

EXCEPTIONS TO PATENT RIGHTS AND THE WIPO DRAFT SUBSTANTIVE PATENT LAW
TREATY (SPLT)

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I. INTRODUCTION

The grant of a patent confers an exclusive right to the patent owner, that is, the right to exclude others from doing certain acts with respect to the protected product or process. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under article 28, for example, confers exclusive rights as follows: (1) for product patents the right to prevent third parties from making, using, offering for sale, selling, or importing products (subject to article 6)¹ for these purposes without the patent owner's consent; and (2) for process patents the right to prevent third parties from using the process and from using, offering for sale, selling, or importing products for these purposes, at least the products obtained directly by that process, without the patent owner's consent.

The Paris Convention did not contain such an enumeration of rights, though by the time of TRIPS, the rights conferred by patents were generally understood to be those enumerated in the TRIPS Agreement. Historically it was also firmly established that the exclusive rights conferred by a patent are not absolute. Indeed, due to the market power conferred by patents and the effect on

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¹ See footnote 6 under the Agreement. The text of the TRIPS Agreement can be found in WTO, *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations*, Cambridge University Press, Cambridge (1999) pp. 320 - 353.

competition, absolute rights have never been contemplated. Consequently, exceptions have always been a part of patent law.

There is no specific definition of the term “exception” in patent law and the term is used variously to refer to at least two kinds of exclusions from the general rules. First, the term is used to refer to exclusions of certain subject matter from patentability meaning that even though an invention meets the three basic requirements for patentability that is novelty, inventive step and industrial application, a patent would not be granted if such an invention falls within the excluded category. Under the TRIPS Agreement, though the term exception is not used, these types of exclusions include the subject matter covered under articles 27(2) and 27(3) of the Agreement.² The European Patent Convention (EPC) on the other hand actually uses the phrase “exceptions to patentability” to refer to subject matter on which patents can not be granted.³

² Article 27(2) provides that:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Article 27(3) on the other hand permits WTO Members to exclude from patentability: diagnostic, therapeutic, and surgical methods for the treatment of humans and animals; and plants and animals.

³ See article 53 of the EPC which, under the heading “Exceptions to Patentability” provides that:

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

Secondly, the term exceptions refer to certain acts which are protected by law from the exercise of the patent holder's right to prevent third parties from using the patented invention. These are usually referred to as exceptions to patent rights, meaning that the general rule that the patent holder has the right to prevent third parties from performing certain acts does not apply. In the TRIPS Agreement, these types of exceptions are covered under article 30. In this regard, article 30 which is titled "Exceptions to Rights Conferred"⁴ provides *inter alia* that "Members may provide limited exceptions to the exclusive rights conferred by a patent".⁵

In addition to the exceptions recognised under article 30 there are other additional acts which are permitted without the authorisation of the patent holder but with the authorisation of a judicial or government body such as compulsory licenses.⁶ A distinction between the exceptions under article 30 and the acts permitted under article 31 is that article 30 exceptions are *per se*

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

⁴ The rights conferred are those under article 28 of the TRIPS Agreement, *supra* note 1.

⁵ Though the TRIPS Agreement does not enumerate the exceptions to patent rights, some of the exceptions that are recognised under national and regional patent laws include: (1) private and non-commercial use exception; (2) teaching and research exception; (3) the early working exception; (4) commercial experimentation aimed at testing or improving on the invention; (5) preparation of medicines for individual prescriptions; (6) prior use exception; (7) parallel imports; and (8) exception for use on foreign vessels.

⁶ Article 31, read together with footnote 7 to the TRIPS Agreement provides that in addition to the exceptions that are possible under article 30 and which have to meet the three step test, another exception, that is an exclusion from the application of the rights of the patent holder's to prevent third parties not having his consent from using the invention is what is commonly referred to as compulsory licenses and government (crown use). Under TRIPS this is referred to as "other use".

exceptions while the acts under article 31 are not. *Per se* exceptions mean that the exception operates automatically without any formal process or authorisation by a judicial or administrative body, that anyone can benefit from them, and that there is no requirement for compensation.

This dual use of the term “exceptions” is important in the consideration of this issue in the context of the draft Substantive Patent Law Treaty (SPLT) because the justifications for each set of exceptions are slightly different and would normally operate under different rules.

