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Patents Examination Guidelines

Section 5: Medical or Diagnostic Use Claims

General principles

5.1. Under section 9A(4) of the Ordinance, methods for the treatment of the human or animal body by surgery or therapy, or diagnostic methods practised on the human or animal body, are not regarded as inventions that are susceptible of industrial application, and thus not patentable.

5.2. The purpose of this exclusion from patentability is set out in *Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.* [1999] RPC 253 by Jacob J at para. 51 as follows:

"The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control what he administers to, or the implements he uses on, the patient."

5.3. This exclusion applies to any method claim comprising at least one feature defining a physical activity or action that constitutes a method for treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body. This contrasts with the exclusion under section 9A(2) of the Ordinance which is only applicable to the extent to which a patent or patent application relates to the excluded subject-matter or activities *as such*.

5.4. The phrase "practised on the human or animal body" in this exception only relates to diagnostic methods, and not methods for the treatment of human or animal body by surgery or therapy (*Schultz's Application* BL O/174/86). In other words, therapeutic methods for the treatment of the human or animal body, whether practised on the body or not, essentially remain to be unpatentable.

5.5. The exclusion applies only to methods of treatment and diagnosis but not to the following—

(a) a product, in particular a substance or composition, for use in any such method, as explicitly stated in the proviso under section 9A(4) of the Ordinance; and

(b) a surgical, therapeutic or diagnostic instrument or apparatus.

Scope of the exclusion

Therapy

5.6. "Therapy" for the purpose of the exclusion under section 9A(4) of the Ordinance includes any medical treatment of disease, whether preventive or curative (see *Unilever Limited (Davis's) Application* [1983] RPC 219 and the EPO Board of Appeal's decision *T 19/86*), and also any treatment which is designed to alleviate, remove or lessen the symptoms of any disorder or malfunction of the human or animal body (see *T 24/91* & *T 1599/09*).

5.7. In the Hong Kong SAR, "therapy" encompasses both practices of Western and Traditional Chinese medicine.

5.8. The following types of claims are generally considered to be therapeutic treatment of human or animal body, thus unpatentable:

(a) Medical treatment which is designed to —

(i) cure a disease, ailment, injury or disability; or

(ii) alleviate or lessen the symptoms of a disease, ailment, injury or disability

(b) Preventive treatment with a direct link to the condition to be prevented

5.9. Conversely, application of substances to the body for purely cosmetic purposes is not considered as a therapy.

5.10. While therapeutic methods normally refers to those carried out by a medical or veterinary professional, the mere fact that a method must be carried out by a medical or veterinary professional (such as the collection of blood or other bodily fluids), or that it may be carried out either by medical or non-medical professionals (such as resuscitation), does not necessarily/conclusively indicate that it is a

method of treatment of human or animal body. The key consideration in deciding whether a claimed invention is a method for "treatment by therapy" is the purpose and inevitable effect of the claimed invention (see the EPO Board of Appeal's decision in *T 245/87*).

5.11. In addition, there must be a direct link between the treatment and the condition to be treated, alleviated or prevented so that the treatment can be treated as a "therapy" under section 9A(4) of the Ordinance.

Example

A method for reducing or preventing wool growth in sheep and related animals was patentable as it was not directly linked to a disease state to be cured, alleviated or prevented, even though it could have the indirect effect of reducing parasite infestation (see Commonwealth Scientific and Industrial Research Organization's Application (BL O/248/04)).

Claims covering both therapeutic and non-therapeutic methods

5.12. A patent application may include both therapeutic and non-therapeutic claims. If the therapeutic and non-therapeutic claims are clearly distinguishable, the fact that the method claim has a possible therapeutic use will not prevent it from being patentable. In some cases, our examiners may require amendments to the relevant claims (e.g. by means of adding thereto appropriate disclaimers for exclusion of the therapeutic methods in question) so as to ensure that such claims only contain/refer to a patentable subject-matter/activity.

