

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 19¹. 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 24⁴. 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.

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 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.³⁰

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.³¹ 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.³²

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”.³³ 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.³⁴ Methods carried out by other medical professionals, such as dentists, paramedics, and nurses may still be regarded as methods of surgery.³⁵

Examples of excluded surgical methods

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

- Implanting or inserting any device by incision;³⁶
- Inserting a device into the lungs;³⁷
- Products that are only formed in the human body following a surgical step;³⁸
- Implanting a human embryo;³⁹
- Endoscopy, puncture, injection, excision or catheterisation;⁴⁰

- “Closed surgery” (i.e. with no incision) such as setting broken bones and manipulating dislocated joints;⁴¹
- Dental surgery;⁴² and
- Lumbar punctures, epidural injections and venipunctures.⁴³

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;⁴⁴
- Methods of ear-piercing or tattooing the body;⁴⁵ and
- Methods of applying a plaster cast or attaching an exoprosthesis to the skin using an adhesive.⁴⁶

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).⁴⁷

68. Methods that may assist a surgeon during surgery, such as a real-time imaging method are not methods of surgery.⁴⁸

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.⁴⁹

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:⁵⁰

- 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.⁵¹ 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.⁵²

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.⁵³

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.⁵⁴

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.⁵⁵

82. Diagnosis also includes the identification of a course of treatment.⁵⁶

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;⁵⁷
- Methods of measuring a parameter in a sample, such as blood glucose;⁵⁸
- Methods of assessing tissue viability by measuring total haemoglobin, oxygen saturation and hydration;⁵⁹
- Methods of determining ear temperature;⁶⁰
- Methods of imaging an artery in a patient using magnetic resonance imaging, without any step or identifying a disease or condition;⁶¹
- Methods of measuring oxygen uptake in the lungs;⁶² 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.⁶³

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)),⁶⁴ or may relate to a computer program 'as such' (see section 11).⁶⁵

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).⁶⁶

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.⁶⁷

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.⁶⁸ 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 2022⁶⁹. 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 2022.⁷⁰

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 1987⁷¹ 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 1/98⁷² and T 1208/12⁷³ 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 1/98 at 3.1, it is the substance of the claims that must be considered, not the form of the claims.⁷⁴

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.⁷⁵

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.⁷⁶

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.⁷⁷

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 TELETRONICS/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.
- ³¹ G 01/07, above n 12, at [4.3.2].
- ³² T 429/12 DENTAL VISION, 19 December 2013, Technical Board of Appeal, EPO.
- ³³ G 01/07, above n 12, at [3.3.10].
- ³⁴ Occidental Petroleum's Application [1973] RPC 684.
- ³⁵ T 1695/07 TRANSONIC SYSTEMS, 28 September 2011, Technical Board of Appeal, EPO.
- ³⁶ Allen's Application [1993] UKIPO BL O/59/92.
- ³⁷ T 05/04 CAMTECH, 17 January 2006, Technical Board of Appeal, EPO.
- ³⁸ T 775/97 EXPANDABLE GRAFTS/Surgical device, 3 April 2001, Technical Board of Appeal, EPO.
- ³⁹ Occidental Petroleum's Application, above n 34.
- ⁴⁰ 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.
- ⁴³ T 1075/06 FENWAL, 17 May 2011, Technical Board of Appeal, EPO at [2.1.1].
- ⁴⁴ T 663/02 PRINCE, 17 March 2011, Technical Board of Appeal, EPO.

⁴⁵ G 01/07, above n 12, at [3.4.2.3].

⁴⁶ T 635/08 DOW CORNING FRANCE, 5 August 2010, Technical Board of Appeal, EPO.

⁴⁷ G 01/07, above n 12, at [4.2.2].

⁴⁸ G 01/07, above n 12.

⁴⁹ T 807/98 ST JUDE, 25 April 2002, Technical Board of Appeal, EPO.

⁵⁰ G 01/04 Diagnostic methods, 16 December 2005, Technical Board of Appeal, EPO.

⁵¹ G 01/04, above n 50.

⁵² T 125/02 AEROCRINE, 23 May 2006, Technical Board of Appeal, EPO.

⁵³ 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.

⁵⁶ T 1016/10 GENERAL HOSPITAL, 11 April 2014, Technical Board of Appeal, EPO.

⁵⁷ T 09/04 KONINKLIJKE PHILIPS ELECTRONICS, 8 September 2006, Technical Board of Appeal, EPO.

