Swiss-type claims

Introduction

1. This guideline outlines IPONZ practice for examining Swiss-type claims.

2. Swiss-type claims are a type of patent claim used to protect the intended medical use of a medicament without interfering with a medical practitioner's ability to treat or diagnose a patient.

3. This provides a balance between the moral policy concerns of excluding medical treatment from patentability while meeting New Zealand's obligations under article 27 of the TRIPS agreement[1] to make patent protection available in all fields of technology.

4. The general form of a Swiss-type claims is:

> "Use of [substance or composition] for the manufacture of a medicament for a [new medical use]."

5. Throughout this document, the reference to 'medical use' is used broadly to refer to both therapeutic and diagnostic uses.

History of Swiss-type claims

6. The key decision in New Zealand relating to Swiss-type claims is *Pharmaceutical Management Agency Ltd v Commissioner of Patents* ("*Pharmac*").[2]

7. In the *Pharmac* decision, the Court of Appeal considered a practice note that the Commissioner published in the journal. This practice note indicated that Swiss-type claims were permitted in New Zealand.

8. The Court of Appeal considered and affirmed two declarations:[3]

> 1. A declaration is made that it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient, provided the requisite novelty (which can be in the intended second or subsequent therapeutic use) can be found.
>
> 2. A declaration is made that the decision of the first defendant that claims of the Swiss-type should not be refused during the examination process as set out in the first defendant's Practice Note dated 7 January 1997 is upheld and the application for review of the first defendant's issuance of the Practice Note is dismissed.

10. This decision confirms that Swiss-type claims are allowable in New Zealand. It also confirms that the novelty of a Swiss-type claim can be found in the intended new medical use of a known medicament.

11. The history of Swiss-type claims is discussed in detail within the *Pharmac* decision. In particular, Swiss-type claims were first allowed by the Swiss Patent Office. These were devised to provide protection for the second medical use of a known substance or composition.

12. This claim format was later confirmed as being allowable by the European Patent Office (EPO) Enlarged Board of Appeal in G 05/83 ("*Eisai")*[4] and by the Patents Court in *John Wyeth's & Brother Ltd's. Application and Schering's A.G.'s application*[5].

13. *Pfizer Inc v The Commissioner of Patents* further discusses the exclusion of medical treatments from patentability and the allowability of Swiss-type claims in New Zealand.[6]

14. *Pharmac* has been widely cited in multiple hearings office decisions under both the Patents Act 1953 and the Patents Act 2013.

Form of Swiss-type claims

15. This section covers what a Swiss-type claim looks like and how its main elements should be defined. The general form of a Swiss-type claim is:

> Use of [substance or composition] for the manufacture of a medicament for a [new medical use].

16. A Swiss-type claim must be a **use** claim that includes three essential elements. These are:

- the substance or composition
- the manufacture of a medicament
- the medical use.

17. In construing these claims most of the focus will be on how the substance or composition and the medical use are defined. This is because these elements are where the patentability of the claim lies.

Form of the substance or composition

18. The substance or composition in a Swiss-type claim can either be new or known in the art. The same construction rules apply to substances or compositions in Swiss-type claims as they do for other claim types.

Functional definitions of the substance or composition

19. Swiss-type claims can include functional definitions of the substance or composition. Functional definitions can be allowable when they are clear to the person skilled in the art and supported by the disclosure in light of the common general knowledge.

Novelty considerations when the substance or composition is defined by function

20. A functional definition of a substance or composition can provide novelty when the definition distinguishes the substance or composition from the prior art.

21. If the functional definition does not distinguish the substance or composition from the prior art the claim may relate to a mere discovery. Manner of manufacture considerations for Swiss-type claims are discussed later in this guideline.

22. In *Vital Food Processors Limited v Anagenix Limited* ("*Vital Food*")[7] the kiwifruit extract comprised a prebiotic material. This functional definition was found to be new as it was not established that the prior art extract had a prebiotic effect.[8]

Clarity and support of functional definitions of the substance or composition

23. A functional definition is clear when the person skilled in the art knows what substances or compositions are included within the scope of the claim. This includes where they may know which substances or compositions fulfil the functional definition from their common general knowledge. Alternatively, where they can determine this by performing routine tests known in the art or outlined in the specification.[9]

24. Below is an example of a Swiss-type claim where the substance has an allowable functional definition.

> Use of **angiotensin-converting enzyme (ACE) inhibitors** for the manufacture of a medicament for the treatment of high blood pressure.