5.13. Conversely, where any non-therapeutic effects are inseparably linked to (or a consequence of) the therapeutic effects, the claimed invention would not be considered as capable of industrial application and would be held as unpatentable under section 9A(4) of the Ordinance.

Example

A claim directed to a cosmetic method of removing plaque from teeth was held to be unpatentable because such a method

would inevitably have therapeutic benefits in preventing tooth decay and gum disease:

> *"…the claimed use of a lanthanum-containing composition for cleaning plaque and/or stains from human teeth…will always inevitably have a therapeutic effect (at least in the prophylactic sense) as well as a cosmetic effect. Thus the invention as here claimed is not directed solely to a cosmetic effect, but is also necessarily defining 'a treatment of the human body by therapy' as well." (see T 290/86)*

5.14. The following subject-matter has been held as therapeutic methods, thus unpatentable:

(a) Treatment of parasites

(i) treatment of parasites residing on the skin of a human or animal (*T 116/85*)

(ii) a method of treating or preventing infestation of internal parasites, even if the host is unaffected and that it is only the parasites that are being killed (*Ciba-Geigy's Application* BL O/35/85)

(iii) treatment of head lice

(b) Oral care

(i) methods for the removal of dental plaque with the effect of treating or preventing dental caries (*Oral Health Products (Halstead's) Application* [1977] RPC 612; *Lee Pharmaceuticals' Applications* [1978] RPC 51)

(c) Treatment of pain and withdrawal symptoms

(i) relief of pain, even without underlying pathology (such as relief of menstrual cramp) (*T 81/84*)

(ii) methods of treatment of addiction or withdrawal symptoms

(d) Weight reduction and fitness

(i) treatment of obesity

(e) Contraception, abortion and fertility treatment

(i) a method of abortion or induction of labour (*UpJohn (Kirton's) Application* [1976] RPC 324)

(ii) a contraceptive method that contains a therapeutic element (*T 820/92*)

(iii) methods of treatment of infertility, including methods utilising *in vitro* fertilization

(f) Methods using implanted devices

(i) a method of operating a pacemaker in which its output to the heart was adjusted (*T 82/93*)

(g) Treatments performed outside the body

(i) treatment of blood by dialysis with the blood being returned to the same body (*Calmic Engineering's Application* [1973] RPC 684, and *Schultz's Application* BL O/174/86)

(h) Vaccination and immunization

(i) vaccination/immunization for prevention against certain disease (*Unilever (Davis's) Application* [1983] RPC 21)

(i) Traditional Chinese medical treatment

(i) methods of acupuncture, gua sha (scraping therapy), qigong that contain a therapeutic element

5.15. The following subject-matter has been held as non-therapeutic methods, thus patentable:

(a) Cosmetic treatments

(i) a cosmetic method of strengthening hair and nails (*Joos v Commissioner of Patents* [1973] RPC 59)

(ii) a cosmetic method to prevent hair loss due to normal aging process (*T 453/95*)

(iii) a cosmetic method for removing wrinkles by phototherapy (*Virulite's Application* BL O/058/10)

(iv) a method of protecting the skin by simply blocking UV radiation without physiological protective effects (*T 1077/93*)

(b) Oral care

(i) treatment of bad breath without underlying pathology (*T 675/11*)

(c) Relief of fatigue

(i) a method of reducing the perception of fatigue which is carried out on healthy individuals (*T 469/94*)

(d) Weight reduction and fitness

(i) a method of improving the bodily appearance of a non-opiate-addicted mammal (relate to cosmetic weight loss only) (*T 144/83*)

(ii) a method for enhancing skeletal muscle performance of normal healthy subjects (*T 1230/05*)

(e) Contraception

(i) methods of contraception without any therapeutic element

(f) Methods using implanted devices

(i) a method for measuring the flow of a drug or other substance from an implant, which did not actually control the flow (*T 245/87*)

(ii) a method of controlling the input energy to a pacemaker, which had the effect of minimizing the energy requirements of the device but did not affect the output to the heart (*T 789/96*)

