

Section 16: Other exclusions to patentability

This guideline outlines IPONZ practice on exclusions to patentability under section 16.

Section 16

16 Other exclusions

- (1) Human beings, and biological processes for their generation, are not patentable inventions.
- (2) An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.
- (3) An invention of a method of diagnosis practised on human beings is not a patentable invention.
- (4) A plant variety is not a patentable invention.
- (5) For the purposes of subsection (4), **plant variety** has the same meaning as in section 7 of the Plant Variety Rights Act 2022.

Introduction

1. Section 16 outlines what is excluded from patentability under the Patents Act 2013.
2. These exclusions stem from policy considerations. It is not in the public interest to grant patents to the subject matter excluded by subsections (1) to (3). Furthermore, protection for plant varieties is available under the Plant Varieties Act. Having these exclusions set out in the legislation provides greater certainty for patent owners and to the public.

Human beings and biological processes for their generation

Human beings are not patentable inventions

3. Section 16(1) of the Patents Act 2013 states that human beings, and biological processes for their generation, are not patentable inventions.

What constitutes a human being?

4. Any entity that might claim the status of a human being is excluded from patentability under section 16(1). This includes:

- Human zygotes, blastocysts, embryos and fetuses¹
- Human ova that have been fertilised or activated by any means²
- Totipotent human cells, including those cells that are the products of nuclear transfer procedures²
- Totipotent cells with human nuclear DNA.²

Human embryos are ‘human beings’

5. A human being is any entity that can reasonably claim the status of a human being. This not only includes a person that has been born, but also extends to a fertilised human ovum and all its subsequent manifestations. For this reason, human embryos are human beings for the purpose of section 16(1).

6. This practice is informed by *Fertilitescentrum AB and Luminis Pty Ltd* [2004] APO 19^{4.1}. The claims at issue were to a method of growing preblastocyst human embryos.

7. The Deputy Commissioner concluded that a human comes into being when the ovum is fertilised. At that time the ovum has all it needs to go on and develop as a human being.²

8. The end of the development was defined as birth – on the grounds that this is when the full status of human being is acquired.³ On this basis, the claimed human embryos were considered to be human beings.

Activated embryos are human

9. An ovum that has been artificially activated is no different to an ovum that has been fertilised by natural means. This is because the resulting embryo still has all it requires to go on develop into a human being.

10. This practice is informed by *Woo-Suk Hwang* [2004] APO 24^{4.4}. In this decision, the Deputy Commissioner didn't see any distinction between ova that had been fertilised by natural or artificial means.

Hybrid embryos that can develop into human beings are human

11. Hybrid embryos comprising human nuclear DNA which are capable of developing into human beings are not patentable. This is regardless of the presence of non-human genetic material.

12. This practice is informed by *Woo-Suk Hwang*. In this case, the Deputy Commissioner determined that the claimed embryos were human beings despite the presence of bovine mitochondrial DNA. This is because the essential characteristics of the embryos were determined by their human-nuclear DNA.⁵

Biological processes for the production of human beings

13. Any biological processes that leads to the production of a human being is excluded. This includes:

- methods of in vitro fertilisation
- processes for intracytoplasmic sperm injection
- processes for cloning at the 4-cell stage
- processes for cloning by replacing nuclear DNA
- processes or methods of growing or culturing fertilised ova, zygotes, or embryos etc
- processes or methods for introducing transgenes and donor genetic or donor cytoplasmic material into fertilised ova, zygotes, or embryos etc.

14. Any method or process that involves the creation of a human embryo is excluded matter, even if the embryo is not the final product of the method. For example, a method of producing human stem cells which includes a step or steps of creating a human embryo would be excluded.

Human Assisted Reproductive Technology Act 2004

15. The Human Assisted Reproductive Technology Act 2004⁶ prohibits certain actions relating to cloning human embryos. The fact that a claim may include a prohibited action does not necessarily mean that the claim relates to excluded matter under section 16(1). However, consideration may also be given to whether such an action is contrary to morality under section 15 of the Patents Act 2013.⁷

Methods of treatment of human beings by therapy or surgery

16. Section 16(2) provides that an invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.

17. The intent of this exclusion is to allow medical professionals to use their professional skills without fear of infringing a patent.

