over the merits of proposals that have raised issues that are pertinent within the mandate of the SCP.

Summary of the twenty-second session of the SCP

The twenty-second session of the SCP was chaired by Mrs Bucura Ionescu of Romania.

Five issues were considered by the Standing Committee of the Law of Patents (SCP) during the meeting: (1) quality of patents, including opposition systems; (2) exceptions and limitations to patent rights; (3) patents and health; (4) confidentiality of communications between clients and their patent advisors; and (5) transfer of technology. In addition, the SCP considered a proposal (SCP/22/5) for the revision of WIPO's Model Law for Developing Countries on Inventions which was submitted by the Group of Latin American and Caribbean Countries (GRULAC).

The Director General of WIPO welcomed the delegates to the meeting and recalled that there has been great difficulty for the SCP to agree on what it wishes to discuss and how to go forward on the agenda. The DG stressed on the normative nature of the mandate of the SCP and noted that it is one of the few multilateral forums for discussion on normative issues relating to the law of patents. He encouraged delegates to find a way to identify those issues on which there is sufficiently common ground to be able to conduct a discussion that will enable the SCP to go forward as a normative committee through effective and efficient utilization of the time.

The meeting was adjourned on the first morning to undertake informal consultations on the adoption of the agenda. The draft agenda as originally proposed had mentioned quality of patents as a distinct agenda item while other substantive issues such as exceptions and limitations, patents and health, transfer of technology, and confidentiality of communications between clients and their patent advisors were grouped together under one agenda item titled "other issues". Developing countries objected to this distinction between the substantive issues and insisted that all substantive issues should be reflected on an equal footing on the agenda as distinct agenda items. This was agreed to and reflected in the revised agenda that was adopted after informal consultations shortly before the end of the morning session on the first day of the SCP.

The Secretariat gave a summary of the update of the Report on the international patent system based on information submitted by a number of countries. Belarus, Australia, El Salvador, Chile, Russia, Poland, Portugal, Romania, Japan presented information about developments in the respective patent legislations.

Australia mentioned that it has recently amended its patent law to allow countries with insufficient pharmaceutical manufacturing capacity to source generic medicines under compulsory license from Australia in accordance with the para 6 system under the Doha Declaration on TRIPS and public health.

Belarus on behalf of the Group of Central Asian, Caucasus and East European states (CACEE) stressed on the importance of discussions on quality of patents. Pakistan on behalf of the Asian Group particularly stressed the importance for developing a balanced work programme on patents and health. Romania on behalf of the Group of Central European and Baltic States (CEBS) stated that it was important for WIPO's relevance in the field of patents to address the needs of users of the patent system and in this context the issue of quality of patents and confidentiality of clients-attorney communications is important. CEBS expressed support for a survey on patent quality as proposed in the past SCP session by Canada, UK and Denmark. Further consideration be given to work sharing between patent offices. Impact of review of WIPO Model law as proposed by GRULAC should be assessed first.

Japan on behalf of Group B stressed that international work sharing is a critical issue and the SCP should conclude on future work in that regard.

Brazil on behalf of GRULAC stressed on the need to review the WIPO Model law on patents in view of the WTO TRIPS Agreement, the Doha Declaration and the WIPO Development Agenda.

Luxembourg on behalf of EU stressed on the importance of advancing the work on quality of patents including a questionnaire survey on quality of patents, dedicated webpages, conferences and studies on work sharing. Also client attorney privilege. GRULAC proposal on model law is unclear about oversight and execution of the exercise and possible revision of model law should not touch upon interpretation of TRIPS provisions.

Ambassador Ajit Kumar of India stressed on the social function of the patent system. Quality of patent examination needs to improve substantially in conformity with the policy objective of a country to

avoid huge social costs of granting patents to insignificant improvements which only leads to litigation and creates barriers for dissemination of knowledge and transfer of technology. Sharing of work of other patent offices is not the remedy for improving quality of patents or for resolving the problem of backlogs. Rather work sharing could weaken the examination of patents and the capability of patent offices in developing countries. Steps should be taken to build the capacity of patent offices in developing countries for enabling them to perform their quasi-judicial functions according to their national laws in the best manner possible. Work sharing should not become an area of norm setting in the future. Ambassador Kumar stressed on the importance of exceptions and limitations to patents for access to affordable medicines. He expressed support for the AFRICA Group/DAG proposal on patents and health and stressed the importance of a feasibility study on disclosure of INNs and implications of Markush formulae claims. India reaffirmed that discussions on client attorney privilege should be discontinued as it did not fall within the purview of the SCP. India also suggested that the study on sufficiency of disclosure be updated to address its implications for transfer of technology.

