

Guidelines for the examination of Swiss-type claims

This document provides guidelines on applications relating to the Swiss-type claims under the Patents Act 1953 (“the Act”). These Guidelines supersede all previous practice notes, guidelines and the like. The Guidelines do not constrain the judgment and discretion of the Commissioner of Patents. Every application and patent will, as always, be considered on its own merits in light of legislation, case law, these Guidelines and any other information as may be considered relevant in view of the particular facts of each application or patent. These Guidelines are to be considered solely as a guide and should not be quoted or considered to be a legal authority. These Guidelines may become obsolete in whole or in part at any time without notice. Authority must be found in the Patents Act 1953, the Patents Regulations 1954, decisions of the Commissioner and in decisions of the New Zealand Courts.

Introduction

The exclusion to patentability of methods of medical treatment has historically caused problems for applicants and the Intellectual Property Office of New Zealand (IPONZ). Where a substance already known to treat a first medical condition is found to be useful in treating a second medical condition and this second new use has previously been unrecognised - the substance itself cannot be patented because it is not new and the method of using the substance as a medicament is not a patentable invention as confirmed by the Court of Appeal in *Pfizer Inc v The Commissioner of Patents* [2005] 1 NZLR 362 (Pfizer).

In Europe and the UK, where methods of medical treatment of humans are also unpatentable, the Swiss-type claim was devised to enable second medical uses to gain some patent protection. These claims were termed “Swiss-type” claims since they were allowed in a decision of the Swiss Intellectual Property Office which was subsequently followed in a corresponding decision by the European Patent Office (EPO) Enlarged Board of Appeal in G 05/83 (EISAI/Second medical use OJ EPO 1985, 64). The Enlarged Board of Appeal held that claims for “the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application” are allowable.

If the use of the compound for the therapeutic purpose is new, then such a claim is considered to be novel, even if the same substance had previously been used in medicine for a different purpose.

The protection of the second or further therapeutic use by Swiss-type claims was allowed in New Zealand by the Commissioner of Patents in a Practice note which appeared in Patent Office Journal 1412 on 7 July 1997, and was approved by the Court of Appeal in *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 (Pharmac).

It should be noted that there is a significant lack of jurisprudence in New Zealand which considers Swiss-type claims. By far the most significant body of case law which addresses Swiss-type claims is to be found in foreign jurisdictions, most especially from the European Patent Office (EPO) and the British Courts. However, caution should be exercised before applying foreign decisions to the examination of New Zealand patent applications, as frequently the foreign decision is based upon specific parts of foreign legislation or directives which provide directly for second medical use claims and which may not have a corresponding provision in New Zealand patent legislation.

Novelty – the new use

The novelty of a Swiss-type claim is assessed using the same criteria as those applied to claims for active substances per se i.e. by application of the test recited in *The General Tire & Rubber Company v The Firestone Tyre And Rubber Company and others* [1972] RPC 457 (General Tire). For a Swiss-type claim to be anticipated, there should be clear and unmistakable directions found in the prior art to make or do that which is claimed in the claim in question. Therefore, the prior art should specifically disclose the use of the active substance in the purported new therapeutic application.

The decision of the Commissioner in the 7 July 1997 Practice Note, and the decision of the Court of Appeal in *Pharmac*, established that the use of a substance for a new and inventive therapeutic use can be protected by a Swiss-type claim. Swiss-type claims are used to effectively protect the use of an active substance or composition in the manufacture of a medicament for the treatment of a “new use”, where the substance or composition had previously been used for the treatment of a different condition i.e. a different use. Providing that the new use is not known, such claims are considered to be novel.

Swiss-type claims that are distinguished from the prior art by a novel dosage regime or mode of administration have been considered in pre-acceptance hearings, see *Abbott Laboratories* (P16/2003), *Merck & Co v Arrow Pharmaceuticals* (P3/2006) and *Genentech* P1/2007. The *Merck* and *Genentech* decisions agree with one another, although a different view was reached in the earlier *Abbott Laboratories* decision which

approved the UK case Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1 (Taxol).