18. What defines a method of treatment of human beings by therapy or surgery is described in more detail in the following sections on **Methods of treatment by therapy** and **Methods of treatment by surgery**.

Methods must be performed on a human being

19. The exclusion under section 16(2) only applies to methods of treatment of human beings (either by therapy or surgery).

20. This exclusion does not apply to methods performed on non-humans. Methods of treatment of non-human animals are therefore allowable. Methods including the terms “animal”, “mammal”, “primate” or “hominid” are considered to include human beings.

Methods of treatment by therapy

When is a method “treatment by therapy”?

21. Therapy includes any treatment designed to cure, alleviate, remove, lessen the symptoms of, prevent, or reduce the possibility of contracting, any disorder or malfunction of the body.⁸

22. Claims to the following are therefore methods of treatment by therapy:

- Curative treatments
- Treatment of the symptoms of a disease, disorder or condition
- Preventative treatment,⁹ including vaccination of healthy individuals

23. Any method that involves a therapeutic treatment is excluded. This is regardless of who is performing the method.

24. Methods performed by (or under the supervision of) a medical professional may indicate that it is a method of therapy and is excluded. However, this is not a requirement. For example, patients self-administering a medicament or automated therapeutic treatment methods are unpatentable, even though a medical professional is not involved.¹⁰

Form of method of treatment claims

25. Any claim where a composition, substance, apparatus or device is used for the therapeutic treatment of human beings is a method of treatment of humans by therapy.

26. When construing the claims, it is the substance of the claims that must be considered, not the claim format. As such, there are various ways in which a method of treatment of human beings may be claimed. This includes:

- i. A method of treating (medical condition Y) by administering (substance X).
- ii. The treatment of (medical condition Y) with (substance X).
- iii. The use of (substance X) to treat (medical condition Y).
- iv. (Substance X) when used to treat (medical condition Y).
- v. The use of (substance X) as a pharmaceutical.

27 Examples (ii)-(iv) are discussed in *John Wyeth's and Schering's Application*.¹¹

28. Swiss-type claims are not merely an alternative form of a method of treatment. As such Swiss-type claims are not excluded under this section. [Further guidance on how Swiss-type claims are examined can be found below.](#)

[How Swiss-style claims are examined](#)

Claims including both therapeutic and non-therapeutic methods

29. In some cases, a claim can include both therapeutic and non-therapeutic methods. These claims will be objected to as encompassing excluded subject matter. Amendment to remove the excluded matter would overcome the objection.

30. However, the claim(s) should be construed in light of the specification. If the specification makes it clear that the claims only relate to non-therapeutic methods, no objection under section 16(2) should be raised.

Disclaiming therapeutic methods from a claim

31. It is allowable to disclaim the excluded subject matter in a claim.¹² Claims can be amended to disclaim excluded matter provided that the claim is supported, and the amendment does not add matter.¹³ An example of this could be limiting the claim to a "cosmetic" or "non-therapeutic" method.

32. However, if a claim directed to a 'cosmetic' or 'non-therapeutic' method inherently results in a therapeutic effect that cannot be separated from the cosmetic or non-therapeutic method, then the method is unpatentable regardless of the claim wording used.

Examples of therapeutic and non-therapeutic methods

Cosmetic treatments

33. Methods that produce purely cosmetic effects, such as cosmetic treatments of the skin, hair, and nails are patentable.¹⁴

34. Methods for preventing hair loss may be cosmetic and patentable where the hair loss is due to the normal aging process. These methods may also be therapeutic and unpatentable if the hair loss results from disease or a side-effect of another therapeutic method (such as radiotherapy).

35. Methods of removing wrinkles caused by aging have no therapeutic effect, so a cosmetic method of removing wrinkles by phototherapy is patentable.¹⁵

Oral or dental care

36. A method of removing plaque from teeth (or preventing its formation) will be unpatentable. Removal of plaque will inevitably have the therapeutic effect of preventing tooth decay and gum disease.¹⁶

37. In this case, a cosmetic effect resulting from plaque removal cannot be separated from a therapeutic effect. Therefore, claiming the method as a 'cosmetic' or 'non-therapeutic' method will not overcome an objection to a method of treatment by therapy.