This paper examines the question of exceptions to patent rights in the context of the SPLT. It should, however be noted that under the rubric exceptions in the draft SPLT, both types of exceptions are contemplated and there are instances in the paper where the discussions address both types of exceptions.⁷ The paper has four sections. In the next section the paper provides a brief background and context to exceptions to patent rights and the proposals made at the World Intellectual Property Organization’s (WIPO) Standing Committee on the Law of Patents (SCP). In section III, the paper examines the objectives and scope of the SPLT and the relevance of exceptions in that context. Finally, in part IV, the paper proposes a number of options on how exceptions could be addressed in the SPLT.

II. BACKGROUND AND CONTEXT

Exception to patent rights are justified on the basis that patent protection is not an end in itself but is aimed at serving certain public policy objectives, particularly developmental and technological policy goals. Considerations

⁷ See the latest draft of article 2 in WIPO document SCP/10/2.

relating to innovation, diffusion of knowledge and technology, competition and accessibility of essential products and services all come into play. Exceptions may apply in relation to non-commercial or commercial acts, with the aim of increasing static efficiency by speeding up competition and or enhancing dynamic efficiency by reducing barriers to future research.⁸ In the context of the TRIPS Agreement on which the SPLT builds, the justification for exceptions to patent rights can be found in article 7 on objectives.⁹

The provisions of article 7, which can be said to constitute the formal justification for the current international patent system and the protection of patents, in particular, provides that the grant of patents should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. If this happens such protection of intellectual property would bring benefits to both the patent holders, referred to as producers of knowledge, and competitors, consumers and the general public, referred to as users of knowledge, in a manner conducive to social and economic welfare.

The objectives of the TRIPS Agreement mirror the previously prevailing understanding within the international community as exemplified by the approach of the United Nations (UN) to patents. The UN approach to the justification of patent protection is best explained in the Agreement between the UN and WIPO establishing the latter as a specialized agency. The agreement in article 1 provides that the UN recognizes WIPO as a specialized agency responsible for: “promoting creative intellectual activity and for facilitating the

⁸ UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, New York (2005), p. 430. Competition could be speeded up or otherwise facilitated by the early working exception or rules on exhaustion of rights while barriers to future research could be reduced though the experimental use exception.

⁹ See the TRIPS Agreement, *supra* note 1.

transfer of technology...to the developing countries in order to accelerate economic, social and cultural development".¹⁰ It is obvious that absolute exclusive rights conferred on patent holders would not achieve these objectives. Absolute rights would severely hampered innovation, diffusion of knowledge, transfer of technology and access to products and services with significant negative socio-economic and cultural consequences.

To the extent that the TRIPS Agreement, regional agreements and virtually all national laws contain exceptions in one form or another, albeit with the scope and underlying justifications varying widely, this paper proceeds on the basis that there is no controversy or international disagreement as to the importance of exceptions to patent rights. Differences or disagreements regarding the content, scope or objectives of such exceptions does not affect the overall international acceptance that exceptions must be part of the overall patent regime whether such a regime is multilateral, regional, bilateral or national.

II. 1 Exceptions and the Draft SPLT: A Historical Appraisal

In order to properly understand the debate in the SPLT regarding exceptions to patent rights it is necessary to provide some background on the evolution of exceptions in the draft treaty. This includes both exclusions to patentability and exceptions to patent rights. The historical appraisal covers both exceptions to patentability and exceptions to patent rights primarily because in the draft SPLT and in the discussions in the SCP both have been dealt with together, admittedly causing some confusion.

¹⁰ See article 1 of the Agreement, WIPO, Agreement between the United Nations and the World Intellectual Property Organization, WIPO Publication No. 111, WIPO, Geneva (1975).

In the initial draft SPLT presented by the International Bureau (hereinafter the WIPO Secretariat) at the fifth session of the SCP in May 2001 no exception was included¹¹. In the second draft of the SPLT discussed at the sixth session a clause on exceptions was introduced.¹² The draft then provided that “This Treaty and the Regulations shall not apply to the applications [and patents] prescribed in the Regulations”.