⁵⁸ T 330/03 ABBOTT LABORATORIES, 7 February 2006, Technical Board of Appeal, EPO.

⁵⁹ T 41/04 NATIONAL RESEARCH COUNCIL OF CANADA, 27 June 2006, Technical Board of Appeal, EPO.

⁶⁰ T 1255/06 EXERGEN CORPORATION, 23 September 2008, Technical Board of Appeal, EPO.

⁶¹ T 663/0, above n 44.

⁶² T 990/03 MEDI-PHYSICS INC, 19 October 2006, Technical Board of Appeal, EPO.

⁶³ G 01/04, above n 50.

⁶⁴ Patents Act 2013, s 14(a).

⁶⁵ Patents Act 2013, s 11.

⁶⁶ Patents Act 2013, s 39.

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

⁶⁸ Plant Variety Rights Act 2022

⁶⁹ Plant Variety Rights Act 2022, s 7.

⁷⁰ Plant Variety Rights Act 2022, n 68.

⁷¹ Plant Variety Rights Act 1987, s 2.

⁷² G01/98 NOVARTIS II/TRANSGENIC PLANT, 20 December 1999, Enlarged Board of Appeal, EPO

⁷³ T1208/12 PIONEER HI-BRED/OILSEED, 7 February 2017, Technical Board of Appeal, EPO, at [30].

⁷⁴ G01/98 above n 72 at [3.1]

⁷⁵ G01/98 above n 72 at [3.10]

⁷⁶ T1208/12 above n 73 at [25] and [36].

⁷⁷ T1854/07 CONSEJO SUPERIOR/OIL FROM SEEDS, 12 May 2010, Technical Board of Appeal. EPO; G01/98 NOVARTIS II/TRANSGENIC PLANT, 20 December 1999, Enlarged Board of Appeal, EPO.

- (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 that given to the term **variety** in section 2 of the Plant Variety Rights Act 1987.

Patentability of human beings

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

2. Section 16(1) is the same as s18(2) of the Australian Patents Act 1990. There have been no rulings from the Australian courts on what is, or is not patentable under s18(2). There have, however, been two decisions of the Australian Commissioner of Patents on this issue – Fertilitecentrum AB and Luminis Pty Ltd [2004] APO 19 (‘Fertilitecentrum’) and Woo Suk Hwang [2004] APO 24. In the absence of any other guidance, these guidelines are based on these decisions.

Patentability of human beings under the Patents Act 1953

3. Practice under the Patents Act 1953 is that claims that include human beings, processes which give rise to human beings, and biological processes for their production will be refused under section

17(1) of the Patents Act 1953, on the ground that use of the invention would be contrary to morality.

4. This practice will not change under s16(1) the Patents Act 2013, however the effect of s16(1) is to codify this practice.

What constitutes a human being for the purposes of s16(1)?

5. The claims at issue in *Fertilitecentrum* were claims to a method of growing preblastocyst human embryos. As the claims related to human embryos, there was no question that they related to a human life form. The question was whether they related to human beings (emphasis added).

6. In deciding this question, the hearing officer considered three approaches to this issue.

- i. What point does a human being come into existence?
- ii. Focus on the 'wrong' that Parliament was trying to address; and
- iii. Specifying the start and end points of the period in which a human being is generated.

7. Of these, the hearing officer considered that the third approach was the most appropriate. After considering the issues, the start of the period in which a human being is generated was defined as the time of fertilisation; that is, when the sperm enters the ovum — for at that time the ovum has all it needs to go on and develop as a human being (paragraph 32 of *Fertilitecentrum*).

8. The definition of the end point of the process was less clear cut to the hearing officer. However, again after considering the issues, he defined the end of the process as birth — on the grounds that this is when the full status of human being is acquired (paragraph 35 of *Fertilitecentrum*). He went on to state:

“The prohibition of ‘human beings’ in my view is a prohibition of patenting of any entity that might reasonably claim the status of a human being. Clearly a person that has been born is covered by this exclusion. But to the extent that there is a process of generation of a human being that lasts from fertilisation to birth, I consider that a fertilised ovum and all its subsequent manifestations are covered by this exclusion.”

9. On this basis, the human embryos that were the subject of the claims at issue were considered to be human beings.

10. The claims dealt with in *Fertilitecentrum* dealt with human embryos originating from ova fertilised by a sperm through an in vitro fertilisation process. However, fertilisation is not necessarily the only way to activate an ovum so that it will develop into a human being.