Relief of pain or fatigue

38. Methods for the relief or treatment of pain are methods of therapy, regardless of the origin of the pain.¹⁷

39. Methods for reducing the perception of fatigue, such as fatigue resulting from exercise, could be considered non-therapeutic and patentable when carried out on a healthy person. However, such methods when carried out to alleviate symptoms of an underlying health problem would be therapeutic.¹⁸

Treatment of addiction

40. Methods for treating drug addiction or withdrawal symptoms, including methods to help people stop smoking, are methods of therapy and unpatentable.

Treatment of obesity, weight reduction and fitness

41. Where weight reduction is for purely cosmetic reasons, claims to weight loss methods may be patented.¹⁹

42. Treatment of obesity is considered therapeutic and is not patentable.

43. Methods of enhancing performance may be allowable when performed on healthy subjects. For example, a method for 'enhancing skeletal muscle performance of normal healthy subjects' is considered to be non-therapeutic and patentable.²⁰

Methods involving pregnancy and contraception

44. Pregnancy is not an illness or disease, so its prevention is not regarded as 'therapy'.²¹ However, contraceptive methods may be excluded from patentability if they are also therapeutic or surgical in nature.²² For example, insertion of an intra-uterine device is invasive and is always carried out by a medical professional. Therefore, it is considered a method of surgery. It may also be considered a method of therapy.

45. Methods for treating infertility in humans, including methods of *in vitro* fertilisation are considered methods of therapy and are not patentable. These are also methods of surgery.

46. Methods of abortion, termination of pregnancy, or induction of labour encompass therapeutic reasons for ending a pregnancy and will always be carried out under medical supervision. They are therefore considered methods of medical treatment of human beings by therapy and/or surgery and are not patentable.²³

Therapeutic methods using implanted devices

47. Methods which include a therapeutic use of an apparatus or device are not patentable under section 16(2). This includes methods which involve the use of an implant.

48. For example, a method of operating a heart pacemaker to regulate heartbeat is a method of therapy.²⁴ However, a method of controlling the energy input to a pacemaker to minimise its energy consumption may be acceptable, provided there are no therapeutic effects.²⁵ This is because the method does not affect the pacemaker's output to the heart.

49. Similarly, a method of measuring the flow of a drug or other substance from an implant, but which does not involve controlling the flow, is non-therapeutic.²⁶

Treatments performed outside the body

50. Section 16(2) extends to treatments performed outside the body. Examples of such methods include dialysis treatment or filtration methods.²⁷

51. However, methods of treating blood outside the human body are only considered 'therapy' if the method includes a step of returning the blood to the body. Therefore, the treatment of blood for storage in a blood bank may be patentable.

Treatment of parasite infestation

52. The treatment or prevention of parasite infestation, either internal or external is a therapeutic method and is not patentable. This applies even if there is no physiological effect on the human host from the treatment.²⁸

53. Methods for the treatment of parasites on the skin of a human are considered therapy regardless of whether the parasites are 'permanent' or 'temporary'. For this reason, methods of treating head lice are considered therapeutic and unpatentable.

Methods of treatment by surgery

When is a method "treatment by surgery"?

54. Surgery includes any method which includes a substantial physical intervention on the body which requires professional skill and entails a substantial health risk.²⁹

55. When considering whether a claimed method encompasses surgery consider:

- Is the method invasive?
- Does it require professional skill?
- Is there a potential risk even when carried out by a medical professional?

56. When deciding whether a method is a method of surgery, it is the surgical nature of the method that is considered, rather than its intended purpose.³⁰⁹

57. Surgery is not limited to cutting the body. It also includes manipulative methods and invasive procedures that may not be explicitly referred to as surgery.

58. A method will fall under this exclusion if it includes a step constituting a method of surgery.³¹³⁰ This is true even if the surgical step is not explicitly claimed. If a surgical step is implicitly and necessarily performed, then the method is a method of surgery.³²³¹

Nature of the surgical method

59. Both therapeutic and non-therapeutic methods of surgery are excluded under section 16(2). As stated in G07/01 *MEDI-PHYSICS/Treatment by surgery*: "... the meaning of the term 'treatment by surgery' is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose".³³³² Methods of cosmetic surgery or other non-therapeutic surgery are still methods of surgery for the purposes of section 16(2) and are not patentable.

60. If any method has a therapeutic effect, it will still be excluded under section 16(2) as a method of treatment by therapy. This is regardless of the degree of risk or invasiveness, or who performs the method.

