

Committee on Development and Intellectual Property

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FUTURE WORK ON PATENT-RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK

prepared by the Secretariat

1. The Committee on Development and Intellectual Property (CDIP), at its ninth session held from May 7 to 11, 2012, discussed document CDIP/9/11. Concerning paragraph 2 (c) of that document, the Committee discussed four possible topics to be addressed in a future document on patent-related flexibilities.
2. The Committee requested the Secretariat to provide information regarding those four topics and to invite Members States to provide comments by August 31, 2012.
3. This document contains the information requested and comments received from Members States.
4. *The Committee is invited to consider the information provided in this document.*

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INTRODUCTION

1. In the context of the discussions on Development Agenda recommendation 14, Member States, at the Ninth Session of the Committee on Development and Intellectual Property (CDIP) held from May 7 to 11, 2012, discussed document CDIP/9/11 on future work on flexibilities. Concerning paragraph 2(c) the Committee discussed four patent-related flexibilities themes as the possible object of the next document to be prepared by the Secretariat. The Committee agreed to request the Secretariat to provide information on the abovementioned topics and also to request comments from Members States.

2. In reply to the request of the Committee, the Secretariat

(i) Invited Member States of the Committee to submit written comments on the list of the following four patent-related flexibilities by August 31, 2012:

- The scope of the exclusion from patentability of plants (TRIPS Art. 27);
- Flexibilities in respect of the patentability, or exclusion from patentability, of software-related inventions (TRIPS Art. 27);
- The flexibility to apply or not criminal sanctions in patent enforcement (TRIPS Art. 61);
- Measures related to security which might result in a limitation of patent rights (so-called "security exception") (TRIPS Art. 73);

(ii) Elaborated the present document describing previous work on the four patent-related flexibilities listed in paragraph (i) which has been undertaken within the framework of the Standing Committee on the Law of Patents (SCP) and providing further explanation on the latter two points in paragraph (i) above. Comments submitted by Members States by the date indicated in item (i) have been included.

3. The Committee discussions on the present document should give guidance to the Secretariat on the content of its next document on patent-related flexibilities, particularly, on which flexibilities to be addressed.

4. Concerning future work, particularly the list of other patent-related flexibilities, the Committee agreed that this should be the subject of intersessional consultations and that a decision should be taken at the eleventh session of the CDIP to be held in 2013.

I. INFORMATION CONCERNING THE WORK OF THE STANDING COMMITTEE ON THE LAW OF PATENTS ON THE FOUR PATENT-RELATED FLEXIBILITIES

5. To comply with the Committee's request, the Secretariat has proceeded to analyze documents presented at the SCP in which reference has been made to the four subjects proposed to be studied in a possible future document on patent-related flexibilities. The following part of this document presents the results of that research:

A. CONCERNING THE SCOPE OF THE EXCLUSION FROM PATENTABILITY OF PLANTS

SCP/12/3 Rev.2: Report on the International Patent System

6. The Report on the International Patent System (Report) is a comprehensive document prepared by the WIPO Secretariat for the twelfth session of the Standing Committee on the Law of Patents (SCP) covering various issues relating to the international patent system. The question of the scope of the exclusion from patentability of plants was discussed in various chapters.¹

Revised Annex II of document SCP/12/3 Rev.2 (SCP/18/2)

7. Annex II of document SCP/12/3 Rev.2, which has been regularly updated,² provides comprehensive information. The table includes information on countries which exclude plants from patentable subject matter without necessarily elaborating on the scope of such exclusions.

SCP/13/3: Preliminary study entitled "Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights"

8. Document SCP/13/3, prepared by the WIPO Secretariat, was submitted to the thirteenth session of the SCP as a preliminary study on the issue of exclusions from patentable subject matter and exceptions and limitations to the rights. The subject of exclusions from patentable

¹ Chapter V(c), the basic standards for patentability and a limited list of exclusions from patentable subject matter provided by Article 27 of the Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS Agreement) are mentioned. It is also pointed out that the Members are left free to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice, and that the Agreement leaves flexibilities for the Members to design their patent systems since certain issues, such as the definition of invention, are not addressed under the Agreement. In Chapter VI(j), it is explained that while Article 27.1 of the TRIPS Agreement provides that, in principle, "any inventions" are patentable subject matter, the definitions of the term "invention" under the national legislations are not uniform, reflecting the policy choices of the countries concerned. In this context, the Chapter looks at how various countries define the term "invention" under their applicable law(s). Against this background, the policy choices in relation to exclusions from patentability under Article 27.2 and 3 of the TRIPS Agreement, including exclusions related to plants, are listed by reciting those provisions. While Chapter VI(m) it informs the reader about the systemic challenges faced by the patent law when the new technologies emerge. It explains inter alia that in new technological areas, including biological materials and transgenic living entities, and software implemented business methods the patentable subject matter is not always straightforward.