11. The patent application dealt with in *Woo-Suk Hwang* differed in two significant ways from that in *Fertilitecentrum*. First, there was no actual fertilisation process, and second, the embryo was a hybrid, with human nuclear DNA and bovine mitochondrial DNA.

12. Notwithstanding these differences, the hearing officer considered that the ovum from which the embryo originated was human (see paragraph 8 of Woo-Suk Hwang):

“In natural reproductive processes, the activation of an ovum arises as a direct result of the fertilisation process. However it is clear that fertilisation by a sperm is not the only way in which an ovum can be activated. In my view, an ovum that has been artificially activated is in principle no different to an ovum that has been fertilised by natural means (noting of course that the DNA content of the ovum will be different.) Accordingly the fact that the claimed method uses postactivation of the ovum does not remove the process from the ambit of s.18(2).”

13. The hearing officer also concluded that the embryo produced by the method claimed in the application was human. This was on the basis that the essential characteristics of the embryo were determined by the nuclear DNA – the embryo was therefore properly described as human regardless of the presence of non-human mitochondrial DNA (see paragraph 9 of Woo-Suk Hwang).

14. It follows from this that any entity that might claim the status of a human being is ineligible for patent protection under s16(1). This includes:

- Human ova that have been fertilised or activated by any means;
- Human zygotes, blastocysts, embryos and fetuses; and
- totipotent human cells, including those cells that are the products of nuclear transfer procedures.

Biological processes for the production of human beings

15. In general, biological processes that would lead to the production of any entity that might claim the status of a human being would be considered to constitute processes for the production of a human being. These include (as listed in s 2.9.5 of the IP Australia patent examiners’ manual):

- 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; and
- processes or methods for introducing transgenes and donor genetic or donor cytoplasmic material into fertilised ova, zygotes or embryos etc.

16. Any method or process that involves the creation of a human embryo will be ineligible for a patent 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. This is the case regardless of how the embryo is created.

Human Assisted Reproductive Technology Act 2004

17. Schedule 1 of the Human Assisted Reproductive Technology Act 2004 prohibits certain actions relating to cloned embryos or human embryos. The fact that a claim may include within its scope an act prohibited by this Act is not, in itself, a justification for refusing the claim under s16(1). Note that this is different from the situation in Australia where s50(1)(a) of the Patents Act 1990 provides that a patent may be refused if an invention is 'contrary to law'. There is no corresponding provision in the Patents Act 2013.

However, the fact that a claim includes actions prohibited by the Human Assisted Reproductive Technology Act 2004 may be relevant to an objection under s15 of the Patents Act 2013.

Methods of treatment by therapy or surgery, or methods of diagnosis performed directly on the human body

Introduction

18. Sections 16(2) and 16(3) of the Patents Act 2013 state:

(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.'

19. This effectively codifies the situation under the Patents Act 1953, where the Court of Appeal in *Pfizer Inc v Commissioner of Patents* [2005] NZLR 362 held that methods of medical treatment of humans did not meet the definition of 'invention' under the Act. As a result, claims to methods of treatment of humans by therapy or surgery, and methods of diagnosis practiced directly on human beings were not accepted under the Patents Act 1953.

20. Sections 16(2) and 16(3) of the Patents Act 2013 have similar wording to s4A(1) of the United Kingdom Patents Act 1977 — the main difference is that the United Kingdom provision also excludes methods of treatment and diagnosis of animals as well as humans. In light of this, these guidelines are based on the approach taken in the United Kingdom Intellectual Property Office Manual of Patent Practice but only to the extent that they apply to methods involving human beings.

Methods of treatment by therapy

Definition of 'therapy'

21. The definition of 'therapy' includes treatments that both cure or prevent disease. It also includes methods of alleviating symptoms of a disease. In *Unilever (Davis') Application* [1983] RPC 19, it was held that therapy should be construed as the medical treatment of disease, including curative and preventative treatments.