Who performs the method

61. A method that is or must be carried out by a surgeon is likely to be excluded as a method of surgery.³⁴³³ Methods carried out by other medical professionals, such as dentists, paramedics, and nurses may still be regarded as methods of surgery.³⁵³⁴

Examples of excluded surgical methods

62. The following are generally considered to encompass methods of surgery:

- Implanting or inserting any device by incision;³⁶³⁵
- Inserting a device into the lungs;³⁷³⁶
- Products that are only formed in the human body following a surgical step;³⁸³⁷
- Implanting a human embryo;³⁹³³
- Endoscopy, puncture, injection, excision or catheterisation;⁴⁰³⁸
- “Closed surgery” (i.e. with no incision) such as setting broken bones and manipulating dislocated joints;⁴¹³⁸
- Dental surgery;⁴²³¹ and
- Lumbar punctures, epidural injections and venipunctures.⁴³³⁹

Examples of methods that are not excluded

63. A method may involve incision or manipulation of the body and not be considered a method of surgery if it is low risk, minimally invasive, and generally not performed by medical professionals.

64. The following examples would generally not be considered methods of surgery:

- Low risk, routine methods (even when performed by a medical professional), such as taking blood samples;⁴⁴⁴⁰
- Methods of ear-piercing or tattooing the body;⁴⁵⁴¹ and
- Methods of applying a plaster cast or attaching an exoprosthesis to the skin using an adhesive.⁴⁶⁴²

Surgical methods involving devices

65. Methods for the implantation of devices within the body are unpatentable, as they are invasive, are performed by a medical professional, and involve a substantial risk.

66. This also applies to methods of controlling surgical devices in a way that impacts the body. For example, the use of surgical robots to make an incision.

67. Methods for internal operation of implanted devices may be patentable provided they do not impact on the body and do not relate to implantation. However, if the operation of the device requires surgery as an essential step (as opposed to a necessary pre-requisite), disclaiming or omitting the surgical step may lead to a support objection under section 39(2)(c).⁴⁷⁴³

68. Methods that may assist a surgeon during surgery, such as a real-time imaging method are not methods of surgery.⁴⁸¹²

Methods of diagnosis

69. Section 16(3) excludes methods of diagnosis performed on a human being from being patentable.

What is a method of diagnosis?

70. Diagnosis is the determination of the nature of a medical condition, usually by investigating its nature and conducting tests. Diagnosis includes both the positive finding that a person has a particular disease, and a negative finding that a person does not have the disease.⁴⁹⁴⁴

71. Determination of a person's general condition, such as their general state of fitness, is not diagnostic if it does not allow a clinical picture to be made.

72. Diagnosis involves four steps leading towards identification of a clinical picture:⁵⁰⁴⁵

- i. The examination and collection of data;
- ii. Comparison of the data with normal values;
- iii. Recording any deviation from the norm; and
- iv. Attributing the deviation to a particular clinical picture (i.e. the presence or absence of a disease or condition).

73. If a method only recites steps i and iv, it can be assumed that steps ii and iii are inherently performed.

74. For a diagnostic method to be excluded it needs to meet two key requirements which are set out in more detail below. Firstly, the method must be performed on a human being; and secondly, the method must allow for a diagnosis to be made.

The method must be "practiced on human beings"

75. A method of diagnosis is only excluded under section 16(3) if it is "practiced on a human being".

76. Methods performed on non-humans are not excluded. Methods including the terms "animal", "mammal", "primate" or "hominid" are considered to include human beings.

A physical step must be performed on the human body

77. A method is "practised on a human being" if the examination and collection of data (step i) involves physical interaction with a live human body. The physical interaction does not need to be invasive.⁵¹⁴⁵ The key requirement is that the patient must be present. For example, while the measurement of nitrogen monoxide content during exhalation is not invasive, it does require the patient to be present.⁵²⁴⁶

78. Diagnostic methods where the physical steps are performed outside the body or on a dead body are patentable. This includes post-mortem procedures for in vitro step such as testing on tissues or fluids removed from the body, or a preparatory step to adjust a device for data collection.

