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**Council for Trade-Related Aspects of  
Intellectual Property Rights**

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## REVIEW OF THE PROVISION OF TRIPS ARTICLE 27.3(B)

### RESPONSES TO THE CHECKLIST OF QUESTIONS<sup>1</sup>

#### KINGDOM OF SAUDI ARABIA

The present document contains responses to the Checklist of Questions which the Secretariat has received from the delegation of Kingdom of Saudi Arabia on 29 November 2020.

## I. RESPONSES TO THE ILLUSTRATIVE LIST OF QUESTIONS PREPARED BY THE SECRETARIAT (DOCUMENT IP/C/W/122)

### A. PATENT PROTECTION OF PLANT AND ANIMAL INVENTIONS

#### 1. To what extent are inventions concerning plants or animals, whether products or processes, patentable under your country's law, if they meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement?

Plants and animals with the exception of micro-organisms shall not be regarded as inventions according to Article 45 of the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs (hereafter "The Law"). Therefore, even though plants and animals meet the conditions for patentability stipulated in Article 27.1 of the TRIPS Agreement, they are not patentable because they are not regarded as inventions.

#### 2. Where any such inventions are not patentable, even if they meet these conditions:

##### (i) To what extent is this due to *per se* exclusions from patentability?

Article 45 (a, c & d) of the Law has stated the excluded subject matters, which related to plants and animals *per se* or methods that are mostly biological of the production of plants or animals. In addition, the methods of treating the human or animal's body, surgically or therapeutically, and methods of diagnosing the disease applied to the human or animal's body.

##### (ii) To what extent is this based on other grounds (for example because conditions for patentability other than those stipulated in Article 27.1 are not met or in order to protect *ordre public* or morality (see Article 27.2 of the Agreement)?

Article 4.a & b of the Law has stated the following:

a- "The protection document shall not be granted if its commercial exploitation violates the *Shari'ah*.

b- The protection document shall not be granted if its commercial exploitation is harmful to life or health of humans, animals or plants, or is substantially harmful to the environment."

<sup>1</sup> Documents IP/C/W/122 and IP/C/W/126.

**3. Please describe any specific provisions, guidelines, final judicial decisions and administrative rulings of general application concerning the application of the conditions for patentability stipulated in Article 27.1 to subject matter addressed by Article 27.3(b).**

Article 2 of the Law has defined the nature of invention. Articles 43 and 44 of the Law clearly point out that a patent may be issued on an invention if it is new, involves an inventive step, and capable of industrial application, which are equal to the conditions for patentability stipulated in Article 27.1 of TRIPs.

**4. Where plant varieties are not as such patentable subject-matter under your country's law, please indicate the extent to which the scope of protection under patents for inventions concerning plants can nevertheless embrace plant varieties or a botanical taxon whose plants express a trait covered by the claims of a patent.**

Provisions governing the protection of new plant varieties are stipulated in Articles 54 to 58 of the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs (The Law).

Article 54 of the Law stated that "A plant variety shall be patentable if it is new, distinct, uniform and stable, and procedures have been taken to designate a denomination for it."

Besides the protection of plant varieties by the Law, micro-organisms, non-biological and micro-biological processes are within the scope of patent protection according to Article 45 (c) of the Law.

**5. Please provide any definitions used under your country's law with regard to subject matter specifically excluded from patentability or specifically patentable (e.g. micro-organisms, microbiological processes, non-biological processes, plant varieties).**

Article 2 of the Law defines plant variety as "A plant grouping within a single botanical taxon of the lowest known rank which, irrespective of whether the conditions for the grant of a breeders right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or a combination of genotypes distinguished from any other plant grouping, by the expression of at least one of the said characteristics, and considered as units with regard to its suitability for being propagated without change."

Article 53 of the Law describes that plant variety can be patentable as plant patent : "The plant variety shall be patentable if it is new, distinct, uniform and stable, and proceedings have been taken to designate a denomination for it."

**6. To what extent is subject matter that is identical to what occurs in nature patentable under your country's law?**

Any substance existing in nature without any modification is mere discovery and therefore it is unpatentable according to Article 45 (a) of the Law.