It is only in the third revision of the SPLT discussed at the seventh session that a security exception was included in the following words: “Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests”. It is in this context that at the same session, the delegation of Brazil proposed the following wording for paragraph 3 to article 2:

Nothing in this Treaty or Regulations shall limit the freedom of Contracting Parties to protect public health, nutrition and the environment or to take any action it deems necessary to promote the public interest in sectors of vital importance to its socio-economic, scientific and technological development.¹³

To this wording, the delegations of Chile, Colombia, Cuba, Dominican Republic, Ecuador, Honduras, Nicaragua, Peru and Venezuela added the phrase: “or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment”. These delegations also suggested changing the title of the article from “Security exception” to “exceptions”. Earlier drafts of the SPLT had used

¹¹ See document SCP/5/2.

¹² See draft article 2(3) in document SCP/6/2.

¹³ See paragraph 27 of the Report of the seventh session of the SCP, document SCP/7/8.

the more general term exceptions.¹⁴ Overtime, the draft article 2 has evolved to have several paragraphs including some alternative language. Box 1 below contains the text of the draft article 2 as it stands in the latest text of the SPLT.

Box 1: Text of Article 2 in the Latest Draft of the SPLT¹⁵

Article 2

General Principles and Exceptions

(1) [*Requirements Relating to Infringement*] Subject to Articles 9(4) and 11(4), nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to apply any requirements in relation to infringement.

(2) [*Security Exception*] Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests.

[(2) [*Exceptions*] Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.]

[(3) [*Public Interest Exceptions*] Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to protect public health, nutrition and the environment or to take any action it deems necessary to promote the public interest in sectors of vital importance to its socio-economic, scientific and technological development.]

¹⁴ See Paragraph 28 of the Report of the seventh session of the SCP, *id.*

¹⁵ The footnotes are excluded. The text is extracted from WIPO document SCP/10/2.

In addition, in the discussions on draft article 12(5) on “Conditions of Patentability”, Brazil, Egypt and Peru suggested that the exceptions to patentability permitted under article 27(2) and 27(3) of the TRIPS Agreement be included by reference in the SPLT. And with respect to article 13 on “Grounds for Refusal of a Claimed Invention”, Brazil and Chile, Colombia, Cuba, Egypt, Kenya, Morocco and Peru proposed the following language:

A Contracting Party may also require compliance with the applicable law on public health, nutrition, ethics in scientific research, environment, access to genetic resources, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development.¹⁶

As with article 2 these articles have also evolved through various revisions to their current form. Box 2 contains the text of the current draft of article 12(5) while box 3 contains the text for article 13.¹⁷

Box 2: Text of Article 12(5) in the Latest Draft of the SPLT

(5) [Exceptions] Notwithstanding paragraphs (1) to (4), a Contracting Party may [, in accordance with the Regulations,] exclude certain inventions from patentability.

¹⁶ See paragraph 200 of the Report of the Seventh Session of the SCP, *supra* note 13.

¹⁷ The footnotes are excluded. The texts are extracted from WIPO document SCP/10/2.

Box 3: Text of Article 13 in the Latest Draft of the SPLT*Article 13**Grounds for Refusal of a Claimed Invention*

(1) [*Grounds for Refusal of a Claimed Invention*] An application shall be refused where the Office finds that such application or a claimed invention in the application does not meet any of the following requirements:

(i) the applicant does not have the right to the patent referred to in Article 4;

(ii) the claimed invention does not meet the requirements of Articles 6, 11(2) and (3) and 12;

(iii) the application does not meet the requirements of the Patent Law Treaty, as implemented in the applicable law, and of Articles 5 and 10; or

(iv) an amendment or correction results in a disclosure as prohibited by Article 7(3).

[(2)[*Other Grounds for Refusal of a Claimed Invention*] The Office may refuse an application where it finds that a claimed invention in the application, which was not available to the public on the priority date of that claimed invention, was on sale in the Contracting Party more than one year prior to the filing date of that application.]

(3) [*Prohibition of Other Requirements*] No Contracting Party may require compliance with any requirement relating to the examination of an application or the grant of a patent on a claimed invention different from or additional to the requirements provided for in paragraph (1).