22. The European Patent Office, in its decisions T24/91 THOMPSON/Cornea OJEP0 1995, 512 and T 58/87 SALMINEN/Pigs III [1989] EPOR 125 58/87 provided a useful definition of 'therapy':

~~'...any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the animal body'~~

Form of claims

23. As with any claim, it is the substance of what is claimed that ultimately determines patentability, rather than the actual form of words used. While claims of the form:

~~'A method of treating medical condition X by administering substance Y', are clearly claims to methods of treatment by therapy, other forms of claim can also be considered claims to methods of treatment by therapy.~~

24. The following forms of claim are considered to relate to methods of treatment by therapy (see John Wyeth's and Schering's Application [1985] RPC 545) and will not be accepted:

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

25. Example (iv) above is interpreted as a claim to the pharmaceutical in a method of treatment as opposed to a claim to its use in a pharmaceutical formulation.

When is a method "treatment by therapy"?

26. One indicator that a method is a method of treatment by therapy is whether the method would normally be carried out by a medical professional. One of the justifications behind s16(2) and (3) is to avoid the possibility that medical professionals (or anyone else) could be restrained or prevented from using their professional skills by fear of infringing a patent.

27. If the nature of a method of treatment is such that it can only be performed by or under the supervision of a medical professional, it is probably a method of therapy and not patentable. However, claimed methods which do not affect a medical professional's discretion may well fall outside the definition of a method of treatment by therapy.

28. The fact that a method must be carried out by a medical professional does not necessarily mean that it is a method of treatment by therapy. If a method has no therapeutic effect, such as collecting blood or other bodily fluids for analysis, the fact that it must be carried out by a medical professional does not mean that it is unpatentable.

29. On the other hand, the fact that a method can be carried out by someone other than a medical professional does not mean that it is not a method of treatment by therapy. Ultimately it is the purpose and inevitable effect of the claimed invention that is important. For example, a method of resuscitation that can be carried out by any person may be unpatentable even though a medical professional is not involved.

Claims including both therapeutic and non-therapeutic methods

30. Some claims may include within their scope methods that are therapeutic (unpatentable) and methods that are not (patentable). An example of this is a method that can be used on both humans (not patentable) and animals (patentable). Another might be a method for inhibiting the coagulation of blood by treating the blood with a compound X. If the treatment is applied to the blood while circulating in the patient the method is not patentable. If it is applied to blood stored outside the body, for example for transfusion purposes, it is not a method of therapy and hence patentable.

31. In such cases the claims will need to be amended to ensure that only patentable subject matter is claimed. No amendment will be required if the specification makes it quite clear that the claims only relate to non-therapeutic methods.

32. Where it is apparent from the specification that the method relates to both therapeutic and non-therapeutic methods, the claims will need to be amended to limit the claims to patentable methods. The specification will also need to be amended to make it clear that therapeutic methods are not part of the invention.

33. If the claims are amended to limit them to patentable methods, examiners should ensure that there is adequate support for this in the specification. For example if claims are limited to non-therapeutic methods, then there must be some disclosure of the use of the method in a non-therapeutic setting. If there is not, the claim is bad for lack of support. The amendment may also constitute new matter, and therefore only be allowable with postdating.

34. This issue was dealt with in ICI (Richardson's) Application [1981] FSR 609 where there was a claim to a method of producing an anti-oestrogenic effect in a human. The claim excluded any method that was a method of treatment by therapy. It was held, though, that the specification did not describe any application of the method other than for the treatment of breast cancer or infertility. On this basis the claim was rejected.

35. Amendments that limit the claim to 'cosmetic' or 'non-therapeutic' methods will be acceptable, subject to the condition set out earlier that there is sufficient support in the disclosure for claims to such methods. Any amendment that excludes therapeutic methods must ensure that the scope of what is actually being claimed is clear. Merely using the words in the Act to exclude therapeutic methods is not considered to provide sufficient clarity.

36. In some cases it may not be possible to separate the therapeutic and non-therapeutic effects of a claimed method. If the non-therapeutic effect is inseparable from the therapeutic effect, or if it is merely a secondary consequence of the therapy, then the invention is unpatentable, regardless of the claim wording used.

37. For example, a method of removing plaque from teeth will be unpatentable as removal of plaque will inevitably have the therapeutic effect of preventing tooth decay and gum disease. Claiming the method as a 'cosmetic' method will not change this, as, however claimed, the method will always have a therapeutic effect that cannot be separated from any cosmetic effect. See Oral Health Products (Halsteads) Application [RPC] 612, and Lee Pharmaceuticals' Applications [1975 RPC 511, and ICI's Application BL O/73/82.

38. If it is possible to separate the therapeutic and non-therapeutic effects of a method, then the fact that the method has a possible therapeutic use will not prevent it from being patented. An example of this is a treatment that could be cosmetic or therapeutic depending on the person being treated.