25. The substance can be of any form as long as it is an ACE inhibitor. The person skilled in the art would know from their common general knowledge what substances are ACE inhibitors. This is because these inhibitors are a

well-known drug class. Alternatively, the person skilled in the art could run a commonly known assay to determine if a substance is an ACE inhibitor.

26. A functional definition of a substance or composition is supported when a principle of general application is established. A principle of general application will be established when the person skilled in the art is taught that the function of the substance or composition results in a new medical use.[10]

Form of the medical use

27. The medical use in a Swiss-type claim must be clearly understood by the person skilled in the art. If the medical use is where the novelty of the claim resides it must distinguish the claim from the prior art.

28. A Swiss-type claim that describes treating a recognised disease or disorder will have a clear medical use. This is because the person skilled in the art will know what the medical use is from their common general knowledge.

29. A medical use can be defined in terms of an underlying pathological mechanism of a disease or disorder. Alternatively, it may be defined by the mechanism of action by which the substance or composition will treat the disease or disorder.

30. These are considered functional definitions of the medical use which can provide novelty if the definition distinguishes the medical use from the prior art. This may require considering if the person skilled in the art can determine if a condition falls within the claim from their common general knowledge or from routine testing.[11]

31. Two examples of functional definitions of the medical use are in *Vital Food* and *The a2 Milk Company Limited* ("*a2 Milk*")[12]. In *Vital Food* the medical use was directed to the treatment of digestive dysfunction and/or gastrointestinal tract disorders by promoting the growth and/or activity of at least one type of beneficial bacteria present in the gut.[13] In *a2 Milk* the medical use was directed to the treatment of symptoms of lactose intolerance by stimulating lactase activity in the duodenum. In both of these decisions these functional definitions were found to be novel in view of the cited art.[14]

32. Below is an example of a claim where the medical use has a functional definition and is clear.

> Use of composition X in the manufacture of a medicament to **lower high blood pressure**.

33. The claim is not directed to treating a specific disease or disorder. However, the person skilled in the art would know from their common general knowledge what medical uses are in the scope of this claim.

34. Below is an example of a claim where the medical use has a functional definition and is unclear.

> Use of substance X in the manufacture of a medicament for the treatment of **diseases modulated by the histamine H1 receptor**.

35. At the priority date, diseases modulated by the histamine H1 receptor were not part of the common general knowledge. Further, it would require more than routine testing to determine what diseases are modulated by the histamine H1 receptor. As such this claim does not define a clear medical use. This example is similar to the claims considered in T 0241/95.[11]

The manufacture of a medicament

36. The manufacture of a medicament is an essential element of a Swiss-type claim. Claims with minor variations in the wording or placement of the three elements will be construed as Swiss-type claims provided that they include all three essential elements.

37. For example, the following claims would be construed as Swiss-type claims:

(i) Use of a substance X **in the manufacture of a composition** for a new medical use.

(ii) Use of a substance or composition **for the preparation of a pharmaceutical** for a new medical use.

(iii) Use, **in the manufacture of a medicament**, of a substance or composition for a new medical use.

Construction of Swiss-type claims

38. As established in *Pharmac,* the novelty and inventive step of Swiss-type claims can reside in the intended medical use.

39. Swiss-type claims must be in the general form as set out previously. Furthermore, they need to be directed to appropriate subject matter. As the subject matter of a Swiss-type claim is generally in the 'substance or composition' and the 'medical use', these are dealt with separately below.

The substance or composition

40. Swiss-type claims must be directed to the use of a substance or composition. The substance or composition must also be responsible for achieving the medical use.

41. This is in line with the declaration in *Pharmac* which confirmed that claims to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application are allowable.[3]

42. Claims directed to the use of an apparatus or device are not Swiss-type claims as they do not include a substance or composition.

The medical use

43. Swiss-type claims must be directed to a medical use. This can include both therapeutic and diagnostic uses.

44. However, this does not generally include surgical uses. Surgical methods that involve the use of a substance or composition may be formulated as Swiss-type claims provided they are directed to the use of the substance or composition.