(g) Treatments performed outside the body

(i) treatment of blood for storage in a blood bank

(ii) a method of preparing a dialysis solution which was carried out while the patient was connected to the dialysis system but without the solution coming into contact with his blood (*T 794/06*)

(h) Treatment of stock animals

(i) treatment of stock animals in order to improve their meat or other products, such as milk yields

(ii) a method for reducing or preventing wool growth in sheep and related animals (*Commonwealth Scientific and Industrial Research Organization's Application* BL O/248/04)

Surgery

5.16. The term "surgery" is defined by the Oxford English Dictionary as the treatment of injuries, deformities, and other disorders of the body by manual operation or instrumental appliances. Surgery is not limited to actually cutting the body, but includes other manipulations such as the setting of broken bones or relocating dislocated joints, and also dental surgery.

5.17. In *G 01/07*, the Enlarged Board of Appeal, in determining whether or not a method on the human body, namely an imaging method involving some kind of physical intervention on the body, was a surgical method, held the following:

"A claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which 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 …" (see Headnote 1 of the Decision)

5.18. Accordingly, if a method, when being carried out, constitutes a substantial physical intervention on the body requiring the exercise of professional medical expertise, and entails a substantial health risk even when carried out with the required professional medical care and expertise, it will be considered as a typical surgical method and be excluded from patentability.

5.19. The *G 01/07* case also held that the exclusion is not limited to therapeutic or curative surgery. In other words, "treatment by surgery" is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose. In *T 1213/10*, the applicant argued that a claimed method of measuring the quantity of a substrate metabolite by using a penetration device (e.g. an

endoscope) to introduce a substrate to an organ in the body was patentable because it was not performed for the immediate health of a patient and did not achieve a curative benefit. The EPO Technical Board of Appeal followed *G 01/07* and held that the claimed method was a method of surgery despite of not having any curative effect and was excluded from patentability.

5.20. Our examiners may look at the level of medical skill needed to perform the claimed method in determining whether such method should be treated as surgery and should be excluded from patentability but such consideration is not decisive. A method may still be considered to be surgical even if it can be carried out by non-medical personnel. In *G 01/07*, it was held that whether or not a method is excluded from patentability cannot depend on the person carrying it out because of the changing reality in the field of the medical and veterinary profession caused by the technological advances altering how and by whom health care is administered.

5.21. In general, when deciding whether a method is a method of surgery, the key consideration is the nature of the method rather than, as in the case of a method of treatment by therapy, the purpose of the claimed invention. Therefore, it is possible that some non-therapeutic methods, such as cosmetic surgery, are considered to be surgical methods and are not patentable.

5.22. There is no precise definition of what surgical methods are to be excluded from patentability under section 9A(4) of the Ordinance. Instead, whether a claimed method is to be considered as a surgical method has to be assessed on a case-by-case basis, by reference to the criteria discussed above.

Examples of surgical methods:

(a) Injection of a contrast agent into the heart

(b) Catheterisation (*T 182/90*)

(c) Endoscopy

(d) Methods of abortion or induction of labour

(e) Dental surgery (*T 429/12*)

(f) Implanting or insertion of devices by surgical means (Allen's Application BL O/59/92)

Examples of non-surgical methods:

(a) Tattooing

(b) Cosmetic ear-piercing

(c) Making and applying a plaster cast

(d) Hair removal by optical radiation

(e) Micro-abrasion of the skin

Diagnostic method

5.23. The core meaning of "diagnosis" was discussed by the EPO Enlarged Board of Appeal in its decision of *G 1/04* as follows:

"Diagnosis in connection with the patent exemption for diagnostic methods practised on the human or animal body under Article 52(4) EPC is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology. It includes a negative finding that a particular condition can be ruled out." (See point 5.1 of the Reasons)

5.24. Whilst the therapeutic or surgical nature of a method claim can be achieved by a single method step, multiple method steps are required to define a diagnostic method due to its inherent nature. The Enlarged Board of Appeal in *G 1/04* held that a claimed diagnostic method is excluded from patentability only if it includes all the following steps:

(a) the examination phase involving the collection of data;

(b) the comparison of these data with standard values;

(c) the finding of any significant deviation, i.e. a symptom, during the comparison; and

(d) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.