On the study on inventive step Japan on behalf of Group B said that further deepening of understanding of practices (methodology) relating to evaluation of inventive step by respective offices could be the fundamental basis upon which international work sharing and collaboration can be built. Romania (CEBS Group) also stressed on understanding the advantages and disadvantages of methods used in evaluating inventive step. India stressed that the study should not be construed as a tool for harmonization of inventive step, noting that an important flexibility under TRIPS is that it did not define inventive step. The United States proposed that the study be updated to address the following issues: how offices determine the conditions under which it is proper to combine prior art references to decide whether a claim has inventive step; the manner in which secondary considerations such as commercial success and supplemental data are applied in the evaluation of inventive step; whether offices consider the content of previously filed applications in evaluating novelty and non-obviousness, or only novelty; how prior art is defined and selected by offices (practice of offices regarding whether prior art meets publication requirements; whether prior art is available to the public; whether prior art should be available locally or anywhere in the world; whether it should be available in written form; how offices handle prior art in patent applications that were filed before but published after the filing of the claims being examined).

On the study on sufficiency of disclosure India said that the study is deficient in respect of sufficiency of disclosure regarding Markush claims. India proposed a special study to survey the problems relating to Markush claims that are found in most of the pharmaceutical and biotechnological patent claims. Such claims encompassing innumerable compounds in a single Markush formula are not supported by sufficient disclosure in the specification. This poses several problems during examination as meaningful search cannot be conducted to assess patentability, and most of the times it is difficult or impossible for a person skilled in the art to reach the invention claimed in Markush formulas without undue burden. The question to be asked is whether enabling disclosure is provided for all the molecules claimed under Markush type of claims? Have all the compounds claimed been prepared by the applicant before the date of filing? Can a skilled person prepare all the compounds without undue burden? India proposed that a survey be undertaken to ascertain common sufficiency requirements for Markush claims. India also called for updating the study in respect of its implications for transfer of technology. Nigeria also stressed on the need to address sufficiency of disclosure in relation to origin and source of genetic resources and associated traditional knowledge used in patent applications.

On the study on exceptions and limitations Japan (Group B) expressed concern that exceptions and limitations are regarded as a tool for development. Exceptions and limitations could only achieve their objectives in an appropriate manner in conjunction with effective patent protection and this aspect should always be kept in mind. Rather than conducting new studies, considering the work that has been produced on this issue in the SCP, Group B favoured a dialogue among interest member States on the circumstances in which exceptions and limitations have been used, rather than adding new material. Belarus supported the proposal by Brazil on exceptions and limitations.

On patents and health, the African Group said that it would update its proposal in the context of subsequent developments since the submission of the proposal, without prejudice to the existing proposal. The updated proposal will be submitted at the next session of the proposal. Group B said that various aspects of access to medicines other than patents should be taken into account. Group B felt that work sharing can be beneficial in this field and a study on this aspect can be a way forward. India reaffirmed its support to the proposal by African Group and DAG. Commenting on the study on the feasibility of disclosure of INNs in document SCP/21/9, India

stressed that though such disclosure is not a statutory requirement under any national law, administrative guidelines by patent offices indicate that INN can be incorporated in a patent specification. Therefore, there is ample room for further discussion on the feasibility of INN disclosure. India noted that the study evaded the question of usefulness of mandatory disclosure of INNs when the applicant is fully aware of INNs and failed to acknowledge the hardship caused to examiners and third parties when the INN is not disclosed when it was available. India also called for a study on the impediments created by Markush claims including their patentability. India also called the US proposal unrealistic in the absence of any empirical data to support assertions made therein. Nigeria supported India's proposal.

On the issue of confidentiality of communications between clients and their patent advisors (client-attorney privilege) the CEBS Group stressed on the necessity to find solutions for cross-border aspects of client-attorney privilege and proposed a study by the Secretariat to explore various possible soft law approaches to this issue. Group B called for pursuit of a soft law approach and suggested the Secretariat to seek member States inputs on this. Group B proposed 2 studies – a questionnaire survey on professionals to be covered by client-attorney privilege, and treatment of foreign patent attorneys; and a study on judicial decisions pertaining to client-attorney privilege. Iran said that this issue is a procedural issue that falls outside the scope of substantive patent law, there is diversity of approach on this issue in domestic laws, it relates to regulation of services, and hence falls outside the mandate of WIPO or SCP. India said that the topic should be taken off the agenda of the SCP. Africa Group also felt that this topic should be discussed outside of SCP. China also felt that this topic should not be discussed in the SCP.