[(4) [*Compliance With Applicable Law on Other Matters*] A Contracting Party may also require compliance with the applicable law on public health, nutrition, ethics in scientific research, environment, access to genetic resources, protection of traditional knowledge and other areas of public interest in sectors of vital importance for their social, economic and technological development.]

These proposals on exceptions, both in terms of exclusions to patentability and exceptions to patents rights, but not the security exception, were opposed vehemently by Germany, Ireland, Japan and the United States on the basis that:

[T]he objective of the SPLT was to establish best practices and to deeply harmonize the substantive requirements; issues concerning the interpretation of other international treaties should not be resolved by the SPLT nor should these issues influence the interpretation of the SPLT itself; matters regarding the WTO Doha Ministerial Declaration related to the use of patent rights after grant, not to the patentability of claimed inventions or the validity of patents; the proposed issues were extraneous to patent law.

At the eighth Session of the SCP in November 2002, the WIPO Secretariat in a direct response to the 12 Member States¹⁸ who had made proposals for additional language on draft article 2(3) and with respect to draft articles 12 and 13 opposed the proposals arguing that, first:

In sum, the SCP agreed to limit the scope of the draft SPLT to the deep harmonization of a number of issues relating to the grant of patent rights as well as the validity of patents. Thus the SPLT itself would not limit the freedom of Contracting Parties to regulate any matters which are not included in the scope of the SPLT as described, for example matters relating to the rights conferred by a patent or the enforcement of the patent rights. Examples of such matters include the types of exclusive rights conferred by the patent, the exceptions to such rights, the use of patented subject matter without the authorization of the right holder, exhaustion of patent rights,

¹⁸ The 12 were Brazil, Chile, Colombia, Cuba, Dominican Republic, Ecuador, Egypt, Honduras, Morocco, Nicaragua, Peru and Venezuela.

and judicial procedures and border measures against acts infringing the patent rights.¹⁹

Secondly, the Secretariat argued that “Member States of WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) specifically as the competent body within WIPO to discuss the relationship of access to genetic resources, protection of traditional knowledge and folklore with intellectual property”.²⁰ Third, it was argued that matters relating to the relationship between the CBD and the TRIPS Agreement and matters relating to public health were being dealt with in the WTO.²¹ Fourth, the Secretariat argued that:

[I]t may be more effective to evaluate the social and economic consequences of a patent on other areas of public policy at the stage of the exercise of patent rights. At this stage, appropriate measures may be taken to limit or control adverse consequences on other priority areas of public policy. This is the way in which considerations of competition law have always been accommodated in relation to the patent system.²²

Finally, it was argued that:

In order to constitute workable exceptions in the context of an internationally harmonized approach to the grant of patent rights, the grounds upon which an exception may operate would usually need to be

¹⁹ See paragraph 6 of document SCP/8/5.

²⁰ See paragraph 11.

²¹ See paragraphs 15 - 17.

²² See paragraph 20.

clearly defined in order to create sufficient certainty for a harmonized approach to be adopted.²³

The arguments by the Secretariat were identical, if only more detailed and reasoned than the arguments made by the Germany, Ireland, Japan and the United States and some industry lobby groups. It is also worth mentioning that the Casablanca Statement excluding the issues related to exceptions and other issues closely mirrors these arguments.²⁴ In the next section, I address each of the arguments above in turn.

II.2 A Critique of the Arguments Against the Inclusion of Exceptions in the SPLT

The first argument advanced against the inclusion of exceptions, particularly as proposed by developing countries, was that there was a prior agreement to exclude such matters from the SPLT. This argument, however, contradicts the

²³ See paragraph 21.

²⁴ The Casablanca Statement which was rejected by the SCP had proposed that:

[T]he following six issues should be addressed in an accelerated manner within WIPO with a view to progressive development and codification of international intellectual property law: prior art, grace period, novelty, inventive step, sufficiency of disclosure and genetic resources. These issues should be addressed in parallel, accelerated processes, the first four issues (prior art, grace period, novelty and inventive step) in the SCP and the other two issues (sufficiency of disclosure and genetic resources) in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Each of the SCP and the IGC should agree on a timetable and report progress on the development of their discussions of the issues to the other.