² The latest updated information is contained in document SCP/18/2.

subject matter is thoroughly addressed from the perspectives of their policy objectives and role, the international legal framework,³ and provisions contained in national and regional laws.⁴

SCP/15/3: Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights

9. The study provides a comprehensive analysis of and discussions on various exclusions and exceptions provided under national and regional laws, including an analysis of the international framework of such exclusions/exceptions. The issue of exclusions from patentability of plants and other life forms has been primarily dealt with in Annex III of that document, entitled "Biotechnology", which was prepared by Professors Denis Barbosa and Karin Grau-Kuntz. The authors looked *inter alia* at exclusions provided by Article 27 of the TRIPS Agreement, surveyed various exclusions relating to humans, animals and plants found in national and regional laws, and discussed the complex relationship between patents and plant variety rights' systems (for example in relation to exceptions for farmers (so-called 'farmer's privilege').⁵

10. Chapter II Annex VI of the study prepared by Professors Richard Gold and Yann Joly deals with how exclusions from patentability may affect research. In that context, the international legal framework, in particular Article 27 of the TRIPS Agreement, regional agreements and national laws have been studied, including provisions and case law concerning exclusions in respect of plants, plant varieties and essentially biological processes for the production of plants.

SCP/16/3 Rev.: Draft Questionnaire on Exceptions and Limitations to Patent Rights; SCP/17/3: Responses to the Questionnaire on Exceptions and Limitations to Patent Rights; and SCP/18/3: Overview of the Responses to the above Questionnaire

11. Concerning Section I of the Questionnaire, 73 completed responses were provided to the SCP, each of which indicated whether the applicable law(s) excluded plants from patentability and, if that was the case, the scope of such exclusion.

SCP/14/4 Rev.2: Preliminary study entitled "Transfer of Technology"

12. This preliminary study addresses primarily the issue of technology transfer. Against this backdrop, it looks at various issues, such as policy challenges, the role of the patent system in technology transfer, the legal framework and flexibilities available in the patent system which concern transfer of technology. In that context, in Chapter VII(d)(i) it is briefly mentioned that the current international framework provides flexibilities as to the exclusion of certain technology from patentable subject matter, and, as a result, many countries exclude plants, animals or computer programs from patentable subject matter.

³ In analyzing the existing international rules, Chapter II(d) of the preliminary study provides an explanation on how the issue of exclusions from patentable subject matter, including the exclusions relating to plants, is addressed by the international treaties, such as the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty (PCT), and the TRIPS Agreement.

⁴ Chapter II (e)(iii) entitled "Inventions Relating to Plants and Animals" offers an overview of the national and regional laws on exclusions from patentable subject matter concerning inventions relating to plants and animals, including the analysis of the scope of such exclusions.

⁵ In addition, in Annex I, Chapter I.B, Professor Lionel Bently in part B of Chapter I offers insight on historical development of exclusions and international and regional standardisation. In this context, he analyzes, *inter alia* Article 27(1), (2) and (3) of the TRIPS Agreement and draws conclusion on the effect of flexibilities contained in that provision on standardisation of national and regional laws.

B. CONCERNING THE PATENTABILITY OR EXCLUSION FROM PATENTABILITY OF SOFTWARE-RELATED INVENTIONS

SCP/12/3 Rev.2: Report on the International Patent System

13. In the framework of the discussion on the scope of the term “invention” in Chapter VI(j) of the Report, it is stated that one of the differences in national laws in respect of this term is that in a majority of countries, the concept of invention includes some form of technical character or technical idea, whereas in other countries, technicality is not a requirement for patentable subject matter.⁶

Revised Annex II of document SCP/12/3 Rev.2 (SCP/18/2)

14. The table in Annex II includes information on countries which exclude software-related inventions from patentability.⁷

SCP/13/3: Preliminary study entitled “Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights”

15. In addition to the observation made in paragraph (8) of the present document, within the analysis of the existing international rules on exclusions, the PCT does allow the International Authorities (International Searching Authority or an International Preliminary Examining Authority) not to carry out any international search or international preliminary examination with respect to certain categories of subject matter, including computer programs to the extent that the International Authority is not equipped to search prior art or to carry out an international preliminary examination concerning such programs.

SCP/15/3: Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights

16. The patentability of software-related inventions has been primarily dealt with in Annex II of this document entitled “Computer Programs as Excluded Patentable Subject Matter” prepared by Professor Brad Sherman. The author examines *inter alia* the justifications for excluding computer programs from patentable subject matter, looks at particularities of computer programs as such and computer-implemented inventions, and explores various modes employed by different jurisdictions for excluding computer programs from patentable subject matter. In addition, in Chapter I.B, Professor Lionel Bently explains that while Article 27 contains an obligation to make patents available in all fields of technology, the term “technology” is not defined. In that context, the author looks into the question of whether certain subject matters can be excluded from patentability on the basis that they are not “technological”, “technical” or “inventions”, and offers his opinion on how this provision of the TRIPS Agreement should be interpreted.

⁶ In relation to software-implemented inventions, Chapter VI (m), in addition to the observation made in paragraph 4 of the present document, provides discussions on the effect of the patent protection of software on competition in this field, and the development of open source models.

⁷ In addition, Annex II of document SCP/12/3 Rev.2 provides information on countries which exclude mathematical and/or methods and rules and methods for mental activities from patentable subject matter. While the interpretation of those terms may vary in different jurisdictions, in some jurisdictions, certain computer programs may be excluded as they fall within the scope of those terms.

SCP/16/3 Rev.: Draft Questionnaire on Exceptions and Limitations to Patent Rights; SCP/17/3: Responses to the Questionnaire on Exceptions and Limitations to Patent Rights; and SCP/18/3: Overview of the Responses to the above Questionnaire

17. The responses to the questionnaire indicated *inter alia* whether the applicable law(s) excluded software-related inventions from patentability and, if that was the case, the scope of such exclusion.