On transfer of technology Group B, EU and CEBS stated that considerable work has been undertaken in the CDIP on this issue and the SCP should not duplicate the same and therefore not consider future work on this. Group B suggested work on voluntary licensing between patent holders and third parties. African Group proposed a study on current practices on transfer of technology in developing countries and LDCs.

On quality of patents Spain proposed that the concept of prior art, disclosures excluded from prior art, and grace period should be studied in terms of how these are treated in different countries. CEBS supported launching a questionnaire survey on quality of patents and further consideration should be given to work sharing through a study on how different laws and practices limit the potential for work sharing. Group B

also supported further studies on the same and proposed a dedicated website and an annual conference by WIPO on work sharing.

On quality of patents Spain proposed under the framework of the “process improvement” component of the proposal by Canada and UK, the concept of prior art should be studied because disclosures made before the grace period are not always considered part of the prior art. Therefore, information on the grace period, filing or priority date should also be provided. Therefore Spain called for a study on prior art and grace period covering three points in particular – disclosures excluded from state of the art, delay of the grace period (6 or 12 months), how the grace period is calculated (filing date or priority date), at what moment and under what conditions prior user rights arise? CEBS group called for launching a questionnaire on the quality of patents and a study on how different laws and practices limit the potential for work sharing, or development of a handbook on avoiding difficulties to work sharing in view of differences in laws and practices. Group B called upon the Secretariat to collect information relating to work sharing from national offices and put them on a website. Group B proposed a study on how work sharing programmes can facilitate efficient search and examination and grant high quality patents.

Presenting the GRULAC proposal on the review of the WIPO Model Law of 1979, Brazil said that funds for the review is available under the Programme and Budget, there is need to respond to demands from developing countries for legislative and policy assistance in line with DA recommendations 13 and 14, and that the Model Law needs to be updated to reflect upon developments such as the adoption of the TRIPS Agreement. South Africa supported the proposal by GRULAC as it viewed the Model Law as outdated and not responsive to development challenges faced by developing countries. Paraguay, Trinidad and Tobago, India and Iran supported the proposal. India stated that the revision should not lead to harmonization at this stage. Group B stated that the review of the Model Law could be part of substantive harmonization of patent law which the SCP should pursue and specifically suggested that the review should address issues such as data protection, grace period, patent term extension, and patent attorneys’ privilege. The US said that the Model Law was developed in a context where there was no international framework on patent law and that it does not reflect current issues such as patent term extension or implementation of the Patent Law Treaty. Today many multilateral and bilateral agreements provide a framework that can guide countries

in designing their patent laws. The DA recommendations incorporate a flexible approach to WIPO technical and legislative assistance based on demands made by member States in a country-specific manner. The one-size-fit-all approach of the Model Law is not consistent with the DA recommendations. Therefore, the US did not support the GRULAC proposal. Revision of the model law would be an exercise in harmonization and should therefore not be limited to a few topics to the exclusion of other topics. CEBS group stated that the revision should not lead to an interpretation of the TRIPS provisions and also regarded this revision as an exercise in harmonization of substantive patent law. Australia proposed a study on how the model law has been implemented by developing countries and LDCs and gauge the unmet need of such countries that the revision would address, and stressed that the revision should address issues such as grace period and client-attorney privilege.

Regarding future work, Group B reiterated its views on limitations and exceptions and did not support future work on limitations and exceptions as proposed by Brazil. Group B held that disclosure of origin or source (proposed by Nigeria) cannot be part of a study on sufficiency of disclosure. Group B also objected to any study on the disclosure of INNs as they view INN disclosure requirement would be an unjustifiable burden on applicants and offices, as well as study on Markush claims proposed by India.

The EU said that a work programme on quality of patents should be established based on the proposals made by Canada and UK, Denmark, US and Spain and a questionnaire should be launched as proposed by Canada, Denmark and US. Elaboration of models of opposition systems, administrative revocation and invalidation mechanisms in a non-exhaustive manner should be considered. EU also proposed a dedicated page on the WIPO website and conferences on margins of SCP on work sharing programmes and studies by the Secretariat on what laws and regulations limit the potential for work sharing and how international collaboration in this respect can be promoted. On patents and health, EU supported the US proposal. EU believed that time is ripe to consider a mechanism to recognize foreign patent advisors’ privilege through a soft law approach and seek convergence among existing national systems in this regard. EU objected to launching any new initiatives in the SCP on transfer of technology until the completion of the project on transfer of technology under discussion in the CDIP. EU also objected to development of a manual on exceptions and limitations.