The Merck and Genentech decisions approved and applied a corresponding European case Genentech Inc (T1020/03). In light of the New Zealand Merck and Genentech decisions, IPONZ will accept Swiss-type claims where the purported novelty of the new use can be found in the new mode of administration or new treatment regime.

The Court of Appeal in Pharmac stated at paragraph [38] of their judgment that:

“The step necessary to render Swiss-type claims acceptable would be to recognise what is in fact the situation that the novelty as well as the inventiveness resides in the newly discovered purpose for which the medicament is to be used.”

Subsequently the Court stated at paragraph [65]:

“Once it is accepted that there can be new invention in the discovery of previously unrecognised advantageous properties in a chemical compound, the obligation to make patent protection available must apply.” (Emphasis added);

and at paragraph [66]:

“It must be emphasised that, because of the manner in which this matter has come before us, we have proceeded upon the assumptions of inventiveness in the discovery of the further pharmaceutical use and lack of anticipation of the use. Those are matters to be considered on a case by case basis” (Emphasis added)

The “previously unrecognised advantageous properties in a chemical compound” referred to in Pharmac is therefore interpreted as referring to properties of the chemical substance which makes it efficacious in the new use e.g. the treatment of a disease or condition (including a new mode of administration or treatment regime).

New mode of administration or treatment regime

As noted above, the interpretation of “previously unrecognised advantageous properties in a chemical compound” also encompasses a novel dosage regime or mode of administration, see the hearing decisions of Merck P3/2006 and Genentech P1/2007.

In Genentech, the Assistant Commissioner when discussing the allowability of Swiss-type claims (where the novelty resides in a new mode of administration or treatment regime) noted that the new method of treatment in the application under review provided a means to overcoming a problem or providing an advantage over the prior art and that it was the contribution, i.e. overcoming a disadvantage in the art, which was patentable:

“Although IGF-1 clearly has valuable therapeutic properties, there are apparently serious problems concerning observed side-effects and the fact that IGF-1 becomes ineffective with continued use. The Applicants have produced a means of overcoming or alleviating these problems by the application of a specific dosage regime and I think it proper that they should be able to obtain patent protection for their contribution” (Emphasis added).

Where the purported new use in a Swiss-type claim relates to a novel dosage regime or mode of administration then an objection generally shall not be made if the claimed subject matter overcomes a particular disadvantage or provides an advantage over the prior art (see Merck, Genentech and T1020/03 Genentech).

Mere novelty in a dosage regime or mode of administration will not automatically render a Swiss-type claim as a new invention unless the new use is a “new result”. Pharmac at [60] discusses the context of the allowability of the “new use” being an invention to the same extent as weed eradication using a novel combination of known compounds was a “new result” (see NRDC’s Application [1961] RPC 134).

“It (a Swiss-type claim) is not a product claim because a combination of the active compound and the carrier not made for the purpose of producing a cancer treatment medicine would not infringe. Nor would sale of the combination for other purposes. It is akin to a method claim by which the newly discovered properties of the active compound can be exploited and an essential element in the use is the intended end result - as it was in the application of the selective herbicide in NRDC...”

The judge in NRDC when reviewing the Elton and Leda Chemicals decision (1957 RPC 257) quoted at p145:

“It has been appreciated that although the inventor may use no newly devised mechanism or device nor produce a new substance, none the less, he may by providing some new and useful effect appropriate for himself a patent monopoly in such improved result by covering the mode or manner by which his result is secured. Seeing that the promise is some new and useful effect, there must of necessity be some product by which his promise can be tested.”

The “product” need not be a product per se where a process is concerned but should result in something upon which the promise of the claimed process can be tested.

As discussed above, the new use in a Swiss-type claim is dependant upon the discovery of a previously unrecognised property of a known chemical. The new use which is purported to be a new mode of administration or treatment regime should therefore be a new result in that it should be a “new and useful effect” in accordance with NRDC. It cannot be supported that mere novelty in the literal text of a claim is sufficient to define a patentable invention where there is not a new result or “new and useful effect” encompassed by the claimed subject matter.