79. Only a single step is required to be practiced on a human being for the method to be excluded. The presence of additional steps not performed on the human body does not overcome a method of diagnosis issue.⁵³⁴⁷

The method must allow a diagnosis to be made ("attribute a clinical picture")

80. Diagnostic methods must attribute a clinical picture to a patient. This includes identification of a disease state, as well as the absence of a disease state.⁵⁴⁴⁴

81. It may also be clear that a method is diagnostic, even if the method does not specify a particular disease or condition. For example, a method for determining lung function by measuring nitrogen monoxide production in the lungs would be considered to attribute a clinical picture.⁵⁵⁴⁶

82. Diagnosis also includes the identification of a course of treatment.⁵⁶⁴⁸

Methods that do not attribute a clinical picture are not excluded

83. Methods which only include the examination and collection of data step (step i) and do not further attribute a clinical picture (step iv) are not considered to be methods of diagnosis.

84. Examples of methods which would generally not be excluded are:

- Methods of determining a person's general condition, such as their general state of fitness;
- Methods of testing drugs *in vivo* to determine efficacy and safety;
- Methods of imaging, such as CT scanning, without any step of identifying a disease or condition;⁵⁷⁴⁹
- Methods of measuring a parameter in a sample, such as blood glucose,⁵⁸⁵⁰
- Methods of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration;⁵⁹⁵¹
- Methods of determining ear temperature;⁶⁰⁵²
- Methods of imaging an artery in a patient using magnetic resonance imaging, without any step or identifying a disease or condition;⁶⁴⁴⁰
- Methods of measuring oxygen uptake in the lungs,⁶²⁵³ and
- Methods performed *in vitro* or *ex vivo* on cells tissues or fluids permanently removed from the body, such as DNA testing.

Diagnosis does not require a medical professional

85. Diagnostic methods are not required to be carried out by a doctor or other health professional to be excluded.⁶³⁴⁵

Incomplete methods may be objected to on other grounds

86. Incomplete methods which do not include at least both steps i and iv may be objected to on other grounds.

87. Methods that only relate to examination and data collection (step i) and/or comparing, recording and processing the data (steps ii and iii) may not constitute a 'manner of manufacture' (see section 14(a)),⁶⁴⁵⁴ or may relate to a computer program 'as such' (see section 11).⁶⁵⁵⁵

88. The act of attributing the clinical picture in isolation (step iv) is generally an intellectual exercise which would not be a 'manner of manufacture'.

89. Where essential steps of a method are missing, the claims may lack clarity and/or support (see section 39).⁶⁶⁵⁶

Multi-step methods

90. Any multi-step method that includes at least one therapeutic, surgical, or diagnostic step as set out in this guideline is excluded from patentability.⁶⁷¹²

91. For example, a multi-step method may include more than one diagnostic, surgical, and/or therapeutic aspect. Each of these will be considered on their own grounds and objected to separately.

Patentability of plant varieties

92. Section 16(4) states that a plant variety is not a patentable invention.

93. The intent of this exclusion is to prevent the grant of two different intellectual property rights for the same thing. Protection for plant varieties is already provided in the form of plant variety rights.⁶⁸⁵⁷ For this reason, plant varieties are excluded from patentability.

Definition of a plant variety

94. Section 16(5) incorporates the definition of plant variety from section 7 of the Plant Variety Rights Act 2022^{69 58}. This definition is:

Section 7 Meaning of plant and plant varieties

(1) A **plant** means a member of any plant genus and species,—

- (a) including a fungus or an alga; but
- (b) not including a bacterium.

(2) A **plant variety** means a plant grouping that—

- (a) is contained within a single botanical taxon of the lowest known rank; and
- (b) can be defined by the expression of the characteristics resulting from a particular genotype or combination of genotypes; and
- (c) can be distinguished from any other plant grouping by the expression of at least 1 of those characteristics; and
- (d) can be considered as a unit because of its suitability for being propagated unchanged.

This definition requires a plant variety to relate to a plant grouping of the **lowest known rank** (section 7(2)(a)) and that has a **distinguishing characteristic** (section 7(2)(b) and (c)). Further the plant grouping also needs to be capable of being **stably propagated** (section 7(2)(d)).

Grouping of plants of the lowest known rank

95. A plant variety must be within a single botanical taxon of the lowest known rank. The lowest known rank is dependent on the identity of the plants and the associated common general knowledge of that plant.

Distinguishing characteristic

96. A distinguishing characteristic relates to any phenotypical trait expressed in a plant that can be used to differentiate the plant from another plant grouping. This includes plants that are defined by a genetic profile that results in the expression of distinguishing characteristic.