**7. Explain the requirements under your country's law for ensuring adequate disclosure of the patentable inventions referred to above.**

An applicant is required to provide sufficient disclosure of his invention and to satisfy that requirements, he may need to provide some data, such as experimental data, to determine technical impact or unexpected benefits. This support is preferably in the application itself.

**8. What rights are conferred upon owners of the patents referred to above? Are product and process patents subject to the same rules as other patents? Do they benefit from the same protection as stipulated in Article 28 of the TRIPS Agreement?**

With regard to inventions, Article 47 of the Law states that " the owner of the protection document may initiate an action before the Committee against any person who infringes his invention by exploiting it in the Kingdom without his consent. The following shall be deemed as exploitation of the invention:

(a) If it is a product: Its manufacture, sale, offering for sale, use, storage or its importation for any of these purposes.

(b) If it is a process: The use of the process, or performing any of the acts referred to in the previous paragraph, in relation to the product which is directly obtained by the use of this process.

The owner of the protection document's right shall not preclude others from exploiting his invention in non-commercial activities relating to scientific research."

With regard to plant varieties, Article 56 of the Law states that " (a) The owner of the plant variety protection document may initiate an action before the Committee against any person who infringes the patented variety by exploiting the propagating material of the patented variety without his consent inside the Kingdom. The following shall be deemed to be exploitation of the propagating material of the patented variety:

- (1) Producing or propagating it.
  - (2) Conditioning it for purposes of propagation.
  - (3) Exporting it.
  - (4) Importing it.
  - (5) Offering it for sale, selling it or any other sort of marketing.
  - (6) Stocking it for any of the above purposes.
- (b) Rights stipulated in paragraph (a) of this Article include harvested material of the variety, including the whole plant or part thereof obtained by unlawful use of the propagating material of the variety. This applies where the owner of the protection document of the plant patent was not given a reasonable chance to exercise his rights in relation to the propagating material of the said variety.
- (c) Rights stipulated in paragraphs (a) and (b) extend to the varieties derived essentially from the protected variety if it is not possible to distinguish such varieties clearly, in accordance with Article 55(b) of this Law, from the said protected variety, or that the production of these varieties requires the repeated use of the said protected variety.
- (d) Rights stipulated in paragraphs (a), (b) and (c) of this Article shall not extend to acts performed for non-commercial personal purposes or for experimental purposes or for purposes of breeding new varieties.

**9. Are there any specific exceptions to these rights (affecting the scope or duration of the patents referred to above)? To what extent are exceptions, available in respect of plant variety rights (e.g. those referred to under B.4(i) below), available in respect of rights conferred upon patent owners?**

Yes, the owner of the patent shall not preclude others from exploiting his protected subject matter in non-commercial activities related to scientific research according to Articles 47 and 56 (d) of the Law.

**10. Are there any specific provisions under your country's law for compulsory licensing in respect of the patents referred to above?**

Yes, the Law includes Article 24 containing provisions related to compulsory licensing of patent for invention and Article 25 containing provisions related to compulsory licensing of plant variety.

## **B. PROTECTION OF PLANT VARIETIES**

**1. Does your country's law provide for the protection of plant varieties by plant breeder's rights, plant patents or any other *sui generis* system for the protection of plant varieties?**

Saudi Arabia protects plant varieties by special provisions on protection of plant variety contained in the Law. Specifically, Article 53 stipulates their protection: "The plant variety shall be patentable if it is new, distinct, uniform and stable, and proceedings have been taken to designate a denomination for it."

**2. (a) If your country is a party to the International Convention for the Protection of New Varieties of Plants (UPOV), please indicate which Act or Acts of the UPOV Convention your country has signed; which it has ratified; to which it has acceded; and to the standards of which its law conforms but to which it has not (yet) adhered.**

Saudi Arabia is not a party to the UPOV Convention.

- (b) If your country is not a party to the UPOV Convention, does the protection offered to plant varieties under your country's law conform to the standards of any of the Acts of the UPOV Convention and, if so, which?**

The provisions regarding protection of new varieties of plants are drafted in reference to "*The Model Law on The Protection of New Varieties of Plants*", 1996 issued by UPOV which was based on the 1991 Act of the UPOV Convention.