New mechanism of action

The new use must be defined in clear and unambiguous terms. If a claim recites the new use in mechanistic terms, then it must be clear that the mechanistic activity itself is therapeutic or prophylactic and that it is a new use as such, rather than mere information on the mechanistic pathways involved when a known compound is used to treat a disease. For example, a Swiss-type claim for the use of a compound for the “occupation” of a receptor, or the amelioration of a condition “associated with a receptor”, may not meet the requirements of section 10(4) of the Patents Act 1953 if it does not clearly define a new use. There is no doubt that generally speaking there is a physiological interaction between the compound of interest and the receptor, but this interaction in itself is not a new use i.e. a new and useful effect. Typically, claims are framed to recite that the medicament is manufactured for the treatment of any disease for which the mechanism of action in question is active. Such claims are generally unacceptable as they do not recite a new use.

Swiss-type claims often recite the use of a group of compounds which are defined functionally; for example, as antagonists of a particular receptor. This type of claim was at issue in the UK case Pfizer’s Patent [2001] FSR 201, which included claims to the second medical use of phosphodiesterase inhibitors. Such claims are not inherently objectionable, and in this case there was no suggestion that this form of claim was unduly broad and speculative.

Although, the mere fact that a member of a functional class of compounds can be used to treat a disease does not mean that all such compounds will do so, more particularly if there is no evidence in the specification that the treatment is related to that specific activity. It was established in Pfizer’s Patent, that a claim to, for example, “the use of an inhibitor of A in the manufacture of a medicament for the treatment of disease X” is anticipated by any disclosure of the use of any compound which inhibits A in treating disease X of a compound regardless of whether the treatment is explicitly stated as being caused by the inhibition of A.

First medical use claims

Where a substance is new then it is permissible to have claims in a first medical use format, wherein the suitability for use of the substance as a medicament is claimed. Acceptable forms of claims for a first indication of a medical use of a compound are:

1. Novel Substance X for use in the treatment of medical condition Y;
2. Substance X for use as a Y-treating agent;
3. As a Y treating agent, the novel substance X; and
4. Novel Substance X for use in therapy or for use as a medicament.

Particular attention to the claim wording of first medical use claims is required. For example, terminology such as “when used” and “used” or any other similar form of wording may indicate that the substance is claimed in use in a therapy or diagnosis performed on the human body.

The form of "Swiss-type" claims

The general form of a Swiss-type claim is:

The use of [known compound X] for the manufacture of a medicament for the treatment of [new therapeutic use]]

Claims presented in the Swiss-type format may be acceptable if the active component is already known and has been used in therapy or if the active component is new. Additionally, a claim is also allowable in the Swiss-type for novel compounds or compositions.

The following claims are not valid Swiss-type claims:

1. Known substance X for use in the treatment of medical condition Y.

The claim merely indicates the suitability for use of known substance X;

1. The use of known substance X in the treatment of disease Y.

The claim recites an unpatentable method of treatment of disease Y;

1. A package containing as a pharmaceutical agent X together with instructions for using agent X ... for treating condition Y.

If the pharmaceutical use of X is already known, then the claim is only distinguished from the prior art by the content of the instructions which is considered to be a mere presentation of information and is not a patentable invention under section 2 of the Patents Act 1953.

If the pharmaceutical agent X is new, then a claim to the package is patentable so long as it contains X; and

1. A process for the manufacture of a medicament X for use in the treatment of medical condition Y, characterised by the use of substance X. The claim does not adequately define the scope of protection desired in that it is recited as a process claim for producing a medicament X wherein the use of X is the novel feature. The claim does not adequately delimit what would or would not infringe the claim as the characterising feature is the unspecified “use” of the medicament X, which would attract a lack of clarity objection under section 10(4) of the Patents Act 1953.

Generally, if a specification discloses methods of medical treatment, then amendment or addition of claims to include Swiss-type claims will not be regarded as added matter. However, the scope of a method of medical treatment claim and a Swiss-type claim are clearly not the same as one another, see below.

Are Swiss-type claims the same as the corresponding method claims?