Stable propagation

97. While this forms part of the definition of a plant variety, as this requires testing to be performed, this is not assessed as part of patent examination.

When this definition applies

98. Section 16(5) was amended on 24 January 2023, the commencement date of the Plant Variety Rights Act 2022.⁷⁹⁵⁷

99. This means that the definition of 'plant variety' from the Plant Variety Rights Act 2022 will apply to patent applications submitted on or after 24 January 2023.

100. For any patent applications submitted prior to 24 January 2023, the definition of 'plant variety' of section 2 of the Plant Variety Rights Act 1987⁷⁴⁵⁹ will apply.

101. A key difference between these definitions is that algae are included in the new definition. In practice this means that algal plant varieties are excluded under s16(4) when the new definition applies.

IPONZ approach to examining plants and plant varieties

102. The approach to assessing claims to plants and plant varieties is based on the decisions G 1/98⁷²⁶⁰ and T 1208/12⁷³⁶¹ before the EPO.

103. The general approach is to first construe the invention and technical contribution as described in the specification. As discussed in G 01/98 at 3.1, it is the substance of the claims that must be considered, not the form of the claims.⁷⁴⁶²

104. The second step is to assess whether the invention relates to plant varieties as defined above. This requires the plant grouping to have both the lowest known rank and a distinguishing characteristic.

105. For example, if an invention relates to a distinguishing characteristic that could be more broadly applied to any plant species within a whole genus or family, it will not be considered to relate to a plant variety.

General considerations

106. The following general considerations are applicable when applying the approach as set out above.

Claims to multiple plant varieties

107. An invention will be considered to relate to multiple plant varieties if the subject matter relates to multiple individual plant varieties which meet the criteria above. This can apply even if the multiple individual plant varieties fall within different taxonomic classifications. These individual plant varieties do not need to be explicitly listed if the subject matter of the invention clearly relates to individual varieties.

108. The decisions G 01/98 and T 1208/12 provide some guidance on this.

109. In G 01/98, it was found that claims to transgenic plants that encompass plant varieties are allowable if they do not implicitly or explicitly define a single variety or multiple individual varieties.⁷⁵⁶³

110. In T 1208/12, it was found that every hybrid seed and resulting plant belonged to a plant grouping that each met the definition of a plant variety. The invention related to multiple individual varieties, rather than a trait that could be more broadly applied to any plant species.⁷⁶⁶⁴

Method of production is not relevant

111. Plants do not need to be produced by conventional breeding techniques to be considered a plant variety. A plant produced by genetic modification or other gene technologies will be a plant variety if it meets the definition as set out above.⁷⁷⁶⁵

Methods involving plant varieties

112. A method of producing a plant variety is also excluded when the invention relates to that plant variety. This is due to the exclusive right granted by patent claims which extends to the products resulting from those methods.

113. This also applies to methods of modifying an existing plant variety which result in a new plant variety. For example, any plant variety resulting from the crossing or genetic modification of known plant varieties are excluded.

114. Where the invention relates to a further use of a plant variety for a particular purpose, this will not be excluded.

Examples

- i. A transgenic plant containing a number of recombinant genes which provide cold resistance.

The above invention lies in the recombinant genes and the application to a broad grouping such as a whole genus, or even plants in general and would be allowable.

- ii. A potato plant comprising a mutation of the AOS2 gene which results in increased pathogen resistance, wherein the plant is selected from a Ranger Russet, Desiree, and Bintje potato plant.

In contrast to example i., this invention relates to a distinguishing characteristic of multiple individual plant varieties of the lowest botanical taxon and would be objectionable.

- iii. A hybrid plant comprising a defined distinguishing characteristic, produced by a cross between a first plant selected from multiple individual plant varieties with a second plant from the same genus.

The invention relates to a hybrid plant with a distinguishing characteristic. Furthermore, the cross of a plant variety with a more general plant will always result in the production of a plant of the lowest known rank. Therefore, the resulting hybrid plant relates to a grouping of multiple individual plant varieties and is objectionable.

Footnotes

¹ [Fertilitescentrum AB and Luminis Pty Ltd](#) [2004] APO 19 (“Fertilitescentrum”).