For the full text of the Casablanca Statement see document SCP/11/3.

record of what happened particularly at the fourth session of the SCP. At the fourth session the Secretariat had proposed that:

In view of the present situation and the objective mentioned above, the International Bureau suggests that *at least* the following basic issues underlying the grant of patents, which are of particular importance to the further development of the international patent system, could be included in the discussions of the SCP: the definitions of prior art, novelty, inventive step (non-obviousness) and industrial applicability (utility); sufficiency of disclosure; and the structure and interpretation of claims.²⁵

Notwithstanding the proposal by the Secretariat, the Chairman of the session clarified that “additional issues were still on the agenda, but that the SCP had decided to limit discussion to the six issues singled out in document SCP/4/2 for the next 12 months”²⁶, that is, between November 2000 and November 2001. There appears to be no record of a specific decision altering this agreement by the SCP. Furthermore, even if there was such an understanding, it would hardly be, alone, a sound reason for not including exceptions in the SPLT. There are a number of reasons for this.

To start with, the process taking place in the SCP is aimed at preparing a basic proposal on the basis of which a diplomatic conference can be convened. The preparation or the existence of a basic proposal, however, does not constitute a waiver by Member States of their rights to raise any matter they deem necessary at anytime before the adoption of a treaty. It is, therefore, difficult to argue that by virtue of some understanding in the SCP, Member States had

²⁵ See paragraph 9 of document SCP/4/2 containing suggestions by the WIPO Secretariat on the further development of international patent law. Emphasis added.

²⁶ See paragraph 49 of the Report of the session, SCP/4/6.

somehow bound themselves not to exercise their sovereign rights to make proposals for inclusion in the treaty. Indeed, it is because there was no such waiver of sovereign rights that the United States and Japan made the proposal on “SPLT-light” at the tenth session of the SCP in May 2004.²⁷

In the second instance, in a fast changing world it is hardly prudent and a judicious exercise of public functions to lock the SCP or indeed any other committee to a specific set of issues and a particular approach whatever the circumstances. This is particularly problematic when one considers that the elaboration of a treaty text can take up to 10 years. Again, the proposal on SPLT-light which was endorsed by the WIPO Director-General and some individuals from several countries was also predicated on arguments regarding change of circumstances.

The second argument is that matters related to intellectual property and genetic resources and traditional knowledge are a preserve of the IGC. This old argument has been used in various fora including in the WTO for many years by certain developed countries, especially the United States and Japan, primarily as a tactic to sideline genetic resources and traditional knowledge discussions.

Developing countries on the other hand, have consistently argued that the relationship between patent rules and genetic resources and traditional knowledge is a matter that should be addressed in a number of fora both within and outside WIPO. This argument has been articulated quite clearly at the IGC

²⁷ See document SCP/10/9 containing the proposal. The term SPLT-light is used here to refer to the proposal for a reduced package of issues by the United States and Japan.

itself.²⁸ Consistent with this argument, developing countries have sought to address these issues in a number of WIPO bodies, including the Working Group on the Reform of the Patent Cooperation Treaty (PCT) and in the SCP, as well as in the context of the TRIPS Agreement. Some developed countries such as Switzerland have also made proposals on these issues in other WIPO bodies such as the PCT Working Group.

It is not necessary to go into the arguments in detail here, since WIPO Member States have conclusively decided on this issue. In 2003 when the mandate of the IGC came up for renewal, the General Assembly specifically decided that the IGC's "new work will focus, in particular, on a consideration of the international dimension..., without prejudice to the work pursued in other fora."²⁹ The work of the IGC is continuing today on this basis. Consequently, the argument that certain matters are the preserve of the IGC and should therefore not be addressed in the SPLT holds no water.

The third argument is that matters relating to the relationship between the CBD and the TRIPS Agreement and matters relating to public health were being dealt with in the WTO. This argument is partly linked to the second argument. It is a rather ironical situation. It is ironical because as the United States and others were arguing in the Council for TRIPS that issues relating the relationship between the CBD and TRIPS (genetic resources and intellectual property) be dealt with exclusively by WIPO's IGC, the WIPO Secretariat was in effect arguing that these issues were being addressed satisfactorily in the Council for TRIPS and there was therefore no need to address them in the SPLT.

