

Medical treatment of humans

This is a guide to the examination of applications relating to the medical treatment of humans under the Patents Act 1953. These Guidelines do not constrain the judgment and discretion of the Commissioner of Patents, and each application will be considered on its own merits.

Introduction

Section 2(1) of the Patents Act 1953 (“the Act”), defines an invention as:

Invention means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention.

Section 6 of the Statute of Monopolies 1623 says (in modern English):

Provided also and be it declared and enacted, that any declaration, before mentioned, shall not extend to any letters patent and grants of privilege for the term of fourteen years, or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such letters patent and grants shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient. The said fourteen years to be accounted from the date of the first letters patent of grants of such privileges hereafter to be made, but that the same shall be of force as they should be, if this act had never been made, and of none other.

The Court of Appeal in *Pfizer Inc v The Commissioner of Patents* [2005] NZLR 362 held that methods of medical treatment of humans do not meet this definition and are therefore not patentable subject matter.

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General

Patent applications in the medical field must meet the same requirements as applications in all other fields of technology; that is, they must be novel, and the claims must clearly define the scope of the invention and be fairly based on the disclosure.

However, patenting in this field is constrained by the exclusion from patentability of methods of treatment of humans by section 2 of the Act, as confirmed by the Court of Appeal in *Pfizer Inc v The Commissioner of Patents*, which held such methods do not meet the definition of invention.

As such claims including methods of treatment of humans by therapy or surgery, and claims including methods of diagnosis that are performed directly on the human body, will not be accepted.

Definition of therapy

The definition of therapy includes both curative and preventative treatments. This clarifies the practice recited in Information for Clients No.3 of October 1998 that stated:

The Office currently allows claims to methods for the treatment of humans except where the treatment identified relates to surgery or to the treatment or prevention of disease.

In *Unilever (Davis’s) Application* [1983] RPC 219 it was stated that therapy should be construed as the medical treatment of disease, including preventative treatment as well as curative treatment. Therapy also encompasses methods of alleviating symptoms as well as curative treatments for a disease.

In *Schering A.G.’s Application* [1971] RPC 337 it was held that the medical treatment exception was not so broad as to extend to any treatment of the human body. In light of this decision, claims that are directed solely to non-therapeutic medical treatments will be accepted.

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Typical forms of therapy claims

In *John Wyeth's and Schering's Applications* [1985] RPC 545 it was held that claims of the form "the use of X to treat Y" were unallowable as they related to medical treatment. Consequently, claims of this form and variations such as i) the treatment of (medical condition Y) with (substance X), and ii) (substance X) when used to treat (medical condition Y) will not be accepted.

Following the decision of the Court of Appeal in *Pharmaceutical Management Agency Ltd. v Commissioner of Patents* [2000] 2 NZLR 529, "Swiss-type" second medical use claims of the general form "Use of compound X in the manufacture of a medicament for the treatment of a particular medical condition" are acceptable. However, following the decision in *Bristol-Myers Squibb Co. v Baker Norton Pharmaceuticals Inc.* [2001] RPC 1, claims drafted in the Swiss format may be rejected if they also relate to mode of administration, dosage or frequency of dosage.

Guidelines for determining whether a method is "treatment by therapy"

With regard to determining whether or not a claim relates to a method of therapy, it is worth considering whether or not the proposed method would normally be carried out by, or under the supervision of, a medical professional. A rationale for the exclusion is to prevent medical professionals (or anyone else) from being restrained or hampered in providing medical treatment by way of therapy, surgery or diagnosis when performed on a human body.

Medical treatment is not considered to be limited to formal or scheduled events such as surgical procedures in a hospital operating theatre as would be performed by qualified medical professionals. The purpose and inevitable effect of the claimed method are more important. If a method has no therapeutic purpose or effect, then the fact it may be carried out by a doctor does not render it unpatentable.

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Claims to both therapeutic and non-therapeutic methods

There are instances where claims may include within their scope both patentable and non-patentable methods. For example, a claim to "A method for inhibiting the coagulation of blood by contacting the blood with compounds X and Y" could include a method of treating the blood in a patient as part of a therapeutic method (not patentable), and also a method of treating stored blood in a bottle (patentable). In cases where it is unambiguously clear from the specification that the claims relate only to non-therapeutic methods, then no amendment is required.

If it is apparent from the specification that the claims could cover non-patentable embodiments of the method then amendment is required to clearly limit the claim to methods which are patentable, and if necessary to amend the description to clarify that therapeutic methods do not form part of the claimed invention. If claims are limited, either by disclaimer or otherwise, to allowable non-therapeutic methods, then there must be support in the description for a non-therapeutic method.