² *Fertilitescentrum*, above n 1, at [32].

³ *Fertilitescentrum*, above n 1, at [35].

⁴ [Woo-Suk Hwang](#) [2004] APO 24.

⁵ *Woo-Suk Hwang*, above n 4, at [9].

⁶ Human Assisted Reproductive Technology Act 2004.

⁷ Patents Act 2013, [s 15\(2\)](#).

⁸ [T 24/91 THOMPSON/Cornea](#), 5 May 1994, Technical Board of Appeal, EPO; [T 58/87 SALMINEN/Pigs III](#), 24 November 1988, Technical Board of Appeal, EPO.

⁹ *Unilever (Davis’) Application* [1983] RPC 219.

¹⁰ [T 1599/09 COVIDIEN](#), 12 June 2013, Technical Board of Appeal, EPO.

¹¹ *John Wyeth’s and Schering’s Application* [1985] RPC 545.

¹² [G 01/07 MEDIPHYSICS/ Treatment by surgery](#), 15 February 2010, Technical Board of Appeal, EPO.

¹³ *ICI (Richardson’s) Application* [1981] FSR 609.

¹⁴ *Joos v Commissioner of Patents* [1973] RPC 59.

- ¹⁵ [Virulite's Application](#) [2010] UKIPO BL O/058/10.
- ¹⁶ *Oral Health Products (Halsteads') Application* [1977] RPC 612; *Lee Pharmaceuticals' Applications* [1975] RPC 511; *ICI Ltd's Application* [1983] UKIPO BL O/73/82.
- ¹⁷ [T 81/84](#) *RORER/Dysmenorrhea*, 15 May 1987, Technical Board of Appeal, EPO.
- ¹⁸ [T 469/94](#) *MIT/Perception of fatigue*, 1 July 1997, Technical Board of Appeal, EPO.
- ¹⁹ [T 144/83](#) *DU PONT/ Appetite suppressant*, 27 March 1986, Technical Board of Appeal, EPO.
- ²⁰ [T 1230/05](#) *BIOENERGY/Increasing energy in vivo*, 28 June 2010, Technical Board of Appeal, EPO.
- ²¹ *Schering's Application* [1971] RPC 337.
- ²² [T 820/92](#) *GENERAL HOSPITAL/Contraceptive method*, 11 January 1994, Technical Board of Appeal, EPO.
- ²³ *Upjohn (Kirton's) Application* [1976] RPC 324.
- ²⁴ [T 82/93](#) *TELECTRONICS/Cardiac pacing*, 15 May 1995, Technical Board of Appeal, EPO.
- ²⁵ [T 789/96](#) *ELA MEDICAL/Therapeutic method*, 23 August 2001, Technical Board of Appeal, EPO.
- ²⁶ [T 245/87](#) *SIEMENS/Flow measurement*, 25 September 1987, Technical Board of Appeal, EPO.
- ²⁷ *Calmic Engineering's Application* [1973] RPC 684; [Schultz's Application](#) [1986] UKIPO BL O/174/86.
- ²⁸ *Ciba-Geigy's Application* [1986] UKIPO BL O/35/85.
- ²⁹ G 01/07, above n 12, at [3.4.2.7].
- ~~³⁰ *Unilever (Davis's) Application*, above n 9.~~
- ~~³¹30~~ G 01/07, above n 12, at [4.3.2].
- ~~³²31~~ [T 429/12](#) *DENTAL VISION*, 19 December 2013, Technical Board of Appeal, EPO.
- ~~³³32~~ G 01/07, above n 12, at [3.3.10].
- ~~³⁴33~~ *Occidental Petroleum's Application* [1973] RPC 684.
- ~~³⁵34~~ [T 1695/07](#) *TRANSONIC SYSTEMS*, 28 September 2011, Technical Board of Appeal, EPO.
- ~~³⁶35~~ *Allen's Application* [1993] UKIPO BL O/59/92.
- ~~³⁷36~~ [T 05/04](#) *CAMTECH*, 17 January 2006, Technical Board of Appeal, EPO.
- ~~³⁸37~~ [T 775/97](#) *EXPANDABLE GRAFTS/Surgical device*, 3 April 2001, Technical Board of Appeal, EPO.

³⁹ ~~Occidental Petroleum's Application, above n 34.~~

⁴⁰³⁸ [T 182/90](#) SEESHELL/Blood flow, 30 July 1993, Technical Board of Appeal, EPO at [2.3].