39. This approach was accepted in the case of an appetite suppressant, where its use in the treatment of obesity (a therapeutic method) did not prevent it from being patented for use in weight loss (cosmetic) — see T 144/83 DU PONT/Appetite suppressant OJEP 1986, 30. A similar approach was taken in the case of an anti-bacterial treatment — see T 36/83 ROUSSEL-UCLAF/Thenoyl peroxide OJEP 1986, 295.

Examples of therapeutic and non-therapeutic methods

Cosmetic treatments

40. Methods that produce purely cosmetic effects, such as cosmetic treatments of the skin and hair are patentable. These may include methods for strengthening nails (see *Joos v Commissioner of Patents* [1973] RPC 59. Methods for preventing hair loss may be cosmetic and patentable where the hair loss is due, for example, to the normal aging process, but may be therapeutic and unpatentable if the hair loss is caused by disease or a side-effect of another therapeutic method (such as radiotherapy). Methods of removing wrinkles caused by aging have no therapeutic effect, so a cosmetic method of removing wrinkles by phototherapy is patentable (*Vurulite's Application* BL O/058/10).

Oral or dental care

41. Methods for the removal of dental plaque, or preventing its formation are regarded as therapeutic and not patentable. All such methods will have the effect of preventing or treating tooth decay, and patents for such methods were refused under the 1953 Act. As mentioned in paragraph 0, the inherent therapeutic effect of such methods cannot be separated from any cosmetic effect, so such methods are not patentable even if claims to them are restricted to cosmetic methods.

Relief of pain or fatigue

42. Methods for the relief or treatment of pain are considered to be methods of therapy, regardless of the origin of the pain as stated in T81/84 RORER/Dysmenorrhea OJEPO 1988, 202:

“Irrespective of the origin of pain, discomfort or incapacity, its relief, by the administration of an appropriate agent, is to be construed as ‘therapy’...”

43. It does not follow from this that all methods for the alleviation of discomfort are necessarily therapeutic. Methods for reducing the perception of fatigue, for example fatigue resulting from exercise could be considered to be non-therapeutic when carried out on a healthy person. On the other hand, such methods, when carried out to alleviate symptoms of an underlying health problem may be therapeutic — see T 469/94 MIT.

44. Methods for treating drug addiction, or withdrawal symptoms, including methods to help people stop smoking, are considered to be methods of therapy.

Treatment of obesity, weight reduction and fitness

45. Where weight reduction is for purely cosmetic reasons, claims to weight loss methods may be patented. Such methods may, of course, also be used for therapeutic purposes, for example, the treatment of obesity. If they are to be patentable, claims to such methods must be limited to use for cosmetic purposes only.

46. A method for ‘enhancing skeletal muscle performance of normal healthy subjects’ was considered to be non-therapeutic by virtue of its limitation to healthy subjects — see T 1230/05 BIOENERGY.

Methods of contraception, abortion, and fertility treatment

47. Methods of abortion, termination of pregnancy, or induction of labour will always be carried out under medical supervision. They are therefore considered methods of medical treatment of human and not patentable — see Upjohn (Kirton’s) Application [1976] RPC 324.

48. Pregnancy is not an illness or disease, so its prevention is not regarded as ‘therapy’ — see Schering’s Application [1971] RPC 337. Contraceptive methods may still be excluded from patentability if they also include a therapeutic element — see T 820/92 GENERAL HOSPITAL/Contraceptive method OJEPO 1995, 113.

49. Methods for the treatment of infertility in humans, including methods of in vitro fertilisation are considered methods of therapy and not patentable. Methods of implantation of human embryos fertilised in vitro are considered methods of surgery and also not patentable. Such methods may also constitute a ‘commercial and industrial’ use of a human embryo and may attract an objection under s15(1) of the Act.

Methods using implanted devices

50. If a claimed method has a therapeutic use then it is not patentable under s16(2). This applies even if the method involves a non-living object such as an implant. On this basis, a method of operating a heart pacemaker to regulate heartbeat is a method of therapy—see T 82/93 TELETRONICS/Cardiac pacing OJEP0 1996, 274.