In *ICI (Richardson's) Application* [1981] FSR 609 a claim was made to a method of producing an anti-oestrogenic effect in a human, but excluded any method of treatment by therapy. It was considered that the specification did not describe any application of the method other than in the treatment of breast cancer or infertility, and so the claim was rejected. Any disclaimer needs to exclude all possible therapeutic methods and not merely those disclosed in the specification and also leave the scope of the remaining monopoly clear.

For example, in appropriate circumstances, the word "cosmetic" in a claim to a method of treatment may be acceptable as a sufficient limitation. Of course, if a claim is amended to "cosmetic methods", there must be disclosure of such methods in the application as filed. If there is not, then the amended claim will constitute added matter, as well as being objectionable through lack of fair basis.

It must be possible to distinguish 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 method is unpatentable, regardless of the wording used. For example, it has been held in the UK courts that it is not possible to claim a cosmetic method for the removal of plaque from teeth; as such a method will inevitably have therapeutic benefits in preventing tooth decay and gum disease (see 'Oral care' below).

Therapeutic and non-therapeutic methods: specific examples

i) Cosmetic treatments

Purely cosmetic treatments of the skin and hair are patentable. These may include cosmetic methods of strengthening hair and nails (following *Joos v. Commissioner of Patents* [1973] RPC 59), and cosmetic methods to prevent hair loss.

Methods of protecting the skin by simply blocking UV radiation are not considered to be therapy, but where a method includes physiological effects then the method is considered to be therapeutic. Cosmetic and therapeutic aspects of a claimed method of protecting skin would be considered to be inevitably linked, such that each one necessarily develops together with the other and such that it would be impossible to separate them.

An argument that the treatment would effectively be directed towards natural ageing of the skin, and would therefore not be therapeutic would be rejected on the grounds that a natural process of cell degeneration is that the cell loses its physiological normality when it develops in an abnormal

manner, and in particular faster than its normal process. The use of a composition for the local treatment of comedones (blackheads) would be regarded as a cosmetic method of non-medical body hygiene, although when applied for the treatment of acne this would be regarded as therapeutic.

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ii) Removal of parasites

Methods of treating or preventing infestation of internal parasites are regarded as therapy; the argument that the host animal is unaffected and that it is only the parasites that are being killed and that therefore this is not therapy of the animal body will not be accepted. Treatment of parasites residing on the skin of a human is considered to be therapy. Treatment of, for example, head lice, is therefore considered therapeutic, see Stafford-Millers Application [1984] FSR 258.

iii) Oral care

Methods for the removal of dental plaque, or preventing the formation of plaque are considered to be therapeutic and thus unpatentable as all such methods have the effect of treating or preventing dental caries, Oral Health Products (Halsteads) Application [1977] RPC 612, and Lee Pharmaceuticals' Applications [1975] RPC 51 (also see ICI Ltd's Application BL O/73/82). The inherent therapeutic effect of removing plaque could not be separated from the purely cosmetic effect of improved appearance of the teeth, and so restriction of such a claim to a cosmetic method is not possible.

iv) Pain and fatigue

The relief of pain is considered to be therapeutic, even where the pain has no pathological cause, and is therefore unpatentable.

However, reducing the perception of fatigue (for example, following exercise) is not comparable with the relief of pain, discomfort or incapacity, and could be considered to be non-therapeutic when carried out on healthy individuals, although there may be therapeutic uses of the treatment as well.

v) Obesity, appetite suppression and weight reduction

Claims to methods of treating obesity, weight reduction and suppression of appetite are considered to be prophylactic treatment of obesity and therefore not allowable.

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vi) Contraception and abortion

Claims to methods of abortion, termination of pregnancy, induction of labour, control of oestrus and menstrual regulation are considered to be unpatentable treatments, as they will always be carried out under medical supervision (see UpJohn (Kirton's) Application [1976] RPC 324). This applies regardless of the reasons for performing these methods.

Methods of contraception are generally not considered to be therapeutic, and may be patented following the decision in Schering's Application [1971] RPC 337. Pregnancy in itself is not an illness or disorder, and so its prevention is not regarded as therapy.

vii) Methods utilising implanted devices

If a claimed method has a therapeutic purpose or effect then it is unpatentable even if the direct effect of the method is targeted on a non-living object such as an implant. For example, a method of operating a pacemaker in which its output to the heart was adjusted would be rejected as being a method of treatment by therapy. On the other hand, a method of controlling the input energy to a pacemaker, which had the effect of minimising the energy requirements of the device but did not affect the output to the heart, would be acceptable. Similarly, a method for measuring the flow of a drug from an implant, which did not actually control the flow, would be considered as non-therapeutic.

viii) Treatments performed outside the body

A therapeutic treatment of the human body is unpatentable even if the actual treatment takes place outside the body, as in an extracorporeal blood dialysis or filtration method.