SCP/14/4 Rev.2: Preliminary study entitled "Transfer of Technology"

18. The Chapter where the issue has been touched upon is Chapter VII(d)(i) "Exclusions from Patentable Subject Matter".

C. CONCERNING CRIMINAL SANCTIONS IN PATENT ENFORCEMENT (TRIPS ART.61)

19. The issue has not been discussed in the SCP. However, reference has been made to it in some documents presented to the Advisory Committee on Enforcement,⁸ although the question has not been treated in detail and without addressing policy options for implementation.

D. CONCERNING MEASURES RELATED TO NATIONAL SECURITY (SO-CALLED "SECURITY EXCEPTION")

Revised Annex II of document SCP/12/3 Rev.2 (SCP/18/2)

20. The table in Annex II includes information on countries which exclude nuclear methods and/or products from patentability.

SCP/13/3: Preliminary study entitled "Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights"

21. Chapter II(e) of the preliminary study lists certain categories of subject matters that are excluded from patentable subject matter in many countries. It further discusses the scope of those exclusions under national/regional laws. Paragraph (iv) of that Chapter, entitled "Inventions affecting national security", broadly mentions that in some countries inventions affecting national security or, more specifically, inventions concerning nuclear processes and products are excluded from patentable subject matter.

SCP/15/3: Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights

22. In Chapter I.B, Professor Lionel Bently touches upon Article 73 of the TRIPS Agreement by citing that provision and listing countries which provide exclusions relating to nuclear methods and/or products.

⁸ Specific reference to criminal sanction on patents is made in the following documents: WIPO/ACE/4/3 pages 15 and 16; WIPO/ACE/5/6 page 21; and WIPO/ACE/5/10 page 11 and 20 to 23. The latter has been prepared taking into account Recommendation 45 of the WIPO Development Agenda.

E. SUMMARY

23. In sum, it appears that the first two suggested flexibilities have been treated in part by the SCP, while the two last one have hardly been addressed at all.

II. COMPILATION OF WRITTEN COMMENTS PRESENTED BY MEMBERS STATES BY AUGUST 31, 2012

A. BELARUS

24. In accordance with the Law of the Republic of Belarus of December 16, 2002, on Patents for Inventions, Utility Models and Industrial Designs (hereinafter the Law of December 16, 2002), legal protection shall not be granted in the form of inventions to plant varieties. At the same time, the means of breeding plants may be patented as inventions.

25. In addition, legal protection for varieties (types) of plants in the Republic of Belarus is granted within the framework of special legislation, in particular the Law of the Republic of Belarus, of April 13, 1995, on Patents for Plant Varieties. According to that Law a plant variety shall be granted legal protection, if it is novel, distinct, uniform and stable. The right in a plant variety shall be protected by the State and certified by a patent. The patent shall be valid for 25 years from the date of entry of the variety in the State Register of Protectable Plant Varieties of the Republic of Belarus. The scope of legal protection of a variety shall be determined by its official description, contained in the State Register of Protectable Plant Varieties of the Republic of Belarus.

26. In accordance with the Law of December 16, 2002 algorithms and computer programs shall not be considered to be inventions. In this regard, the possibility of including such subject matter among inventions shall be excluded only where an application for the grant of a patent for an invention relates solely to such subject matter per se.

27. Flexibility in relation to patenting lies in the fact that a program algorithm may be protected as a means to an invention. In this connection, the algorithm must be presented not as a program language but in terms of the stages of what is done to produce it. Each such algorithm must necessarily be backed up by flow charts or diagrams of its production.

28. Pursuant to the Criminal Code of the Republic of Belarus, the illegal dissemination or other unlawful use of the subject matter of an industrial property right, performed within 12 months of the imposition of an administrative sanction for such an infringement or relating to the receipt of a large amount of income shall be punished by means of community work, a fine, or restriction of freedom for up to three years, or deprivation of freedom for up to two years. Such repeat offenses, either by a group of people by prior agreement, or by an official in the performance of his professional duties, as well as offenses which cause major damage shall be punished by a fine or detention for up to six months, restriction of freedom for up to five years, or deprivation of freedom for a similar period.

29. The procedure for granting legal protection for inventions, utility models or industrial designs, recognized in accordance with the established procedure as secret, and the procedure for dealing with secret inventions, utility models or industrial designs shall be established by the Regulations on Secret Inventions, Utility Models and Industrial Designs, approved by Decree of the Council of Ministers of the Republic of Belarus No. 900 of July 2, 2003. In accordance with those Regulations, where a decision is taken to grant a patent for an application for a secret invention, utility model or industrial design to the author of the invention, utility model or industrial design, certification of the author shall be granted, on the basis of which he shall be

entitled to compensation and remuneration. The grant of a patent for a secret invention, utility model or industrial design shall be suspended for the term of validity of restrictions on the dissemination of the information contained in an application and the applicant informed accordingly. The authorized body which took the decision to include information contained in an application for an invention, utility model or industrial design among State secrets, and also the use of a secret invention, utility model or industrial design shall specify the period of validity of the restrictions on such information. An applicant, or author of a secret invention, utility model or industrial design, or their legal successors, for whom the grant of a patent has been suspended, shall be entitled to compensation for the losses arising as a result of the imposition of restrictions on the dissemination of information contained in an application, and to remuneration for use of a secret invention, utility model or industrial design.