51. However, a method of controlling the energy input to a pacemaker so as to minimise energy consumption that does not affect the pacemaker's output to the heart may be acceptable—see T 789/96 ELA MEDICAL/Therapeutic method OJEP0 2002, 364. Similarly, a method of measuring the flow of a drug or other substance from an implant, but which does not involve controlling the flow, has been held to be non-therapeutic—see T 245/87 SIEMENS/Flow measurement OJEP0 1989, 171.

52. Methods for the implantation of devices within the body are always unpatentable as this will always involve an invasive procedure. A similar comment applies to methods of controlling surgical devices, for example, surgical robots, in a way that impacts the body, by, example making an incision.

53. If methods for the internal operation of implanted devices do not impact on the body and do not relate to implantation, they may be patentable. The fact that a device must be implanted by surgery does not, in itself, mean that any method of operating the device is unpatentable. However, if the operation of the device involves surgery as an essential step (as opposed to a necessary pre-requisite), disclaiming or omitting the surgical step may lead to an objection under 39(1)—see G 01/07 MEDI-PHYSICS/Treatment by surgery OJEP0 2011, 134.

54. It was also held in G01/07 that methods that may assist a surgeon during surgery, such as a real-time imaging method are not methods of surgery as such.

Treatments performed outside the body

55. The fact that a method of therapeutic treatment of humans is performed outside the body does not avoid the exclusion in s16(2) of the Act. Examples of such methods are dialysis treatment or filtration methods.—see Calmic Engineering's Application [1973] RPC 684, and Schultz's Application BL O/174/86. It should be noted here that the exclusion for methods of therapy in s16(2) of the Act is not limited to methods 'practised on human beings'—this wording only appears in s16(3).

56. Methods of treating blood outside the human body are only considered 'therapy' if the blood is returned to same body. For example, dialysis treatment will therefore be unpatentable, but the treatment of blood for storage in a blood bank may be patentable.

Treatment of parasite infestation

57. The treatment or prevention of parasite infestation, either internal or external in human beings is considered a therapeutic method and not patentable. The argument that it is not therapy because the host human is not affected and only the parasite has been killed has been rejected—see Ciba-Geigy's Application BL O/35/85.

58. Methods for the treatment of parasites on the skin of a human are considered therapy regardless of whether the parasites are 'permanent' or 'temporary'. On this basis, methods of treatment for head lice are considered therapeutic and unpatentable, despite the decision in *Stafford Miller's Application* [1984] FSR 258.

Surgery

Definition of surgery

59. The Oxford English dictionary defines surgery as the treatment of the body by incision or manipulation. It is not limited to actually cutting the body, but also includes manipulative methods of setting broken bones or relocating dislocated joints. It also includes dental surgery.

60. A method of implanting a human embryo can still be considered surgery even if it does not involve making an incision — see *Occidental Petroleum's Application* [1973] RPC 684. Other methods of implanting devices into bodily cavities such as the lungs that do not require incision have been considered to be surgical methods by the European Patent Office — see T 05/04 CAMTECH.

61. While there is no authoritative definition of 'method of surgery' in the context of s16(3), the European Patent Office Enlarged Board of Appeal did provide some useful guidance on whether a particular method could be considered a method of surgery — see G 01/07 MEDI-PHYSICS/Treatment by surgery OJEP0-2011, 134. The Board of Appeal stated that a method should be excluded if:

"A ... method ... comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery"

Accordingly the following concept was developed by the Board of Appeal:

"In order to be excluded from patentability a method should involve a non-insignificant intentional physical intervention which is sufficiently invasive, and which entails a substantial health risk even when carried out with professional medical expertise (by a medical professional) on a human body"

62. On this basis, factors that examiners should consider when considering whether a claimed method relates to a method of surgery include:

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

63. Taking these factors into account, methods for taking blood samples, or injection methods would not generally be considered methods of surgery as they require little skill and involve low risk. If a method requires more specialist medical skills, such as lumbar puncture, it will probably not be patentable. In deciding whether a method is surgical, it is the risk of the invasive procedure itself that must be considered, not any side effects of the procedure.

Surgery defined by nature of treatment

64. When deciding whether a method is a method of surgery, it is the nature of the method rather than its purpose that is the deciding factor. Methods of cosmetic surgery or other non-therapeutic surgery are still methods of surgery for the purposes of s16(3) and are not patentable:

“...surgery can be curative of the disease or diseased conditions, or prophylactic, that is, preventative of diseased conditions, as for example, where an appendix or tonsils may be removed before any diseased condition starts up, and surgery may even be cosmetic without being curative or preventative. So that the subsection it seems to me is saying that any method of surgical treatment, whether it is curative, prophylactic or cosmetic, is not patentable.”—

65. See Unilever (Davis’s) Application [1983] RPC 219 (Note—remarks on surgery were obiter).

Who carries out the method?