The scope of method of treatment claims and Swiss-type claims was considered in the Australian case *Prosidion Limited v Novo Nordisk* [2006] APO 6 in which the patentee sought an amendment after acceptance to add a number of method of medical treatment claims to the granted method of Swiss-type claims. The amendment was refused upon application of the “Distillers test” by the Hearing Officer (The Distillers Co Ltd's Application (1953) 70 RPC 221) and meant that what was not an infringement earlier (prior to amendment) was now an infringement post amendment i.e. that the amendment was a broadening amendment. The Hearing Officer in Distillers Application noted that a Swiss-type claim is “directed to the manufacture of the medicament with the intention of a specified medical use, but does not extend to the actual method of treatment. It is therefore limited to the preparation and sale of a product for the purpose of carrying out a specific medical treatment”.

Diagnosis

Swiss-type claims are allowable where they recite to the use of a substance in the manufacture of a medicament to treat/diagnose a disease or condition, which is otherwise not allowable in a corresponding method claim where it is excluded as being a method of medical treatment of humans or a method of diagnosis when performed directly upon the human body. It follows then that a Swiss-type claim can be used to protect the use of a known substance in the manufacture of a medicament for use in a diagnosis to be performed upon the human body (see T 958/94 THERAPEUTIQUES SUBSTITUTIVES/Anti-tumoral agent OJEPO 1997, 241).

New patient groups

The novelty of a Swiss-type claim residing in a particular patient group was considered in the pre-acceptance hearing P24/2007. The Hearing Officer decided that there could be novelty in a new patient group. The patient group should be clearly defined to ensure that there is no overlap with an existing group in the prior art.

An attempt to distinguish over the prior art merely on the basis that the prior art does not disclose the particular patient group in question is likely to attract an objection of lack of novelty if the prior art discloses the use of the same active substance(s) in the treatment of the same diseases/conditions as those in the subject claim. Generally, for a Swiss-type claim to rely on novelty residing in the “new” patient group, it must be shown that the “new” patient group clearly possesses a distinct physiological or pathological difference which is neither arbitrary nor overlapping with a known patient group, i.e. the known compound is to be manufactured for the purpose of achieving a new use, that is a new result. In determining whether or not the difference is arbitrary, consideration will be given to whether there is a functional relationship between the particular physiological/pathological status of the patient group and the therapeutic/physiological effect achieved (MEDCO RESEARCH, T233/96). If there is no functional relationship, then the claim is likely to be rejected as relating to a mere discovery of a new property of a known medicament (section 2) and/or lacking in novelty.

Fair basis for the therapeutic use in Swiss-type claims

Swiss-type claims like all other claimed subject matter should be fairly based on the disclosure of the specification. The specification as filed should therefore provide at least an indication that the claimed subject matter is fairly based. The claimed subject matter must meet the well-known test for fair basis as set out in *Mond Nickel* (Mond Nickel Co. Ltd.'s Application 65 RPC 123).

“Particularly described” and that the ‘best mode’ in Swiss-type claims

For a claim to be avoid an objection under section 10(3)(a) it is insufficient to merely recite the use of the known compound in the manufacture of a medicament for the new use, such as treatment of a disease or condition not previously treated by the known compound and repeat the text of the

claim in the description. As noted in *Vidal Dyes Syndicate Ltd. v Levinstein Ltd. and Read Holliday & Sons Ltd.* 29 RPC 245:

“Two duties are incumbent upon a patentee in preparing his Complete Specification. In the first place, he must "particularly describe and ascertain the nature of the invention," and, in the second place, he must particularly describe and ascertain "in what manner the same is to be performed". These two duties are distinct and have distinct objects. The first is to ensure that the monopoly granted by the Patent extends no further than the invention which the applicant for the patent has made. The second is to ensure that the public shall, in return for the grant of the monopoly, be put in full possession of the way to carry out the invention, in order that, after the Patent has expired, they may enjoy the benefit of the invention.”

It is settled law that a patentee must act towards the public in good faith, and must give the best information as to how to carry out the invention. But the applicant is not limited to claiming only the best way of carrying it out.