CEBS group said that the primary objective of the SCP should be to advance discussions on quality of patents.

Work on concrete steps to improve the quality of patents would be necessary for the benefit of all member States and supported launching of a questionnaire on quality of patents, a study on how different laws and practices limit the potential for work sharing, or a handbook on best practices that could provide solutions and avoid difficulties that arise from differences in laws and practices. CEBS supported a soft law approach on client attorney privilege and proposed a study by the Secretariat advancing various types of soft law approaches in this area. CEBS questioned the value addition of a manual on exceptions and limitations and said that work on exceptions and limitations cannot progress without comparable progress on substantive patentability criteria.

CACEE supported further studies on practical application of inventive step and sufficiency of disclosure in various jurisdictions. It supported the proposal for a study on the level of prior art and grace period.

India reiterated that the future work of SCP be limited to fact finding and not lead to harmonization at this stage. India proposed a study on use of exceptions like compulsory licensing, parallel imports, government use, Bolar exceptions be considered, as well as a study on various impediments in licensing agreements in relation to transfer of technology. A thorough study on the use of the patent system for fulfilling the needs of developing countries for access to affordable medicines, and socio-economic development should be considered. Work sharing should not become an area of norm setting in future. India proposed a study on mandatory disclosure of INNs in patent specifications, Markush formula and impediments caused by them, transfer of technology and sufficiency of disclosure.

GRULAC called upon WIPO to develop a non-exhaustive manual on exceptions and limitations for the reference of member States based on an analysis of the use of exceptions and limitations for specific public policy objectives. GRULAC requested the Secretariat to prepare terms of reference for the revision of the WIPO Model Law of 1979.

After extensive informal consultations between the Chair and regional group coordinators on the Chair's proposal on future work, Group B observed that the level of ambition in the Chair's proposal in relation to quality of patents and confidentiality of communications between patent advisors and their clients was very low and did not meet the expectations of the group. Group B suggested that on the topic of transfer of technology and activity which appeared in an earlier version of the chair's proposal

be reintroduced. Group B thus suggested a compilation of member states' information on national legislation regarding voluntary licenses and licensing agreements. On patents and health, the group held that half day-seminar proposed in the work programme include not only the challenges related to availability of medicines in developing countries and least-developed countries, but also the benefits of the patent system. China held that client attorney privilege should not be discussed in the SCP but would show flexibility in the interest of progress. India stressed on the need for further amendments to the study on disclosure of INNs and study on Markush claims. The US called for further work on the effect of licensing on technology transfer.

Group B was insistent that the Chair's proposal on future work should reflect the two proposals from the group about work on licensing and technology transfer and on the contribution of patents to innovation of new medicines. However, other groups held that the Chair's text struck a balance between opposing interests between different groups and any further amendment to the text would open it up for further discussion and create uncertainty about any possible outcome. Group B ultimately compromised at the request of the Chair and the Chair's proposal on future work was adopted. Accordingly, it was agreed that SCP will continue to work on the same issues at its twenty-third session to be held in November 2015 and will continue to be confined to fact-finding and not lead to harmonization. On exceptions and limitations, the Secretariat will compile member States' experience and case studies on the effectiveness of exceptions and limitations in addressing development issues. A half-day sharing sessions will be held during the next session of the SCP on the experiences of experts from different regions on inventive step assessment in examination, opposition and revocation procedures, and the Secretariat will improve the webpage on work sharing and collaborative activities by the twenty-fourth session of the SCP. A half-day seminar on the relationship between patents and availability of medicines, including fostering innovation and transfer of technology to facilitate access to generic and patented medicines will be held during the next session of the SCP. The SCP will continue discussions on the feasibility study on disclosure of INNs. A sharing session among member States will be organized on the types of protection applied to patent professionals and national and foreign patent advisors. The SCP will also discuss transfer of technology vis-à-vis sufficiency of disclosure based on the study on sufficiency of disclosure. Discussions will continue on the proposal by GRULAC for the revision of the WIPO Model Patent Law at the next session of the SCP.

India, Iran and China stressed that the Chair's summary should reflect that on the issue of confidentiality

of communications between clients and their patent advisors some delegations had said that this issue should be discontinued from further consideration in the SCP. The Chair said that this will be reflected in the final version of the Chair's summary.

In his closing remarks, WIPO Deputy Director General (Patents and Technology Sector) John Sandage mentioned that WIPO spent CHF 215000 for this meeting where only half of the time was spent on discussing substantive issues. He hoped that the time would be spent more on substantive discussions at the next session of the SCP and looked forward to guidance from member States on what they would like to do with the SCP.