5.25. When deciding whether a claim is in essence a method of diagnosis, our examiners will adopt the test set out in *G 1/04* above as the starting point. Therefore, if a claimed method comprises all of the above steps by which it is possible to determine a course of treatment or lead to the identification of a clinical state, our

examiners will consider such claim as a diagnostic method and raise an objection thereto under section 9A(4) of the Ordinance. In practice, the intermediate steps (b) and (c) as set out in *G 1/04* may be considered to be implicit if the first and last steps are clearly included in the claimed method.

5.26. The EPO Boards of Review, for instance, found that the subject-matter of a claimed method of assessing the presence of glaucomatous damage to the visual system of a subject (*T 1197/02*) and a claimed method of diagnosing Alzheimer's disease in a living subject (*T 143/04*) included all the features of a diagnostic method and were, therefore, excluded from patentability.

5.27. On the other hand, a method that is merely for obtaining information (data, physical quantities) from the human or animal body, and which does not by itself lead to full diagnosis or treatment is not excluded from patentability under section 9A(4) of the Ordinance. Such a method is at best a method of data acquisition or data processing which can be used in a diagnostic method. Likewise, a method that leads only to intermediate results, rather than a decision on treatment or diagnosis, is also not excluded from patentability.

5.28. A method claim falling under the diagnostic method exclusion does not necessarily have to involve a medical or veterinary practitioner (see *G 1/04*).

5.29. Moreover, the intensity or quality of the interaction is not decisive in terms of the criterion "practised on the human or animal body"; the criterion is satisfied if the claimed method involves any interaction which necessitates the presence of the patient, so will include both invasive and non-invasive methods.

5.30. A diagnostic method being excluded from patentability under section 9A(4) of the Ordinance is required to be “practised on the human or animal body.” Based on the construction of the statutory provision as a whole which also relates to methods of surgery and therapy, it can be inferred that the diagnostic methods as excluded from patentability should also serve curative purposes and are thus meant to be practised on the living human or animal body. This criterion is to be considered only in respect of method steps of a technical nature and does not apply to the deductive medical or veterinary decision phase (see *G 1/04*). Accordingly, a method

practised on a dead body, such as performing an autopsy, would not be excluded from patentability.

5.31. Following the narrow interpretation adopted in *G 1/04*, the EPO's Technical Boards of Appeal have found a number of techniques of obtaining information from the human or animal body to be patentable:

(a) A method for measuring at least one parameter of a biological sample, such as blood glucose in blood

In *T 330/03*, the claimed method yields only intermediate results and includes neither the comparison of the parameter with a standard value, nor the finding of any symptom. Essentially, it does not enable a decision to be made on the treatment.

(b) A method of determining ear temperature

In *T 1255/06*, the acquisition of the temperature data leads to the detection of a deviation from the normal values but it does not allow *per se* the attribution of the detected deviation to a particular clinical picture.

(c) A method of imaging an artery in a region of interest in a patient using magnetic resonance imaging and a magnetic resonance contrast agent

In *T 663/02*, the claimed method only includes the steps of gathering information and does not include the deductive medical or veterinary decision phase.

(d) A method of detecting regional variations in oxygen uptake from the lungs

In *T 990/03*, the final data provided by the claimed method, i.e. a qualitative or quantitative value or image, represent intermediate findings of diagnostic relevance, which must not be confounded with the diagnosis for curative purposes *stricto sensu*.

5.32. While previous decisions suggest that the construction of the exclusion applicable to diagnostic methods is narrower than that applicable to surgical and therapeutic methods, our examiners will consider the circumstances of each claim on a case-by-case basis. Accordingly, caution must be exercised in generalizing the above examples to all cases. If it turns out that a claimed method akin to

any of the above cited method would allow *per se* the attribution of the symptom to a particular clinical picture, such method may still be considered as a diagnostic method under section 9A(4) of the Ordinance.