- 3. Please indicate whether concurrent protection under your country's plant variety protection law and its patent law is available (see also question A.4 above).**

The protection of plant variety is provided solely by specific provisions on protection of plant varieties included in "The Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs".

- 4. Please provide the following details of your country's *sui generis* system for the protection of plant varieties:**

- (a) the relevant laws and regulations and, if they have been notified to the Council for TRIPS, a reference to the relevant WTO documents;**

The Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs & its Regulations.

- (b) the definition of "plant variety";**

The plant variety is defined according to Article 2 of the Law as "A plant grouping within a single botanical taxon of the lowest known rank which, irrespective of whether the conditions for the grant are fully met, can be defined by the expression of the characteristics resulting from a certain genotype or a combination of genotypes distinguished from any other plant grouping, by the expression of at least one of the said characteristics, and considered a unit with regard to its suitability for being propagated without change."

- (c) the conditions required for protection;**

Article 54 of the Law states that "the plant variety shall be patentable if it is new, distinct, uniform and stable, and procedures have been taken to designate a denomination for it".

- (d) the extent to which subject-matter that is already known to the public or identical to what occurs in nature is protectable under your country's *sui generis* system for the protection of plant varieties;**

Any subject -matter that is identical to what occurs in nature or is already known to the public is not patentable according to Articles 54 and 55 of the Law.

- (e) the extent to which protection can be based on characteristics of germplasm, as opposed to characteristics of plant varieties derived from such germplasm;**

Germplasm characteristics are not taken into account in the evaluation of patentability of plant varieties.

- (f) who is entitled to the rights;**

The plant breeder is entitled to the rights according to Articles 2 and 5(e) of the Law. Article 2 of the Law defines the plant breeder as "Plant breeder: The person who breeds, discovers or develops a new plant variety". Article 5(e) of the Law states that "The person who develops the subject matter of protection shall have the right to state his name in that capacity in the protection document".

- (g) the procedure for the acquisition of rights, including the authority in charge of administering the rights;**

Procedures for the acquisition of rights are stipulated in the Law and its Implementing Regulations. Article 8 of the Law states that "The application for granting a protection document shall be submitted to SAIP in the prescribed form. The Regulations shall specify the information and documents required to be enclosed with the application." Section Three of the Implementing Regulations (Articles 20 to 26) specify the "terms and Conditions for Filing an Application for a Plant Patent.

Article 10 provides rights of priority. Article 11 is about the publication of the application. Article 12 covers the formal examination. Article 13 of the Law and Articles 39 to 44 of the Implementing Regulations provide provisions on substantive examination. Article 14 provides provisions on grant. Article 19(C) provides the term of protection

The authority in charge of administering the rights is the Saudi Authority for Intellectual Property (SAIP), Article 3 of the Law states that "SAIP shall have the authority to apply the provisions of this Law and its Implementing Regulations.

**(h) the rights conferred;**

Article 56 of the Law states that

"(a) The owner of the plant protection document may initiate an action before the Committee against any person who infringes upon the patented variety by exploiting the propagating material of the patented variety without his consent inside the Kingdom. The following shall be deemed exploitation of the propagating material of the patented variety:

- (1) Producing or propagating it.
- (2) Conditioning it for purposes of propagation.
- (3) Exporting it.
- (4) Importing it.
- (5) Offering it for sale, selling it or any other sort of marketing.
- (6) Storing it for any of the above purposes.

(b) The Rights stipulated in paragraph (a) of this Article include harvested material of the variety, including the whole plant or part thereof obtained by unlawful use of the propagating material of the variety. This applies where the owner of the protection document of the plant patent was not given a reasonable chance to exercise his rights in relation to the propagating material of the said variety.

(c) The Rights stipulated in paragraphs (a) and (b) of this Article extend to the varieties derived essentially from the protected variety if it is not possible to distinguish such varieties clearly, in accordance with Article 55(b) of this Law, from the protected variety, or that the production of these varieties requires the repeated use of the said protected variety.

(d) The Rights stipulated in paragraphs (a), (b) and (c) of this Article shall not extend to acts performed for non-commercial personal purposes or for experimental purposes or for purposes of breeding new varieties".