30. Thus, in accordance with the provisions of Articles 27, 61 and 73 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), concluded in Marrakesh on April 15, 1994, patent-related flexibilities are provided for in the legislation of the Republic of Belarus.

B. SOUTH AFRICA

The scope of exclusion from patentability of plants (TRIPC Art. 27):

31. In terms of the current Patent Act 57 of 1978 in South Africa the scope of patentable inventions is determined in negative according the Section 25 of the Act. The parts of the Section 25 given below in bold are related to plants:

“Patentable inventions

25.(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

(2) Anything which consists of:

- (a) a discovery;
- (b) a scientific theory;
- (c) a mathematical method;
- (d) a literary, dramatic, musical or artistic work or any other aesthetic creation;
- (e) a scheme, rule or method for performing a mental act, playing a game or doing business;
- (f) a program for a computer; or
- (g) the presentation of information, shall not be an invention for the purposes of this Act.

(3) The provisions of subsection (2) shall prevent, only to the extent to which a patent or an application for a patent relates to that thing as such, anything from being treated as an invention for the purposes of this Act.

(4) **A patent shall not be granted:**

- (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or
- (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.**

(5) An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention.

[Sub-s.(5) substituted by s.31(a) of Act no. 38 of 1997.]

(6) The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.

(7) The state of the art shall also comprise matter contained in an application, open to public inspection, for a patent, notwithstanding that the application was lodged at the patent office and became open to public inspection on or after the priority date of the relevant invention, if:

(a) that matter was contained in that application both as lodged and as open to public inspection; and

(b) the priority date of that matter is earlier than that of the invention.

[Sub-s. (7) substituted by s.31(b) of Act no. 38 of 1997.]

(8) An invention used secretly and on a commercial scale within the Republic shall also be deemed to form part of the state of the art for the purposes of subsection (5).

(9) In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.

[Sub-s.(9) substituted by s.31(c) of Act no. 38 of 1997.]

(10) Subject to the provisions of section 39(6), an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8)).

[Sub-s.(10) substituted by s.31(d) of Act no. 38 of 1997.]

(11) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry or agriculture.

(12) Subsection (11) shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method."

32. However, there is a sui generis legislation in force South Africa that protects the plant varieties, that is the Plant Breeder's Rights Act No. 15 of 1976:

"2.(1) This Act shall apply in relation to every variety of any prescribed kind of plant if it is new, distinct, uniform and stable.

(2) A variety referred to in subsection (1) shall be deemed to be-

(a) new if propagating material or harvested material thereof has not been sold or otherwise disposed of by, or with the consent of, the breeder for purposes of exploitation of the variety-

(i) in the Republic, not more than one year; and

(ii) in a convention country or an agreement country, in the case of-

(aa) varieties of vines and trees, not more than six years; or

- (bb)* other varieties, not more than four years, prior to the date of filing of the application for a plant breeder's right;
- (b)* distinct if, at the date of filing of the application for a plant breeder's right, it is clearly distinguishable from any other variety of the same kind of plant of which the existence on that date is a matter of common knowledge;
- (c)* uniform if, subject to the variation that may be expected from the particular features of the propagation thereof, it is sufficiently uniform with regard to the characteristics of the variety in question;
- (d)* stable if the characteristics thereof remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

- (3) If the application of this Act is extended to a kind of plant to which this Act, or any law repealed by it, did not previously apply, the registrar may deem a variety of such a kind of plant which existed at the time of the extension to be new for the purposes of subsection (2)(a), notwithstanding the fact that propagating material or harvested material thereof was sold or disposed of prior to the periods of time referred to in that subsection.
- (4) If an application, in any country, for the grant of a plant breeder's right in respect of, or for the entering in the official register of varieties of, a variety in fact leads to the grant of a plant breeder's right in respect of, or to the entry in the official register of, that variety in the country in question, the existence of that variety shall, as from the date of the application, for the purposes of subsection (2)(b), also be deemed to have been a matter of common knowledge.
- [S.2 amended by 2 of Act no. 5 of 1980 and substituted by s.2 of Act no. 15 of 1996.]”

33. In terms of the Plant Breeder's Rights Act , exceptions to the breeder's right are the use of the variety privately and for non-commercial purposes, experimental purposes, and for breeding other plant varieties. A protected variety could be used for these acts without the authorization from a plant breeder's right holder. Farmers were also allowed to use for propagating purposes, on their own holdings, the product of the harvest that they had obtained by planting on their own holdings the protected variety:

- “(1) Notwithstanding section 33(a), a plant breeder's right in respect of a variety obtained in a legitimate manner does not extend to:
- (a)* any act done in respect of that variety for private or non-commercial purposes;
 - (b)* any act done in respect of that variety for experimental purposes;
 - (c)* any act done in respect of that variety for the purposes of breeding other varieties and, except where section 6(3) applies, any act contemplated in section 6(1) and (2) in respect of such other varieties; or
 - (d)* a farmer who on land occupied by him or her uses harvested material obtained on such land from that variety for the purposes of propagation, as long as that harvested material is not used for the purposes of propagation by any person other than that farmer.
- (2) The provision of subparagraph (1) *(d)* shall not apply to vegetatively propagated crops and shall only apply as prescribed.”