²⁸ See, e.g. the interventions of the delegations of Egypt on behalf of the African Group paragraph 143; Brazil paragraph 148; Venezuela paragraph 149; and Senegal paragraph 161 of the Report of the sixth session of the IGC, document WIPO/GRTKF/IC/6/14.

²⁹ Emphasis added.

These contradictory arguments primarily reflect a desperate attempt to throw these issues anywhere, but the SCP where the patent law purists reside. The primary justification for this approach is that certain countries or industry lobbies or individuals think that these matters are extraneous to patent law. The argument with respect to public health is not worth responding to partly because the Council for TRIPS has no exclusive mandate to address intellectual property and public health issues just as it does not have an exclusive mandate to address the relationship between intellectual property and the CBD. In this regard, it is also important to remember that not all Members of the WIPO are WTO Members. Essentially therefore, as with the second argument, addressed above, this argument holds no water and can not be a basis for the exclusion of exceptions to patent rights or exceptions generally from the SPLT.

The fourth argument is that it may be more effective to evaluate the social and economic consequences of a patent on other areas of public policy at the stage of the exercise of patent rights. As a statement of fact, this argument holds, but that is how far it goes. Exceptions to patentability relate to the determination of whether or not to grant a patent while exceptions to patent rights relate to limitations on the exercise of the exclusive rights conferred by a patent. This distinction, however, only has relevance to the SPLT if one accepts the argument that there is an irreversible agreement to exclude such matters from the SPLT. As demonstrated above, this argument can not be valid considering the circumstances. As a corollary, the argument that it may be more effective to evaluate the social and economic consequences of a patent on other areas of public policy at the stage of the exercise of patent rights provides no basis for the exclusion of exceptions from the SPLT.

The fifth and final argument is that for exceptions to be workable in an internationally harmonized approach the grounds upon which an exception may

operate would usually need to be clearly defined. Again as a statement of fact there is no disputing the veracity of this observation. As a basis for excluding exceptions from the scope of the SPLT, however, the statement is questionable. It is probably correct that there may be need to refine the exceptions as currently framed. In addition, there may be need to separate and formulate specific language for exceptions to patentability and exceptions to patent rights. But this is the case with all the draft articles of the SPLT. Indeed, it is because all the draft articles and draft regulations have this character that from the first elaboration of the SPLT in 2001 there have been at least six revisions to the draft language of most if not all the articles in the draft treaty.

In essence, the fact that a proposed provision may not be clearly defined can not be a basis for the exclusion of an issue from the scope of the draft SPLT. Furthermore, the proponents of the proposals on exceptions were never given the opportunity to present the proposals exhaustively as the discussions on article 2(3) and 12(5), in particular, was reserved for a later date.³⁰ It is only after an exhaustive discussion and revisions of the proposed provisions that a conclusion on whether the provisions are clearly defined or not could have been reached.

In sum, while the opponents of exceptions in the SPLT, especially the arguments proffered by the WIPO Secretariat raise a number of important questions on exceptions no basis has been established to exclude exceptions from the SPLT. The fact that there are valid issues to be addressed and questions to be answered provides no such basis. As already noted, this is the case with virtually all the articles in the SPLT including those relating to prior art, grace period,

³⁰ See footnote 1 and 7 to document SCP/10/2 which indicates that the SCP agreed at its eighth session to include these paragraphs, but to postpone substantive discussions on the provisions.

novelty and inventive step. Indeed, even the proposal on SPLT-light recognises this premise. For example, in the SPLT-light proposal by the United States and Japan and in subsequent proposals including at the General Assembly, there is an explicit disclaimer that *“Since grace period and first-to-file are linked, grace period, although included in the first package for discussion, is subject to movement on first-to-invent.”*

In the circumstances, the question as to whether exceptions generally or exceptions to patent rights, in particular, should or should not be part of the SPLT will depend on the agreed objectives and scope of the SPLT. An *a priori* exclusion is imprudent.

III. THE OBJECTIVES AND SCOPE OF THE SPLT AND EXCEPTIONS TO PATENT RIGHTS

Exceptions in patent law and in the current international framework embodied in the TRIPS Agreement, in particular, are essential to ensure, as envisaged in article 7, that the protection of intellectual property rights including patents, contributes to the promotion of technological innovation by allowing, for example, experimental use of patents, and the transfer and dissemination of knowledge.