Conclusion

The twenty-second session of the SCP failed to offer any guidance regarding the way forward on the issues that have effectively remained stagnant on the agenda for more than two years. It is interesting to note that in the face of this stalemate, while the Secretariat continues to encourage member States to find a way forward and focus more on substantive issues, there is a discernible lack of any guidance from the WIPO Secretariat on what issues could be taken forward and the modalities of the same. The outcome of the SCP has been left at the hands of member States who have taken extremely polarized positions.

For example, the sentiment expressed by developed countries that any work on exceptions and limitations to patents or the revision of the WIPO Model Law of 1979 could only advance if the work programme also focuses on strengthening patent protection and substantive harmonization are clearly unacceptable propositions that would block any possibility of progress on these two issues that have critical development and public policy considerations attached. However, such a proposition is also antithetical to the WIPO Development Agenda recommendations which mandate that WIPO's norm-setting activities must be development-oriented, take into consideration differences in levels of development and take into account flexibilities available for developing countries and LDCs. In this context it would be pertinent for the Secretariat to provide guidance in the light of the Development Agenda recommendations to the member States with regard to the proposals that have been advanced in the SCP to explain how they align with the spirit of the Development Agenda recommendations which all member States have unanimously agreed to adhere. In particular, Recommendation 22 of the

Development Agenda specifically mandates the WIPO Secretariat to play such a guiding role. It states:

The WIPO Secretariat, *without prejudice to the outcome of Member States considerations*, should address in its working documents for norm-setting activities, as appropriate and as directed by Member States, issues such as: (a) safeguarding national implementation of intellectual property rules (b) links between intellectual property and competition (c) intellectual property -related transfer of technology (d) potential flexibilities, exceptions and limitations for Member States and (e) the possibility of additional special provisions for developing countries and LDCs.

However, the working documents for the SCP that are produced by the Secretariat do not provide any guidance on how the work of the SCP can be advanced while safeguarding national implementation of patent laws, how flexibilities, exceptions and limitations can be used in the context of development and public policy concerns raised by member States in the SCP.

In the SCP, developing countries have made very significant proposals relating to both the quality of patents as well as on patents and health. However, developed countries fundamentally refused to acknowledge the real problems arising from the patent system that motivated these proposals and suggestions. On quality of patents, the focus of developed countries has been limited to promoting work sharing to facilitate faster disposal of patent applications with the assumption that sharing search and examination results would improve the quality of the examination itself and ensure that patents of questionable validity are not granted. This perspective refuses to acknowledge the real problem of how lowering the criteria of patentability i.e., regarding what constitutes novelty, inventive step and industrial applicability has encouraged the filing of questionable patents as a strategic manoeuvre by firms and how the expectation of faster and increasing grant of patents on such questionable applications has contributed to the deterioration of the quality of patents. Thus, the issue on quality of patents continues to be viewed from a myopic perspective of improvement in patent office processes, and does not address substantive patentability issues that are a major part of the problem. Moreover, discussions on quality of patents have failed to address the role of opposition systems in enhancing the quality of patent examination. Again, the Secretariat has also not taken any initiative to address this real problem and provide guidance to the SCP to take this important discussion forward in a constructive manner.

The failure of the SCP to advance work on patents and health is most glaring. Developing countries had submitted a proposal suggesting many interesting elements that are very pertinent to addressing challenges to access to medicines arising from the grant of low quality patents on medicines. The narrative that has been presented to counter this proposal is that considerable work is being undertaken by WIPO along with WHO and WTO to address patents and health issues and therefore there is no need for addressing this in the SCP. However, none of the existing initiatives by the trilateral organizations address the problems identified under the developing country proposal in respect of how to utilize the flexibilities available to developing countries to facilitate access to affordable medicines. In fact, the Trilateral report by WHO, WTO and WIPO acknowledge some of the problems identified in the proposal but do not explore solutions to the same. Instead of seeking solutions to the problems within the patent system that impede access to medicines, developed countries have proposed that the SCP should focus on the benefits of the patent system. The twenty-second SCP failed to agree to two significant proposals by India that could have taken this discussion forward - to study the impact of Markush claims on both the examination of pharmaceutical patent applications and their public health implications, and sufficiency of disclosure in Markush claims.

Thus, it can be said in conclusion that the SCP has continued to skirt addressing substantive issues relating to patents and development. Effectively, it has merely changed the dressing of the wounded patient (the patent system) who still awaits for the surgeon to intervene. And the patient is running out of time.



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