However, methods of treating blood removed from the body are regarded as therapeutic where the blood is returned to the same body or to another body. Treatment of blood for storage in a blood bank is not regarded as therapeutic treatment.

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Definition of "surgery"

Surgery is defined as the treatment of the body by operation or manipulation. It is not limited to cutting the body but includes manipulation such as the setting of broken bones or relocating dislocated joints (closed surgery), and also dental surgery. Furthermore, a method of implanting an embryo could still be viewed as surgery even if the method did not require incision.

The definition of surgery used relates to the nature of the treatment, and not its purpose. The exclusion of methods of surgery is not limited to therapeutic surgery; methods of surgery for cosmetic purposes, or other non-therapeutic purposes such as sterilisation, are not patentable.

Guidelines for determining whether a method is "treatment by surgery"

In general, any operation on the body which requires the skill or knowledge of a surgeon or other medical professional is regarded as being surgery, whether or not it is therapeutic. A method of embryo implantation which required the intervention of a surgeon would be held to be a surgical method, regardless of its purpose. If a method requires a surgeon for its execution then it must be surgery. However, even a method which does not require a surgeon it does not necessarily follow that the method could not be considered to be surgery – each claimed method will be considered on its merits. A physical intervention which requires the medical skills of, for example, a nurse, could still be regarded as surgery. Similarly, methods of dental surgery require specialist dental skills and are not patentable. If a method does not require medical skills or knowledge, on the other hand, (such as, for example, a method for cosmetic ear-piercing, or a method of tattooing the body) then it may not be excluded as a method of surgery.

Similarly, the setting of bones is carried out by doctors and is considered to be surgical in nature (closed surgery), while making a plaster cast is normally carried out by a technician and would not be regarded as surgery. However, the application of a plaster cast to for example a broken limb, would be considered to be a method of surgery as it has a therapeutic effect.

Methods of making artificial limbs or taking measurements or making casts are also not regarded as surgery or therapy.

Use of parts of bodies in surgery

Surgical procedures used to obtain parts from a dead human body do not fall within the excluded category under section 2 of the Act. However, such methods will be considered on a case-by-case basis as to whether or not the use of the invention is contrary to morality (section 17).

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Diagnosis

General

Diagnostic methods when practised on the human body are excluded from patentability. In vitro diagnostic tests, performed on blood or other samples removed from the body are patentable as it is considered to be an intellectual exercise. To be excluded from patentability, diagnostic methods must be carried out on the living human body. A method carried out on a dead body, for example to determine the cause of death, would be acceptable.

Definition of diagnosis

Diagnosis is the determination of the nature of a medical condition, usually by investigating its history and symptoms and by applying tests. Diagnosis in itself is an intellectual exercise which is not patentable. Diagnosis includes a negative finding that a particular condition can be ruled out, as well as a positive identification of a disease. However, determination of the general physical state of an individual (for example, for a fitness test) is not considered to be diagnostic if it is not intended to identify or uncover a disease or condition.

For a claim to a method of diagnosis to be clear it may be required that the claim specifically recites what constitutes a positive or negative finding of diagnosis of a disease or condition.

The meaning of "methods of diagnosis"

Typically, the process of diagnosis involves a number of steps leading towards identification of a medical condition. Steps including data gathering, comparison of the data with normal values and recording any deviation, and finally attributing the deviation to a particular clinical picture would be considered to be a method of diagnosis of a disease or condition. If a claimed method includes all these steps, and thereby makes it possible to decide on a particular course of treatment, it clearly constitutes an unpatentable diagnostic method (provided it is performed directly on the human

body).

More commonly, claims are directed towards methods which are of value in diagnosis, but which do not in isolation enable a full diagnosis to be made. Examples include methods of imaging, or methods of blood sugar determination or other chemical tests. Methods performed on the human which are solely directed towards diagnosis are considered to be unpatentable methods, regardless of whether additional steps are needed to allow a complete diagnosis. A patent to a diagnostic step performed on the body, even where other steps were needed, would still prevent the doctor from carrying out a diagnostic procedure which required that step. Where a method may be of use for diagnostic or other purposes, then it may be acceptable if restricted to exclude its use in diagnosis (and therapy or surgery, if appropriate).

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Multi-step methods involving a surgical therapeutic or diagnostic step

Where a claimed method involves a number of steps, one or more of which is surgical, therapeutic or diagnostic, then the effect of the method as a whole should be considered.

Apparatus for surgery, therapy or diagnosis

Claims to medical apparatus are allowable in the same way as claims to non-medical apparatus. However, the exclusion of methods of surgery, therapy or diagnosis performed on the human body means that claims to such apparatus "when used" in such a method are not patentable. In other words, while a surgical instrument is patentable, it cannot derive novelty from the way it is intended to be used in a surgical method.

A claim to 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.