Exceptions are also important in ensuring the balance between the advantages that accrue to the patent holders, referred to as producers of knowledge in TRIPS, and those that accrue to consumers, competitors and the general public, referred to in TRIPS as users of knowledge. Further, exceptions are important in putting into practical effect the principles in article 8 of TRIPS which contemplate measures to protect public health and nutrition and public interest in sectors of vital importance to the economy, prevent abuse of rights

and practices that unreasonably restrain trade or adversely affect transfer of technology.

Therefore, at issue in the SPLT is not whether exceptions should be part of the international patent regime, since all WIPO Members agree on their importance, recognise their balancing effect and have enshrined such exceptions in their national laws, but rather, (1) whether such exceptions fall within the scope of the draft SPLT and (2) whether some of the exceptions, such as those relating to genetic resources, should be discussed in the SCP. The question of forum for addressing exceptions such as references to the IGC or the WTO, as already noted, is only a distraction and I therefore do not address it here.

The determination of whether exceptions to patent rights should be part of any SPLT turns on the following question: *WHAT SHOULD BE THE OBJECTIVE AND SCOPE OF THE SPLT?* According to the WIPO Secretariat,

The need for further patent harmonization beyond the PLT arises mainly from the fact that the costs of obtaining broad patent protection on an international level have become extremely high. The objective of further harmonization should therefore be to lower costs. This goal can, however, only be envisaged if a number of basic legal principles underlying the grant of patents are harmonized.³¹

This is the only available justification for deep harmonization since the draft SPLT does not contain either a preamble or other stated objectives or aims. While the reduction of the cost for obtaining patents is no doubt a laudable aim, considering the significant impact of this process of “deep harmonisation” on the

³¹ See paragraph 8 of document SCP/4/2 containing suggestions by the WIPO Secretariat on the further development of international patent law.

international patent system, reduction of cost for patent applicants as the sole aim of such a profound international effort is highly questionable.

Today the international patent system faces a number of major challenges ranging from adapting to new technologies to responding appropriately, and effectively, to the concerns of the increasing number of stakeholders. There are huge and rising problems of patent quality characterised by extremely broad claims, weak inventiveness and insufficient disclosure.³² Although recently claims have been made that the proposed SPLT-light is meant to address patent quality, these claims arose only after question were raised about the objective of the SPLT. If one reads research such as that by Jaffe and Lerner and compare with the proposals on the draft SPLT, one is left with little choice but to conclude that the claims about patent quality are just rhetoric.³³ There is no evidence that the original intention of simply reducing costs has been superseded by a desire to really improve patent quality.

The stakeholders in the patent system have also significantly changed. Unlike in the 90s and in 2000/2001 when the SPLT discussions were largely between the patent offices of developed countries and industry and lawyer groups, with intermittent and disjointed participation of developing countries and civil society groups, the stakeholders in WIPO processes including the SPLT, are much larger today. More and more developing countries, international organisations, civil society organisations, non-governmental organisations

³² OECD, *Patents, Innovation and Economic Performance*, OECD Conference Proceedings, OECD, Paris (2004), p.23.

³³ Jaffe, Adam and Josh Lerner, *Innovation and Its Discontents – How Our Broken Patent System is Endangering Innovation and Progress, and What to do About it*, Princeton University Press, Princeton and Oxford (2004).

(NGOs) of various sorts, scientists, academics, entrepreneurs, and a variety of other players are now claiming their stake in the processes.

The democratisation of the international patent system means that such important processes as the SPLT can not proceed without a clear explanation of its objectives and scope. As the Casablanca experience demonstrates, there can no longer be “an understanding” which was reached among a few individuals from patent offices and industry groups which is unquestionable. The more the stakeholders the more critical it is to have clarity of purpose. The open forum should serve as an important basis to think about purpose.