Flexibilities In Respect Of The Patentability, or Exclusion From Patentability Of Software-Related Inventions (Trips Art. 27)

34. The exclusion from patentability of the software programs is provided for in Section 25 of the Patent Act. The parts of this section given in bold are related to this exclusion:

“Patentable inventions

25.(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

(2) **Anything which consists of:**

- (a) a discovery;
 - (b) a scientific theory;
 - (c) a mathematical method;
 - (d) a literary, dramatic, musical or artistic work or any other aesthetic creation;
 - (e) a scheme, rule or method for performing a mental act, playing a game or doing business;
 - (f) a program for a computer; or**
 - (g) the presentation of information
- shall not be an invention for the purposes of this Act.

(3) The provisions of subsection (2) shall prevent, only to the extent to which a patent or an application for a patent relates to that thing as such, anything from being treated as an invention for the purposes of this Act.

(4) A patent shall not be granted:

- (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour; or
- (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

(5) An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention.
.....”

The flexibility to apply or not criminal sanctions in patent enforcement (TRIPS Art.61)

35. The patent Act 57 of 1978 does not provide for criminal sanctions in case of patent infringement.

Mesures related to security which might result in a limitation of patent rights (so-called “security exceptions”)
(TRIPS Art. 73)

36. The following provisions of the Patent Act 57 of 1978 are relevant to the above topic:

“ CHAPTER XIV of the Patent Act 57 of 1978
Acquisition of rights to inventions and patents by the state

Acquisition of invention or patent by State

78. The Minister may, on behalf of the State, acquire, on such terms and conditions as may be agreed upon, any invention or patent.

Assignment of certain patents to the State

79.(1) The proprietor of an invention relating to any armaments as defined in section 1 of the Armaments Development and Production Act, 1968 (Act no. 57 of 1968), shall, if called upon to do so by the Minister of Defence, assign the invention or the patent obtained or to be obtained for the invention to that Minister on behalf of the State.

(2) The assignment and any agreements therein contained shall be valid and effectual and may be enforced by appropriate proceedings in the name of the Minister of Defence.

(3) Where an invention has been so assigned, the Minister of Defence may, by notice in writing to the Registrar, direct that the invention and the manner in which it is to be performed shall be kept secret.

(4) Every application, specification, amendment of specification or drawing received at the patent office relating to any invention in respect of which notice in terms of subsection (3) has been given, shall be sealed up by the Registrar and the contents of such application, specification, drawing or other document shall not be divulged without the written permission of the Minister of Defence.

(5) The patent for any such invention may be made out in the name of the proprietor and sealed, but such patent shall be delivered to the Minister of Defence and not to such proprietor and shall be the property of the State, and no proceedings shall lie for the revocation of the patent.

(6) The communication of any such invention to the Minister of Defence or to any person authorised by him to inquire into the invention shall not, nor shall anything done for the purpose of the inquiry by such person, be deemed to be publication or use of the invention so as to prejudice the grant or validity of any patent for the invention.

(7) The Minister of Defence may by notice in writing to the Registrar direct that any invention directed to be kept secret need no longer be kept secret, and thereupon the specification and drawings may be published.

(8) The said Minister shall pay to the proprietor of the invention or patent such reasonable compensation as may be agreed upon or as may, in default of agreement, be determined by arbitration or, if the parties so agree, by the Commissioner.

Minister may require inventions to be kept secret in certain circumstances

80.(1) If the Minister is of opinion that in the national interest an application, specification, drawing or other document relating to any invention should be kept secret, he may order the Registrar to keep the invention secret and to notify the applicant accordingly, and if any Minister of State desires to acquire such invention on behalf of the State, the provisions of section 79 shall as far as applicable apply, and for that purpose the reference in section 79 to the Minister of Defence shall be deemed to be a reference to the said Minister of State.

(2) Whenever any order issued by the Minister under this section is withdrawn, any steps which were prior to the date of that order taken under this Act in connection with the application which was the subject of that order, and which were interrupted in consequence of that order, may be proceeded with as if the interruption had not occurred, and any period which may have elapsed between the date on which that order was lodged with the Registrar and the date of withdrawal thereof shall not be taken into account in the computation of any period of time prescribed by or under this Act.

(3) If the proprietor of an invention has suffered loss or damage by reason of that invention having been kept secret in pursuance of an order under subsection (1), the Minister shall pay to him such reasonable compensation as may be agreed upon or as may, in default of agreement, be determined by arbitration or, if the parties so agree, by the Commissioner.”

C. UNITED STATES OF AMERICA

37. The United States thanks the Secretariat for preparing the list of four patent-related flexibilities and inviting Member States to comment on it.

38. We would like to reiterate our support for WIPO's efforts to make available advice to developing countries and LDCs on "the rights and obligations and the understanding and use of flexibilities contained in the TRIPS Agreement," as expressly required by Development Agenda recommendation 14. However, the Committee should ensure that any future work on flexibilities is not duplicative and respects both the subject matter expertise of other committees and CDIP's unique mandate.

39. Regarding the four listed flexibilities proposed for a study at CDIP, at least two of them (i.e. those arising from Article 27 of TRIPS) have been studied extensively at the Standing Committee on the Law of Patent (SCP)⁹.

40. The United States favors organizing and making more accessible the studies and resources on flexibilities that WIPO has already produced in the subject matter committees and would encourage the Secretariat to transmit those studies to CDIP.

D. URUGUAY

41. Uruguay reaffirmed its interest that WIPO continues in carrying out a wide, rigorous and detailed study concerning the flexibilities contained in the TRIPS Agreement in accordance with what is determined by the Committee on Development and Intellectual Property.