⁴¹ ~~T 182/90, above n 40.~~

⁴² ~~T 429/12, above n 32.~~

⁴³³⁹ [T 1075/06](#) FENWAL, 17 May 2011, Technical Board of Appeal, EPO at [2.1.1].

⁴⁴⁴⁰ [T 663/02](#) PRINCE, 17 March 2011, Technical Board of Appeal, EPO.

⁴⁵⁴¹ G 01/07, above n 12, at [3.4.2.3].

⁴⁶⁴² T 635/08 DOW CORNING FRANCE, 5 August 2010, Technical Board of Appeal, EPO.

⁴⁷⁴³ G 01/07, above n 12, at [4.2.2].

⁴⁸ ~~G 01/07, above n 12.~~

⁴⁹⁴⁴ [T 807/98](#) ST JUDE, 25 April 2002, Technical Board of Appeal, EPO.

⁵⁰⁴⁵ [G 01/04](#) Diagnostic methods, 16 December 2005, Technical Board of Appeal, EPO.

⁵¹ ~~G 01/04, above n 50.~~

⁵²⁴⁶ [T 125/02](#) AEROCRINE, 23 May 2006, Technical Board of Appeal, EPO.

⁵³⁴⁷ [T 1197/02](#) THE AUSTRALIAN NATIONAL UNIVERSITY, 12 July 2006, Technical Board of Appeal, EPO.

⁵⁴ ~~T 807/98, above n 49.~~

⁵⁵ ~~T 125/02, above n 52.~~

⁵⁶⁴⁸ [T 1016/10](#) GENERAL HOSPITAL, 11 April 2014, Technical Board of Appeal, EPO.

⁵⁷⁴⁹ [T 09/04](#) KONINKLIJKE PHILIPS ELECTRONICS, 8 September 2006, Technical Board of Appeal, EPO.

⁵⁸⁵⁰ [T 330/03](#) ABBOTT LABORATORIES, 7 February 2006, Technical Board of Appeal, EPO.

⁵⁹⁵¹ [T 41/04](#) NATIONAL RESEARCH COUNCIL OF CANADA, 27 June 2006, Technical Board of Appeal, EPO.

⁶⁰⁵² [T 1255/06](#) EXERGEN CORPORATION, 23 September 2008, Technical Board of Appeal, EPO.

⁶¹ ~~T 663/0, above n 44.~~

⁶²⁵³ [T 990/03](#) MEDI-PHYSICS INC, 19 October 2006, Technical Board of Appeal, EPO.

⁶³ ~~G 01/04, above n 50.~~

⁶⁴⁵⁴ Patents Act 2013, [s 14\(a\)](#).

⁶⁵⁵⁵ Patents Act 2013, [s 11](#).

⁶⁶⁵⁶ Patents Act 2013, [s 39](#).

⁶⁷ ~~G 01/07 MEDIPHYSICS/Treatment by surgery, 15 February 2010, Technical Board of Appeal, EPO~~

⁶⁸⁵⁷ Plant Variety Rights Act 2022

⁶⁹⁵⁸ Plant Variety Rights Act 2022, [s 7](#).

⁷⁰ ~~Plant Variety Rights Act 2022, n 68.~~

⁷¹⁵⁹ Plant Variety Rights Act 1987, [s 2](#).

⁷²⁶⁰ [G 01/98](#) NOVARTIS II/TRANSGENIC PLANT, 20 December 1999, Enlarged Board of Appeal, EPO

⁷³⁶¹ [T 1208/12](#) PIONEER HI-BRED/OILSEED, 7 February 2017, Technical Board of Appeal, EPO, at [30].

⁷⁴⁶² G_01/98 above n 72₂, at [3.1]

⁷⁵⁶³ G_01/98 above n 72₂, at [3.10]

⁷⁶⁶⁴ T_1208/12 above n 73₂, at [25] and [36].

⁷⁷⁶⁵ [T 1854/07](#) CONSEJO SUPERIOR/OIL FROM SEEDS, 12 May 2010, Technical Board of Appeal₂, EPO;
[G 01/98](#) NOVARTIS II/TRANSGENIC PLANT, 20 December 1999, Enlarged Board of Appeal, EPO.