**(i) exceptions to the rights conferred, such as:**

- **acts performed for research or experimental purposes;**
- **acts performed to develop new varieties of plants;**
- **acts performed to commercialize such newly developed varieties;**
- **any "farmer's privilege" (e.g. acts performed by a farmer on his own land in respect of seed saved from the previous harvest);**
- **acts done privately and for non-commercial purposes;**
- **compulsory licensing.**

Exceptions to the rights are stated in Article 56 (d) as "rights stipulated in paragraphs (a), (b) and (c) of this Article shall not extend to acts performed for non-commercial personal purposes or for experimental purposes or for purposes of breeding new varieties"

**(j) the duration of protection;**

According to Article 19(C) of the Law, "The plant patent protection period shall be twenty years from the date of filing the application. However, the protection period for trees shall be twenty-five years".

**(k) transfer of rights;**

The rights can be transferred to others by inheritance according to Article 5 (a) or by assignment according to Article 16 of the Law.

**(I) enforcement of the rights.**

Article 56 (a) of the Law states that " (a) The owner of the plant protection document may initiate an action before the Committee against any person who infringes upon the patented variety by exploiting the propagating material of the patented variety without his consent inside the Kingdom ....."

**II. RESPONSES TO REPRESENTATIVE QUESTIONS FOR TRIPS 27.3(B) REVIEW SUBMITTED BY THE DELEGATIONS OF CANADA, THE EUROPEAN UNION (FORMERLY EUROPEAN COMMUNITIES), JAPAN AND THE UNITED STATES (DOCUMENT IP/C/W/126)**

**A. PATENT SYSTEM QUESTIONS**

**1. In your territory, is there *any* basis for denying a patent on an invention consisting of an entire plant or animal that is novel and involves an inventive step?**

An invention consisting of an entire plant or animal as such that is novel and involves an inventive step can be denied according to Article (4), and Article 45 (a, c) of the Law.

**2. If the answer to question 1 is 'yes', please respond to the following questions:**

**(a) Does your patent system exclude entire plants or animals as inventions? If it does, please cite the legal basis for this.**

Yes, Article 45 (c) of the Law states that:

"In the application of the provisions of this Law, the following shall not be regarded inventions:

(c) Plants, animals, and processes-which are mostly biological- used for the production of plants and animals.

**(b) If your patent system does recognize entire plants and animals as inventions, does it exclude all such inventions from being patentable subject-matter, or does it only exclude certain types of plants or animals? If it excludes all, please cite the legal basis for their exclusion (e.g. lack of industrial applicability). If it excludes only certain types, please identify the categories or characteristics of inventions that are excluded and cite the legal basis for their exclusion.**

Plants and animals are excluded from being patentable according to Article 45 (c).

**(c) Is there any other basis in your law that precludes the grant of a patent on any categories of plant or animal inventions that otherwise are novel, involve an inventive step and are capable of industrial application? If so, please cite the legal basis for that exclusion from patent eligibility.**

No, Article 45 (c) is the only provision.

**3. Other than with respect to subject-matter you defined as being ineligible to be patented under question (2), is it possible in your territory to obtain a patent claim defined in any of the following ways?**

**(a) A patent claim that is not limited to a specific plant or animal variety.**

No.

**(b) A patent claim that is *expressly limited* to a plant or animal variety.**

No.

**(c) A patent claim that is expressly limited to a group of plants or animals, where the group is defined through reference to a shared characteristic such as incorporation of a particular gene.**

No.

- (d) **If the answers you provide to question (3)(a) to (c) vary, please provide the definitions of a "plant variety" and an "animal variety" that are used by your examining authority.**

**4. Is it possible to obtain a patent in your territory on a microorganism that is novel, involves an inventive step and is capable of industrial application? If not, please identify the legal basis under which these inventions are deemed ineligible to be patented.**

Yes, it is possible to obtain a patent on a microorganism that is novel, involves an inventive step and is capable of industrial application.