E. EUROPEAN UNION

42. The European Union supports the effective implementation and use of the rules and flexibilities set out in the TRIPS Agreement.

43. We believe that the World Trade Organisation is the relevant forum to discuss the application of TRIPS rules and flexibilities and, at the least, should be associated and consulted in any such discussion.

44. It is equally worth recalling that, to a large extent, the information currently requested is already available at the WTO by means of the data submitted through the notification mechanism under Article 63 of the TRIPS Agreement.

F. DEVELOPMENT AGENDA GROUP

45. In accordance with the conclusions of the 9th session of the Committee on Development and Intellectual Property (CDIP), the Development Agenda Group (DAG) would like to submit its contribution to the discussion on the following four patent-related flexibilities: (a) the scope of the exclusion from patentability of plants (TRIPS Art. 27); (b) flexibilities in respect of the patentability, or exclusion from patentability, of software-related inventions (TRIPS Art. 27); (c) the flexibility to apply or not criminal sanctions in patent enforcement (TRIPS Art. 61); and (d) measures related to security which might result in a limitation of patent rights (so-called "security

⁹ Please see at least the following documents: SCP/13/3; SCP/15/3 Annex 1, 2 and 3; and SCP/17/3.

exception”) (TRIPS Art. 73). The DAG reserves the right to submit further comments during the next session of the CDIP, when those four patent-related flexibilities will be subject to debate.

46. The CDIP has an important role to play in the discussion on flexibilities in the IP regime. Due to its cross-cutting nature, the CDIP has the credentials to promote a wide and substantive debate on IP flexibilities. That is why the DAG supports the strengthening of the Work Program on Flexibilities in the Intellectual Property System that includes not only studies on the matter, but also very practical activities, such as the development of a database that compiles national experiences regarding the implementation of such flexibilities. Work on flexibilities in the IP system should be as extensive and effective as possible. This is important to ensure a balanced and effective IP system.

47. We believe that the results of such work program will contribute to the implementation of the recommendation 14 of the Development Agenda, since they will support and give due orientation to the work to be developed by WIPO regarding technical assistance on the use of flexibilities contained in the TRIPS Agreement. They will also help Member States to calibrate their national IP systems in order to achieve the fundamental trade-off of the patent system, which was to guarantee the temporary monopoly of a given product or process in order to stimulate, not stifle, innovation.

48. Document CDIP/9/11 continues to form the basis for discussions on the work program in addition to the Secretariat’s paper on the four patent-related flexibilities and comments submitted thereon. The discussion on those four patent-related flexibilities should be within the framework of the elements proposed in document CDIP/9/11.

49. We note that the four patent-related flexibilities identified during CDIP 9 are non exhaustive of all patent-related flexibilities. Further, document CDIP/9/11 is not limited to patent-related flexibilities and the CDIP should give further consideration to other IP flexibilities. It is important that Member States reach agreement on the other elements of document CDIP/9/11. The DAG is ready to contribute constructively to that discussion.

(a) Scope of the exclusion from patentability of plants (TRIPS Art. 27)¹⁰

50. Article 27 of the TRIPS Agreement provides the coverage of patentable subject matter. It is one of the most important provisions regarding the protection of patents under the TRIPS Agreement since it provides general orientation to that protection. Given the importance and the impact of the protection of patents, Article 27 does not only establish parameters, but also provides important flexibilities in the implementation of such protection, especially concerning what Members may exclude from patentability.

51. Article 27.3 (b) of TRIPS allows countries to exclude plants, animals other than micro-organisms and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes from patentability, but it also requires countries to provide for protection of plant varieties either through patents or through an effective sui generis system. While plants are excluded from patentability in many jurisdictions in accordance with Article 27.3 (b) of the TRIPS Agreement, the scope of such exclusion varies across national jurisdictions. Conversely in some other jurisdictions patents are allowed on plants. Moreover, while plants as such may be excluded from patentability, patents may cover cells and sub-cellular parts

¹⁰ Article 27

including genes and plant variety. Therefore the issue of exclusion of plants from patentability needs to be seen broadly to include not just the issue of patentability of plants, but also the patentability of parts of plants, including plant varieties and genes, as well as processes for the production of plants.

52. This flexibility was studied under the SCP Experts' Study on Exclusions, Exceptions and Limitations (SCP/15/3) under the section on biotechnology protection, authored by Professor Denis Borges Barbosa and Professor Karin Grau-Kuntz. The

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. 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.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

5. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

study is a very good basis to further enhance the discussion on the topic. However, as the study itself concludes, "empirical studies would be required before reaching any conclusions on the developmental dimensions of patent and plant variety protection and exclusions, exceptions and limitations there from in relation to biotechnological inventions." It is also important to note that the ongoing SCP survey on exceptions and limitations is only limited to farmers' privilege and/or breeders' exception. It does not address the issue of exclusion of plants from patentability. Taking that observations into account, the DAG is of the view that there is scope for further work on this issue within the CDIP without duplicating the work that has been undertaken or ongoing in the SCP. We note that this a very important flexibility, which may have impact on crucial development issues, such as food security.

53. It is thus proposed that for the purposes of the CDIP there is a need to take a more comprehensive approach to Article 27.3(b). The issue of the scope of exclusion of plants should be analyzed together with other components of Art. 27.3(b). It is thus submitted that the CDIP provide a mapping of how countries have implemented this provision nationally and regionally (where applicable). The analysis should also provide other relevant information regarding Art. 27.3(b) for e.g. patent examination guidelines, judicial decisions and interpretations, decisions taken by administrative authorities (e.g.