Compositions adapted to a particular use

Known substances may be protected by per se product claims to pharmaceutical compositions containing them, if the composition is in a form which is novel over any known products. In particular, a claim may be made to a medicament having a form of administration which is novel and distinct from the previous use. For example, an anti-eczema ointment containing X would be regarded as clearly distinct from a tablet containing X for controlling blood pressure. The ointment is new because X has never been formulated in this form before, and it would be inventive if the previous use of X would not suggest its use in topical form. However, a claim to a composition "adapted to" a specific use should be objected to on clarity grounds as being defined by its intended result, unless it would be clear to the person skilled in the art as to what is meant.

Claims to compositions with a novel physical characteristic, such as shaped forms or tablets with particular surface features may be acceptable providing the feature relates to a genuine technical effect. For example, a claim to tablet of a particular shape or structure would be acceptable if this resulted in a particularly favourable release profile for the active agent. However, if the new shape or form is merely presentational or conveys information (for example, by allowing blind patients to distinguish different types of pill), then it represents either an aesthetic creation or a mere presentation of information. As aesthetic creations and the presentation of information are not in themselves patentable, these features cannot impart novelty to the claim.

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Clarity of composition claims

Composition claims of the form "a pharmaceutical composition containing compound X together with a diluent, excipient or carrier" are considered to be clear; X being a medically active compound which characterises the composition, and the diluent, excipient or carrier being any material suitable for the purpose and being selectable by knowledge of the art or by non-inventive experiment. There is no requirement for the diluent, excipient or carrier to be further characterised. A claim to a solution of the compound, where the compound was known to be water soluble, could not make a claim novel. Terms such as "therapeutically effective amount" of an active ingredient are considered to be clear. However, the purity of a product cannot be defined merely by defining the substance "as a pharmaceutical product".

Compositions with a new non-medical purpose or property

Compositions which are allegedly distinguished from the same compositions in the prior art by the discovery of a new non-therapeutic property in one of the ingredients are not considered to be novel. Claims to the use of the agent in its non-therapeutic role are also not novel if the overall composition has previously been used in the same manner and the newly discovered property already put into effect, albeit unknowingly.

Toothpastes with sodium bicarbonate as a cleaning/tingling agent are known, therefore claims to the use of sodium bicarbonate as a masking agent for bitter ingredients present in the known toothpaste formulations are not novel. This follows the general principle of novelty in NZ law that once a substance or composition is known for whatever purpose then it cannot be patented again for another purpose - second medical use claims are the

only accepted exception to this rule

Claims to unit dosage forms

A unit dosage form consists of a tablet, suppository, ampoule or other device, containing a definite amount of a drug, the whole of which is intended to be administered as a single dose. It is thus distinguished from a supply of an indefinite amount of a medicament, eg a bottle of medicine, from which a dose has to be measured out.

It may be possible in cases where the required dosage for a new medical use is markedly different from that for the known use, to allow a claim to a unit dosage form containing the known active ingredient in such an amount that the unit dosage form is novel and not obvious to have been made up in that amount for the prior art use. Thus if the new medical use requires a dose of, for example, ten times (or one tenth) that for the prior art use, then a claim to a unit dosage form might be judged to be novel and allowable. In assessing such claims it should be remembered that dosages required are usually related to body weight so that children's doses are smaller than those for adults. It is also well known in medicine for patients to be asked to take more than one tablet at a time and it is known for half tablets to be taken.

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Claims to packs of medicaments

Claims to packs of medicaments are sometimes made in cases where an applicant has discovered a new use for a substance and in particular the use of two or more substances together. Claims to a pack or container containing a known substance with instructions for the new use should be rejected on the grounds that the only novel feature - the instructions - is merely a presentation of information and thus not a patentable invention under section 2 of the Act. However, the acceptance of "Swiss-type" second medical use claims has now made such claims redundant in the medical fields.

A new package may be new and inventive if there is some physical relationship between the new and inventive method and the package, which goes beyond merely presenting instructions for the new use. In Organon's Application [1970] RPC 235, a claim was allowed under the UK Patents Act 1949 to a pack containing two types of known contraceptive pill arranged in the order in which they were to be taken, the arrangement being novel and an invention.

Pack or "kit of parts" claims are usually used where the invention comprises the administration of two or more different drug compositions at particular time intervals, or merely simultaneously or sequentially. Claims such as these will be considered in light of L'Oreal's Application [1970] RPC 565. In addition there must be clear support in the description for such a pack, and a claim for a kit or pack for carrying out a method must define all the essential elements for carrying out the method:

In our view, the mere putting up of two ingredients in separate containers in one pack, the ingredients in separate containers in one pack, the ingredients being intended to be mixed together before use to produce a known compound, cannot prima facie amount to a manner of new manufacture