66. Whether a method is excluded as a method of surgery does not depend on who carries it out. A method that is or must be carried out by a surgeon is likely to be excluded as a method of surgery (see *Occidental Petroleum’s Application* [1973] RPC 684. Methods carried out by other medical professionals, such as dentists, paramedics, and nurses may still be regarded as methods of surgery.

67. If a method that may involve incision or manipulation of the body can be carried out by people who are not medical professionals, these would not generally be excluded. So, for example methods of tattooing the body, or for ear piercing would be allowable. Tasks which otherwise might be considered surgery, but which have low risk, or are carried out on a routine basis, such as a method for collecting blood samples, may be patentable—see T 663/02-PRINCE.

68. Setting of bones is normally carried out by medical professionals and is unpatentable as a method of surgery. The making and applying of plaster casts would not normally be considered surgery as this work is normally done by a technician rather than a medical professional.

Methods of diagnosis

Definition

69. Diagnosis involves the determination of the nature of a medical condition, usually by investigating its nature and conducting tests. The act of diagnosis itself is an intellectual exercise which is not a manner of manufacture and is not patentable. Diagnosis can include a finding that a person does not have a particular condition, as well as a positive finding that the person has a disease – see T 807/98 ST JUDE. However, determination of a person’s general condition, such as their general state of fitness is not diagnostic if it is not intended to determine whether the person is suffering from a medical condition.

Methods of diagnosis

70. Diagnosis generally involves carrying out a series of steps that contribute towards the identification of a medical condition. The EPO Enlarged Board of Appeal suggested that these could be characterise as (see G 01/04 Diagnostic methods OJ EPO 2006, 334):

- 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 medical condition(s).

71. If a method includes all of these steps, so that it is possible to determine a course of treatment, it is clearly a method of diagnosis. In practice if a method includes only the first and last steps, it can be assumed that the second and third steps have also been carried out.

72. Where a method includes steps which assist in diagnosis, but which do not, by themselves allow a full diagnosis to be made it is not considered to be a method of diagnosis and claims to such methods may be allowable. Examples include methods of internal imaging, or methods of taking samples for in vitro analysis. If a method does not include all the steps to enable a diagnosis to be made, it is not a method of diagnosis:

“The method steps to be carried out prior to making a diagnosis as an intellectual exercise... are related to examination, data gathering and comparison.... If only one of the preceding steps which are constitutive for making such a diagnosis is lacking, there is no diagnostic method, but at best a method of data acquisition or data processing that can be used in a diagnostic method...”, see G 01/04 Diagnostic methods OJ EPO 2006, 334.

73. Methods of data acquisition and processing may be objectionable on other grounds, for example they may not constitute a ‘manner of manufacture’, or may relate to a computer program ‘as such’.

74. Methods that are performed on the body that do not, in themselves, enable a medical condition to be identified are not considered diagnostic methods and will, in general, be allowable. Examples include CT scanning, the measurement of blood glucose, and methods of assessing tissue viability.

75. Methods which include all the steps necessary to make a diagnosis are excluded and should be objected to under s16(3). Where a claimed method relates to the diagnosis of a specific condition, it

is clearly a method of diagnosis. In some cases, the claims may not specify a particular medical condition, but it may be clear from the complete specification that the method does, in fact relate to a method of diagnosis. For example, if a method allows a specific course of treatment to be identified, even though a specific medical condition is not mentioned, it is likely to be a method of diagnosis—see T 125/02 AEROCRINE.

76. There may be cases where essential steps of a method may be omitted (including the final step of attributing a deviation to a particular medical condition). In such cases the claims may not adequately define the invention and objection should be taken under s39 of the Act. This does not mean that every detail of a method must be set out in the claims. For example, where a method is performed in vitro the process of obtaining a sample from the body need not be explicitly included (unless the invention lies in the process for obtaining the sample).

When is a method of diagnosis ‘practised on the body’?

77. The exclusion for methods of diagnosis in s16(3) of the Act is limited to methods ‘practised on the body’. Tests that are performed outside the body, such as in vitro tests are patentable. Further only tests carried out on a living human being are unpatentable, so methods for determining cause of death carried out on dead bodies are also patentable.