(patent offices). This should be followed by empirical studies regarding the developmental impact of Art. 27.3(b).

(b) Flexibilities in respect of the patentability, or exclusion from patentability, of software-related inventions (TRIPS Art. 27)

54. The flexibilities in respect of the patentability, or exclusion from patentability, of software-related inventions (TRIPS Art. 27) were also addressed by the SCP Experts' Study on Exclusions, Exceptions and Limitations (SCP/15/3) under the section on "Computer Programs as Excluded Patentable Subject Matter", authored by Professor Brad Sherman. As it is widely recognized, the TRIPS Agreement is being interpreted as flexible in what regards the patentability of computer programs or software since it leaves it to the Parties to determine what constitutes a patentable invention. National legislations address the question under different approaches. Some countries protect such programs as patents. Other, as copyrighted works. Other may even combine both, establishing specific criteria to each kind of protection. As document SCP/15/3 has highlighted, different approaches are arising based on legislative initiatives and judicial decisions. The question that remains in any model is which form of protection is best suited to promoting innovation in the software sector.

55. In that regard, the DAG believes that document SCP/15/3 is a good basis to discuss this specific flexibility. However, we are of the view that there is space for further development on the issue. One important question that should be addressed by a study that could be provided by the CDIP is an analysis on how the exclusion of software from patentability has contributed to the development of the software industry in different countries.

(c) Flexibility to apply or not criminal sanctions in patent enforcement (TRIPS Art. 61)

56. According to Article 61 of the TRIPS Agreement¹¹, "Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting and copyright piracy on a commercial scale." Thus, the minimum obligation under TRIPS is that criminal procedures and penalties should be provided, but these can be limited to cases of willful trademark counterfeiting (and not to any form of trademark infringement) and copyright piracy on a commercial scale. This flexibility provides the Parties of the TRIPS Agreement room to decide whether to apply or not criminal procedures and penalties to other IPR infringements, such as violations against patents. The same article provides for other important parameters regarding the application of criminal sanctions in cases of IPR infringements by recognizing that they should include only willful infringements on a commercial scale.

57. Therefore, under the TRIPS Agreement, there is no obligation to apply criminal sanctions to cases of patent infringement. Further, this provision should be read taking

¹¹ Article 61 - Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

into account the provisions of Article 41 of the TRIPS Agreement. In particular, Article 41.5 of TRIPS which states that the enforcement provisions under TRIPS (including Article 61) do not create any obligation to put in place a judicial system for IP enforcement distinct from the system for the enforcement of law in general, Art. 41.1 and 41.2 of TRIPS which state that enforcement procedures “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse” and “shall be fair and equitable”.

58. The DAG estimates it important to analyze this specific flexibility in a broader sense and together with other very important flexibilities regarding Part III of the TRIPS Agreement (“Enforcement of Intellectual Property Rights”) that applies to patents. In that regard, beyond Article 41, it would be very useful to discuss how Parties have been implementing Art. 44.2¹², which also provides a very important flexibility in the sense that it allows Members to limit the use of injunctions as a remedy.

(d) Measures related to security which might result in a limitation of patent rights (so-called “security exception”) (TRIPS Art. 73)

59. The flexibility provided for in Article 73¹³ follows the same rationale of Article XXI of the GATT and Article XIV *bis* of the GATS. It has been explored by the study SCP/13/3 (“Exclusions from patentable subject matter and exceptions and limitations to the rights”). Some legislations exclude from patentability inventions affecting national security or, more specifically, inventions concerning nuclear processes and products, in accordance with Article 73.

60. Despite the importance of this flexibility, the DAG is of the view that other flexibilities would be preferably explored by the CDIP, considering its nature and objectives. That is why we believe it would be more useful to discuss those flexibilities that have a direct impact on social and economic development such as Article 27.1, 27.2, 27.3(a), Article 30 and Article 31 of the TRIPS Agreement. The CDIP should also conduct studies on national experiences in using patent related flexibilities to achieve

¹² Article 44: Injunctions:

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

¹³ Article 73: Security Exceptions Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

developmental and public policy objectives such as industrial development, access to medicines and food security. Studies should also be conducted to identify legal, institutional and administrative constraints including challenges and barriers in the implementation and use of patent related flexibilities to promote development and public policy objectives. This kind of information would contribute positively to Member States while implementing in a balanced manner their obligations concerning IP and also to WIPO while providing technical assistance to its Members. It would also be very useful that the WIPO Academy make available to the CDIP its training materials on patent related flexibilities. Thereby, Member States could provide comments and due guidance to the materials that have been provided by WIPO in its training activities regarding such an important issue.

61. Finally, it would be useful to have a study that could provide a comparative analysis on national experiences regarding the implementation of those four patent related flexibilities and a review of the literature on those topics. The DAG Members would be prepared to contribute with their national experiences.

III. BRIEF DESCRIPTION OF TWO OF THE FLEXIBILITIES DISCUSSED, NAMELY, THE FLEXIBILITY TO APPLY OR NOT CRIMINAL SANCTIONS IN PATENT ENFORCEMENT AND MEASURES RELATED TO NATIONAL SECURITY “THE SECURITY EXCEPTIONS”

62. The Committee agreed that a preliminary illustration be given concerning two of the patent-related flexibilities discussed in the Ninth Session.