Medical use claims

5.33. Under sections 9B(4) and 9B(5) of the Ordinance, an invention consisting of a known substance or composition for novel use in a method for the treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body in circumstances known as the "first medical use" (see sections 5.36 – 5.39 of these Guidelines) and the "second and further medical use" (see sections 5.40 – 5.44 of these Guidelines) may still be regarded as new for the purpose of determining its patentability.

5.34. Where the medical claim in question relates to a therapeutic use of a known substance or composition, it has been established that such claim may only be patentable if such substance or composition serves as an active agent in the claimed therapeutic use (see *T 1758/07*). In other words, both sections 9B(4) and (5) of the Ordinance do not apply to address the novelty of those medical use claims in which a known substance or composition is used as an inactive carrier or excipient for a therapeutic agent.

5.35. Moreover, it is also important to note that both statutory provisions does not apply to surgical, therapeutic or diagnostic instruments or apparatuses.

First medical use

5.36. Section 9B(4) of the Ordinance addresses the novelty issue of the first medical use, namely use of a known substance or composition in a method of treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body is not prevented from being regarded as new, provided that its use in any such method is new.

5.37. First medical use claims are usually broad in form without specifying a disease or medical condition. The following examples

of formats of the first medical use claims are acceptable, providing there is credible evidence, in the specification as filed, of the efficacy of the claimed substance for at least one medical use:

(a) *Substance X or composition comprising X for use as a medicament*

(b) *Substance X or composition comprising X for use in therapy*

5.38. In addition to those acceptable formats of claims relating to the first medical use of a known substance or composition without specifying the therapy/diagnosis in question, a medical use claim specifying the relevant therapy/diagnosis may also be used to protect the first medical use of a known substance or composition. The following example of a specific formulation of a first medical use claim (which is commonly associated with a second or further medical use claim adopting the same acceptable formulation (see sections 5.40 – 5.44 of these Guidelines)) is acceptable:

Substance X or composition comprising X for use in the treatment of Y (medical condition).

5.39. As with any claim, it is the substance of what is claimed for a medical use that ultimately determines its patentability, rather than the actual form of words used. As a general guidance, a "use" claim in a form such as "*the use of substance X as an insecticide*" will be treated as equivalent to a "process" claim in a form such as *"a process of killing insects using substance X"*. It should <u>not</u> be interpreted as being directed to the substance X recognizable (*e.g.* by further additives) as intended for use as an insecticide. Accordingly, the following formats of claims are considered to define methods of treatment, and are thus considered to lack industrial applicability under section 9A(4) of the Ordinance.

(a) *The use of substance X or composition comprising X as a medicament*

(b) *The use of substance X or composition comprising X in therapy*

Second and further medical uses

5.40. A known substance or composition with the "first medical use" can be found to have a new therapeutic/diagnostic use as its second or further medical use. The classic case is aspirin which was originally

used to relieve pain but was subsequently found to be useful as an anticoagulant (blood-thinner).

5.41. Section 9B(5) of the Ordinance addresses the novelty issue concerning the second or further medical use, under which a specific use of a known substance or composition in a method of treatment of the human or animal body by surgery or therapy, or a diagnostic method practised on the human or animal body is not prevented from being regarded as new, provided that such specific use is new.

5.42. In view of the above, for the purpose of substantive examination of standard patent (O) applications and short-term patents, the Registrar of Patents generally accepts direct purpose-limited product claims relating to second or further medical uses in straightforward/undisputed cases, having the following general format:

Substance X or composition comprising X for use in the treatment of Y (medical condition)

5.43. It is important to note that the absence of the term "for use" in an independent or dependent claim may render the claim unacceptable because it is not evident whether the claim is directed to a product suitable for a specified use or the claim is limited by a medical use.

5.44. A claim relating to a medical use specifying a disease or medical condition in the form "*substance X for use in the treatment of disease Y*" is only anticipated by the use of X for the specific purpose of treating disease Y, and is considered to be novel over a broad first medical use claim in the form "*substance X for use in therapy*".