At the same time, as patents play a more complex role in industry and society, the idea which has prevailed for a long time in the patent community that there are technical issues and policy issues which are somehow separate and compartmentalised no longer holds true. To attempt to proceed on this basis is counterproductive. In this regard, to suggest that the SPLT should reduce the costs of obtaining patents without any honest and serious thought being given to patent quality will only have the effect of further eroding confidence in the system. Such an approach means an even larger increase in patents of doubtful quality making a consideration of the impact of such increase, for example, the role of exceptions to patent rights absolutely essential.

Consequently, the starting point even before addressing the issue of exceptions to patent rights should be to define the object and purpose of the proposed SPLT and on that basis the scope. Only with a well defined and agreed object, purpose and scope can one hope to satisfactorily address the question of how to deal with exceptions to patent rights. In other words, the lack of a clear and acceptable objective, purpose and scope for the SPLT, renders an objective determination of whether or not to include exceptions to patent rights almost

impossible. If one assumes that the SPLT is an attempt to address the most pressing problems in the patent system today, then exceptions, both in terms of exclusions from patentable subject matter and exception to patent rights must be addressed. This does not, however, mean that there must be articles upon articles on these matters. There are several basic options which I consider below.

IV. OPTIONS FOR ADDRESSING EXCEPTIONS TO PATENT RIGHTS IN THE SPLT

It is fairly clear that the further harmonisation of patent law can not proceed without a conscious effort to think about the effect of such harmonisation on the balancing mechanisms in the system such as exceptions to patent rights. Whether and how such exceptions are addressed in such harmonisation efforts is a separate question. In the context of the SPLT, the question relating to the balancing mechanisms in general can be addressed by thinking about the object, purpose and scope of the SPLT.

Based on defined object, purpose and scope, there are various options that could be considered in addressing exceptions to patent rights. One obvious option is to be silent and assume that the SPLT, as argued by the WIPO Secretariat, would not limit the freedom of WIPO Members to regulate any matters which are not included in the scope of the SPLT, for example, matters relating to the rights conferred by a patent, the enforcement of the patent rights or exceptions to patent rights. It is arguable that such an approach should satisfy the proponents of exceptions.

It is submitted, however, that silence on exceptions generally, and exceptions to patent rights, in particular, has significant potential dangers especially for developing countries. The clearest indication that silence in the SPLT would introduce uncertainty for governments, patent holders and third

parties causing considerable problems follows from the statement by the delegation of the United States at the seventh session of the SCP. The delegation, referring to the proposal on exceptions to patentability opposed the:

[B]lanket inclusion of the exceptions provided for under Articles 27.2 and 27.3 of the TRIPS Agreement into the SPLT because of the different nature of the SPLT and the TRIPS Agreement. The TRIPS Agreement was a result of a complex negotiation which involved many other global trade issues and trade-offs, not only within intellectual property, including many issues that were beyond the issues concerning patents being discussed by the Committee. A specific example that did not fit within the confines of the SPLT was the exclusion of plants and animals that were currently allowed under Article 27.3(b) of the TRIPS Agreement, because these were examples of important subject matters in developing fields of innovation, such as biotechnology.³⁴

This statement suggests that silence on exceptions would not be golden. In other words, it is foolhardy to think that the TRIPS Agreement and other agreement will provide security when it comes to implementation of the SPLT. This leaves two options: (1) a general saving clause, or (2) specific enumeration and the definition of the rules for the application of exceptions to patent rights.

The purpose and scope of exceptions to patent rights vary considerably between countries depending on the policy objectives being pursued. It is therefore generally difficult to define and enumerate the range of permissible exceptions. The current international consensus therefore is to only go as far as defining certain criteria for determining legitimate exceptions to patent rights

³⁴ See paragraph 164 of the report of the session, *supra* note 13.

and leave the actual determination of the exceptions to each country. Taking this situation into account it is not likely or necessarily prudent, especially for developing countries, to seek to push for an agreement beyond the three-step-test under article 30 of TRIPS.

Taking into account the danger of silence and the challenges of attempting to go beyond the three-step-test, the best option is to have a general saving clause which would explicitly provide that the SPLT, in whatever form, will have no effect and will not be interpreted as affecting the rights of WIPO Members to take any measures or use any mechanisms such as exceptions to patent rights, to achieve the objectives set out in article 7 of the TRIPS Agreement and any other similar objectives.