**5. Is it possible to obtain a patent in your territory on an essentially biological process for the production of a plant or animal (i.e. a process limited to those acts that are necessary for sexual or asexual reproduction of a plant or animal)? If not, please identify the legal basis under which a patent on such a process would be denied.**

No, it is not possible to obtain a patent on an essentially biological process for the production of a plant or animal. Article (45) of the Law stated "In the application of the provisions of this Law, the following shall not be regarded inventions:

(c) Plants, animals, and processes-which are mostly biological- used for the production of plants and animals with the exception of microorganisms and non-biological and microbiological processes.

**6. Is it possible to obtain a patent in your territory covering subject-matter that is identical to that found in nature (e.g. a plant or animal in its natural state)?**

No, they are not patentable because they are considered as discoveries. Article 45 of the Law states that: "In the application of the provisions of this Law, the following shall not be regarded inventions: (a) Discoveries, ....."

## **B. PLANT VARIETY PROTECTION SYSTEMS**

**7. Do the laws applicable to your territory provide for a *sui generis* form of protection for a new plant variety?**

Yes, it is protectable as plant variety under the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties and Industrial Designs

**8. If the answer to question 7 is "yes", does that protection conform to the standards defined in one of the Acts of the International Convention for the Protection of New Varieties of Plants (UPOV)?**

Saudi Arabia is not a party to the UPOV Convention. However, the provisions regarding protection of new varieties of plant are drafted in reference to "The Model Law on The Protection of New Varieties of Plants", 1996 issued by UPOV which was based on the 1991 Act of the UPOV Convention.

**9. If the answer to question 8 is "yes", please specify the Act of the UPOV Convention upon which your legislation is based (i.e. the 1991 Act, the 1978 Act or the 1961/1972 Act).**

It was based on "The Model Law on The Protection of New Varieties of Plants" issued by UPOV which was based on the 1991 Act of the UPOV Convention.

**10. If *sui generis* protection for plant varieties is provided in your territory, would any of the following acts require the prior authorization of the right holder:**

- (a) **acts performed for research or experimental purposes, or to develop new varieties of plants;**

No, such acts would not require prior authorization of the right holder. Article 56 (d) states that "The rights stipulated in paragraphs (a), (b), and (c) of this Article shall not extend to acts performed for non-commercial personal purposes, for experimental purposes, or for the purpose of breeding new varieties".

**(b) acts performed to commercially exploit a variety distinct from the protected variety but sharing its essential characteristics;**

No, according to Article 56 (b, c).

**(c) acts performed by a farmer of harvesting seed from his planting of a protected variety legitimately obtained, storage of that seed, and replanting of that seed on the farmer's land.**

Yes. According to Article 56 (A)(1, 2, 6) of the Law, these acts require prior authorization of the right holder. Article 56(A) states that: "The owner of the plant protection document may initiate an action before the Committee against any person who infringes upon the patented variety by exploiting the propagating material of the patented variety without his consent inside the Kingdom. The following shall be deemed exploitation of the propagating material of the patented variety:

- 1- Producing or propagating it.
- 2- Conditioning it for purposes of propagation.
- 6- Storing it for any of the above purposes."

**If prior authorization is not required for any of the above examples of activities, is there any requirement that the party undertaking the specified actions provide the right holder with remuneration in any form?**

No, there is not any additional requirement.

**11. Can protection be obtained for a plant variety that was known to the public, or was publicly available, prior to the application for *sui generis* protection for that plant variety, and, if so, under what conditions (i.e. what are the time-limits during which public disclosure or availability will not preclude the grant of protection).**

According to Article 55 (a) of the Law, "A plant variety shall be deemed new if, at the date of filing the application or the date of the claimed priority, propagating or harvested materials of the variety have not been sold or otherwise made available to others by the breeder or with his consent, for the purposes of exploiting the variety in accordance with the following:

- (1) In the Kingdom of Saudi Arabia for more than one year.
- (2) In other countries for more than four years or, in case of trees or vines, for more than six years."

**12. Can protection be predicated on identification of an unexpressed gene, on an unexpressed set of genes present in the genome of the plant variety, or on the characteristics of germplasm, rather than the *expressed characteristics* of plant varieties derived from such genes or germplasm?**

Germplasm characteristics are not taken into account in the evaluation of patentability of plant varieties.

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