Swiss-type claims

5.45. In the Hong Kong SAR, prior to the commencement of the *Patents (Amendment) Ordinance 2016*, it was recognized in *Abbott GMBH & Co KG & Another v Pharmareg Consulting Co Ltd. & Another* [2009] 3 HKLRD 524 that patent protection of second or further medical uses could be obtained by using a specific type of claim drafting known as the "Swiss-type claim" which is usually drafted in the format as:

The use of substance X or composition comprising X in the manufacture of a medicament for the treatment of Y (medical condition)

5.46. "Swiss-type claim" is directed to a method of manufacture rather than being considered a claim relating to a method of medical treatment and can be used even when the first medical use of a substance or composition is not previously known.

5.47. At present, the CNIPA, EPO and UKIPO, being the three designated patent offices under the "re-registration" regime for grant of standard patents (R), differ in their own practices of accepting or rejecting the Swiss-type claims. The EPO and UKIPO no longer allow the Swiss-type claims for second or further medical uses due to lack of clarity (see decision of EPO Enlarged Board of Appeal on *G 02/08* which was reaffirmed in *Actavis v Merck* [2008] RPC 26) while such claims are still accepted by the CNIPA.

5.48. In view of the prevailing case law of the Hong Kong SAR and that standard patents (R) may consist of the Swiss-type claims, our examiners are prepared to allow applicants to claim inventions relating to second or further medical uses by using either the direct purpose-limited product claim format, the Swiss-type format, or both, subject to any evolution of local case authority.

5.49. Although a second or further medical use claim can be formulated in either the Swiss-type format or the direct purpose-limited product claim format in the Hong Kong SAR, the two formats are not necessarily identical in terms of the scope of the respective claims. The case law developed from the EPO has suggested that the scope of protection conferred by a purpose-limited product claim is likely to be broader than that conferred by a Swiss-type claim (see *G 02/08*).

5.50. Accordingly, our examiners will, where appropriate, consider an application for post-grant amendment from a Swiss-type claim to a purpose-limited product claim objectionable by virtue of section 103(3)(b) of the Ordinance on the ground that such proposed amendment has the effect of extending the scope of protection conferred by the patent.

New dosage, administration regime, or route of administration

5.51. While second or further medical use claims are usually directed to the treatment of another disease, the phrase "specific use" under section 9B(5) of the Ordinance may cover medical indications which differ from the prior art use merely in dosage, administration regime (for example, at a reduced dosage), or route of administration (for example, intramuscular as opposed to intravenous injection) while treating the same disease (see *G 02/08* and *Actavis v Merck* [2008] RPC 26).

5.52. It is equally important that such medical use claims covering new dosage, administration regime or route of administration are directed at the activity of the manufacturer rather than at the doctor to avoid an objection under section 9A(4) of the Ordinance (see *Actavis v Merck* concerning the use of finasteride in the treatment of androgenic alopecia (a type of baldness in men) in which the disputed claim was distinguished from the prior art by a reduced dosage of finasteride used in the treatment of the same condition of androgenic alopecia, and in which the court found that the claim was not excluded from patentability because it was directed at the manufacturer, rather than at the doctor).

5.53. A claim for a new dosing regime is generally presumed to be invalid for lack of inventiveness as investigations into the best dosing regimes are regarded to be a standard practice (c.f. *Actavis v Merck* in which the new dosing regime was found to be inventive because evidence showed that at the priority date, a skilled person would have considered finasteride to be ineffective for the treatment of alopecia, and so would not have made further investigations into the better dosing regimes).

5.54. Claims in which the distinguishing features is a new dosage, administration regime, or route of administration may be drafted in the following acceptable format:

(a) *Substance X or composition comprising X for use in the treatment of Y (medical condition) by administration of a dosage of A (dosage regime);*

(b) *Substance X or composition comprising X for use in the treatment of Y (medical condition) by B (route of administration)*.