A. THE FLEXIBILITY TO APPLY OR NOT CRIMINAL SANCTIONS IN PATENT ENFORCEMENT

63. Concerning criminal sanctions in case of patent infringement, attention is drawn to the fact that neither WIPO administered treaties nor the TRIPS Agreement provide for commitments in this regard. The obligation under article 61 of the TRIPS Agreement to implement criminal procedures and penalties is limited to “trademark counterfeiting” and “copyright piracy”.

64. Therefore, in the implementation of the TRIPS Agreement, Members have the freedom to enforce patents recurring to other measures, such as through civil law actions and/or administrative measures, as it is the case in a significant number of jurisdictions.¹⁴ In fact, criminal sanctions are usually considered an *extrema ratio*, which means that only when the other means of protection, and in particular civil actions, prove to be without effect in order to protect a specific right, then the law allows to recur to criminal sanctions. The TRIPS Agreement, in its article 61, provides that “Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale”, which has motivated an important number of Members to adopt criminal sanctions for the enforcement of intellectual property rights beyond trademarks and copyrights, including for patents.¹⁵

65. The purpose of addressing this topic in a future document on patent-related flexibilities is to shed some light on the options available to Member States when putting into place their own patent legal system and particularly the enforcement provisions, to analyze which are the tendencies worldwide on this subject and to map the present situation.

¹⁴ Such as the United States, Canada, India and the United Kingdom.

¹⁵ Such as Japan and Brazil.

B. MEASURES RELATED TO NATIONAL SECURITY “THE SECURITY EXCEPTIONS”

66. Experience has shown that different approaches have been taken by countries at the national level to adopt measures, either within the patent law or in related legislation, that allow for the scrutiny of inventions that may be deemed essential to national security interests. In this connection some patent laws provide for measures that prohibit the publication of the invention until clearance is given by the competent authorities, and in some cases this is coupled with the obligation to impose to the applicant not to file abroad until clearance is received; in other cases, this type of provisions refers not merely to delays on the prosecutions of the patent application – particularly regarding publication-, but to the obligation of transfer of ownership and, in particular, the transfer of economic rights to a Governmental entity, against adequate compensation. Other laws exclude from patent protection subject matter considered to be sensitive in terms of national security interests, such as fissionable materials.

67. Provisions on patent-related matters considered to be relevant to national security are also frequent in bilateral,¹⁶ regional¹⁷ and international agreements.¹⁸ Particular attention has been given by multilateral agreements on patents to the need to maintain the necessary freedom of members to adopt measures considered appropriate to protect national security interests. Such provisions are found in the PCT, the TRIPS Agreement and the PLT. They were drafted with special care in order to secure a maximum room for maneuver.

68. Concerning the PCT, attention is drawn to article 27(8) which clearly states that nothing in the treaty would limit the freedom of any Contracting State to apply “measures deemed necessary for the preservation of its national security”, as well as to Rule 22.1 (a) which recognizes that based on prescriptions concerning national security, the receiving Office may be prevented from transmitting the record copy of the international application to the International Bureau. Therefore, under the PCT, an essential flexibility exists for Contracting States to adopt provisions that aim to protect national security in their national patent laws; e.g., provisions that allow the patent office, acting as a receiving Office in respect of an international application, to prevent the transmission of the record copy until clearance is given by the competent national body.¹⁹

69. On the other hand, the TRIPS Agreement provides a general exception for matters which are deemed to be essential to national security interests; a Member is not required to furnish any information if it considers disclosure to be contrary to its essential security interests. In addition, it may take any action which it considers necessary for the protection of its essential

¹⁶ See in that context the Agreement between the Government of the United States of America and the Government of Turkey to Facilitate Interchange of Patent Rights and Technical Information for Purposes of Defense signed at Ankara on May 18, 1956, or the Agreement between the Government of the United States of America and the Government of Japan to Facilitate Interchange of Patent Rights and Technical Information for Purposes of Defense signed at Tokyo on March 22, 1956.

¹⁷ Agreement on Mutual Preservation of Inter-State Secrets in the Area of Legal Protection of Inventions signed between Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Ukraine and Uzbekistan.

¹⁸ See in that context the NATO Agreement for Safeguarding of Secrecy of Inventions Relating to Defense (version 1974).

¹⁹ Since the PCT makes no provision for suspending the procedures based on national security measures, in case the record copy is not transmitted to the International Bureau before the expiration of the 13th month from the priority date, the international application is considered withdrawn.

security interests relating to fissionable materials or the materials from which they are derived, relating to traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment, or taken in time of war or other emergency in international relations. It may also take any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.²⁰

70. In respect to the PLT, the so called “security exception” (PLT Article 4) has been regulated in a very wide manner: “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 interest”.

71. The purpose of addressing this topic in a future document on patent-related flexibilities is to illustrate different mechanisms that have been implemented by member States to accommodate their own national security interests within the framework of the patent system and to analyze the flexibilities available in the multilateral legal framework that allow implementation of those policies at the national and regional levels.

[End of document]

²⁰ “Article 73. Security exceptions. Nothing in this Agreement shall be construed:
(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or
(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests; (i) relating to fissionable materials or the materials from which they are derived; (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment; (iii) taken in time of war or other emergency in international relations; or
(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.”