78. For a method to be excluded because it is ‘practised on the body’ all of the physical steps of the method must be performed on the body. If a method involves both in vivo and in vitro steps, then the method as a whole is not considered to be practised on the body:

“if... some or all of the method steps of a technical nature... are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion “practised on the human or animal body”, because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out in vitro in a laboratory.” G 01/04 Diagnostic methods OJEP0 2006, 334.

79. Of the steps set out in paragraph 0, the first, the examination and collection of data, is the only one that can actually be ‘practised on the body’, and is, in most cases the only ‘physical’ step. The final step is purely intellectual in nature, and the other steps will not, in most cases, be considered to be ‘physical’ steps, and so are not taken into account when determining whether a method is ‘practised on the body’. Steps that are preparatory steps, or additional to the steps set out in paragraph 0 are irrelevant, even if they are physical steps performed outside the body—see T 1197/02.

Nature of the person who performs the method

80. The question of whether a claimed method is a method of diagnosis is not dependent on who carries out the method, or whether a doctor is present:

‘whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC should neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medicinal or non-medicinal support staff, the patient himself or herself or an automated system.’ G 01/04 Diagnostic methods OJEP0 2006, 334.

In vivo testing of drugs

81. In vivo testing of drugs to determine efficacy and safety would not normally be considered methods of diagnosis.

Multi-step methods involving at least one surgical, therapeutic and diagnostic step

82. Any multi-step method that includes at least one surgical, therapeutic or diagnostic step is excluded from patentability—see G 01/07 MEDI PHYSICS/Treatment by surgery OJEP0 2011, 134.

83. The principle described in paragraph 82 that the presence in a claim of one excluded surgical, diagnostic or therapeutic step renders the whole claim unpatentable does not apply to methods of diagnosis practised on the body. Diagnostic methods are inherently multi-step methods, and are only excluded if they include all the steps required to make a diagnosis, and the new and inventive physical steps are practised on the body.

Apparatus used in surgical, therapeutic or diagnostic methods

84. While claims to medical apparatus per se are allowable, claims to such apparatus ‘when used’ in a method of surgery, therapy or diagnosis practised on the body are not allowable. Such claims are effectively claims to methods of surgery, therapy or diagnosis and cannot derive novelty or inventive step from the intended method of use—see *Visx v Nidex* [1998] FSR 405.

85. An implanted piece of apparatus, or assembly of items, which can only be constructed inside the body in a process involving a surgical step is not patentable, as such a claim is effectively a claim to a method of surgery even if it is framed as a product claim.

“...no European patent can be granted with claims directed to a new and even possibly inventive way of using devices, in particular endoprostheses, involving a treatment by surgery. This is equally true in the case of product claims defined by a construction which is only arrived at in the human or animal body following a surgical method step.” T 775/97 EXPANDABLE GRAFTS/Surgical device [2002] EPOR 24.

86. While the use of a device in a method surgery, therapy or diagnosis is unpatentable, this does not, in itself, mean that functional features in a claim to a product or apparatus is also unpatentable. Claims of this sort may, however be objectionable on other grounds, as defining the invention by a desired result, rather than by the physical features of the product or apparatus.

Patentability of plant varieties

87. Section 16(4) of the Patents Act 2013 states: A plant variety is not a patentable invention.

88. Plant varieties can be protected under the Plant Variety Rights Act 1987. To be eligible for a plant variety right a plant variety must be new, distinct from existing varieties, homogeneous and stable.

89. Plant variety rights can only be granted for new varieties of plants. The term plant variety as used in s16(4) has the same meaning as the term variety in s2 of the Plant Variety Rights Act 1987:

‘a cultivar, or cultivated variety, of a plant, and includes any clone, hybrid, stock, or line, of a plant; but does not include a botanical variety of a plant.’

90. While plant varieties are not patentable, claims that include plant genera or species may be allowed. Where there may be doubt as to whether a claim relates to a variety rather than plant genera or species, it may be useful to seek the advice of the Plant Variety Rights Office before making a final decision.

91. The exclusion in s16(4) applies regardless of how the variety is produced. For example a plant variety produced by genetic modification would not be patentable under s16(4). While it is not possible to be definitive in this area, if the claims relate to plants produced by conventional breeding processes, they probably relate to a plant variety rather than genera or species.

92. However, claims to transgenic plants may be allowable unless they are limited to the modification of a particular variety.