In considering whether or not a Swiss-type claim is particularly described, consideration should be given to the points noted in *IBM (International Business Machines Corporation's Application [1970] RPC 533)*:

“in fact the skilled addressee can from the wording of all the specification carry out the invention there described”

There is no requirement that a claimed invention be exemplified across to entire width of its scope. However, the description should place the skilled person in a position of being capable of putting the invention into effect.

Where a known compound is to be manufactured as a medicament for a specific “new use”, then it follows that the manufacturing process of the compound per se is known. Additionally, it also follows that the purpose of manufacture is not likely to require the notional skilled person to “do” anything different from what is already known in the art when manufacturing a medicament using the known compound per se.

In considering “best mode” the description should disclose the “best” embodiment of performing the invention known to the applicant.

“New” mechanism of action

Information on how a medicament works is not patentable, as the information as such is merely a discovery (section 2 Patents Act 1953). Earlier publication of the use of the medicament for the same condition will also be considered to have been prior published even if there is no mention of the specific mechanism or if a different mechanism is mentioned in the prior publication. The “new” mechanism will have been in effect as an inevitable consequence (General Tire) of using the medicament to treat the condition according to the prior art.

However, where the knowledge of the new mechanism of action is put into effect and leads to a new use (e.g. an improved therapy not anticipated by the prior art), and the new use is fairly based upon the description, then a Swiss-type claim to a new use based upon the new mechanism of action may be allowable.

Unity of invention

The novelty in a Swiss-type claim is to be found in the “new use”, whether it be a new disease or condition, or in the mode of administration or treatment regime (as noted above).

A Swiss-type claim which recites a number of new uses will generally not be viewed as being unified as there would not be common novel subject matter linking the new uses. The discovery of a mechanism of action of a known pharmaceutical in a previously known use would not generally be sufficient to allow a claim to a number of further uses including that of the known use.

Apparatus – new therapeutic or prophylactic use

The Court of Appeal in *Pharmac* approved Swiss-type claims for known pharmaceutical compositions or medicaments having a previously unrecognised property which would result in a new use. The mere novelty of purpose of manufacturing known apparatus for a new use will not be accepted by IPONZ as providing patentable subject matter wherein the new use is in effect a method of medical human treatment. However, where the new use or purpose of manufacture inherently necessitates a novel material difference in that product or apparatus, then the apparatus will be novel per se and therefore patentable when claimed as the apparatus.

The patentability of a known substance in the manufacture of a medicament resides in the discovery of previously unknown or unrecognised property of the substance which makes it useful in a previously unknown therapy or diagnosis i.e. the “new use”. The same condition cannot be satisfied by a known apparatus which does not exhibit a previously unknown property in the same context as was considered in *Pharmac*, which was limited to the consideration of Swiss-type claims relating to second medical uses of compounds/compositions, see *Pharmac* at [66]:

“It must be emphasised that, because of the manner in which this matter has come before us, we have proceeded upon the assumptions of inventiveness in the discovery of the further pharmaceutical use and lack of anticipation of the use. Those are matters to be considered on a

case by case basis” (Emphasis added)

When discussing the *Pharmac* decision, the court noted at [29] that:

“The device of the Swiss claim was created in order to overcome rules prohibiting the patenting of methods of human treatment, particularly Article 52(4) of the European Patent Convention. Such a claim is typically for the use of a particular compound in the manufacture of a medicine for the treatment of a particular medical condition. As Gault J said in giving the judgement of this Court in *Pharmac* at para [17], the Swiss form of claim has been devised to avoid claiming the method of treatment, but to secure protection for use of the known compound in the preparation of a medicament for the new medical use.” (Emphasis added)

It would appear to be clear that both the *Pharmac* and *Pfizer* (in the very limited reference to *Pharmac*) did not consider the issue of patentability of known apparatus when manufactured for a specific new use, wherein the new use was in essence a method of treating humans.

Therefore, IPONZ will not accept claims to for example: use of a scalpel in the manufacture of an instrument/medicament for the treatment of condition X (or any variation thereof including where the novelty is purported to reside in the method of use of the instrument/medicament).