Active language in Swiss-type claims

45. Active language in Swiss-type claims is where a step of administration of the substance, composition or medicament, is described in the claim. This is described through phrases such as "is administered", "is used", "is provided", "when used" or similar.

46. Active language is not permissible where the administration step reads back on the substance, composition or medicament as opposed to being part of the intended medical use. This is because the substance, composition or medicament must be given to the subject to fulfil the promise of the claim. Therefore, such active language includes an excluded medical treatment that will be objected to under s16(2)[15].

47. The following is a typical example of a Swiss-type claim that contains active language:

> Use of an anti-PD-L1 antibody for the manufacture of a medicament for the treatment of cancer, wherein the antibody **is administered** at a dose of 10 mg/kg.

48. The wording "is to be administered" or "treatment comprises administration of" is not active language. This is because the claim does not require administration of the substance, composition or medicament to the subject. This will therefore not be objected to under s16(2). The wording "formulated for" or "adapted for" may also be used. However, whether this wording will limit a claim is dependent on whether there is disclosure in the specification of a difference in the actual formulation or adaptation of the medicament.

49. The following is a re-wording of the example above so that it does not contain active language:

> Use of an anti-PD-L1 antibody for the manufacture of a medicament for the treatment of cancer, wherein **the treatment comprises administration** of the antibody at a dose of 10 mg/kg.

50. In this example, the administration reads back on the **intended** treatment and will therefore not be objected to.

Swiss-type construction only applies to excluded medical uses

51. IPONZ considers that the different construction applied to Swiss-type claims only applies to medical uses that would be otherwise excluded under sections 16(2) or 16(3).[15]

52. It was not envisaged in either *Eisai* or subsequently in *Pharmac* that this different claim construction would apply to other technological fields.

53. As specifically discussed in *Pharmac* (quoted from *Eisai*):[16]

> "It is to be clearly understood that the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions intended for use in a method referred to in Article 52(4) EPC.
>
> …
>
> To prevent the exclusion from going beyond its proper limits, it seems appropriate to take a special view of the concept of the "state of the art" defined in Article 54(2) EPC."

54. Further discussed in *Pharmac*:[17]

> "In such a claim the integer representing the inventive subject-matter and novelty is the new use for which the medicament is made. In this particular field where that cannot be captured with a method claim, we would accept the designation of purpose as sufficient. In this way the somewhat anomalous distinction between first and second pharmaceutical uses will no longer apply and the international obligation will be satisfied."

55. This is understood to mean that the different construction applied to Swiss-type claims only applies where there is a relevant exclusion under sections 16(2) or 16(3).

56. Details regarding this exclusion are discussed in detail in the Patent Examination Manual page Section 16: Other exclusions to patentability.[18]

57. In practice this means that claims directed to a medical use that is not excluded under sections 16(2) and 16(3) are not Swiss-type claims. Any objections should be raised under appropriate grounds based on the appropriate construction.

58. Some specific examples of this are discussed in more detail below.

Non-human animals

59. Claims directed to non-human animals are not Swiss-type claims.

60. The exclusion to patentability in New Zealand under sections 16(2) and 16(3) only applies to methods performed on humans.

61. Medical uses applied to non-human animals are not excluded from patentability. This means that protection is available for a method claim, see the sub-section "Methods of treatment of human beings by therapy or surgery" of the section 16 page of our Patent Examination Manual.

62. This differs from other jurisdictions where the medical use exclusion generally extends to non-human animals.

63. This means that the construction afforded to Swiss-type claims does not extend to medical uses that are applied to non-human animals. Subsequently a claim directed to non-human animals that is proposed as a Swiss-type claim cannot rely on the novelty being in the intended medical use.

64. Swiss-type claims that refer to a "subject" or "patient" will be construed as being directed to humans unless the purposive construction indicates it is also directed to non-human animals. Swiss-type claims that refer to a "mammal" will be construed to include both humans and non-humans unless the purposive construction indicates otherwise. The purposive construction should take account of the specific disclosure of the specification including the examples, definitions and any applicable dependent claims.

65. This will also require relevant objection grounds to be established for an objection to be raised. As such, claims that are construed as being directed to non-humans should only be objected to if the novelty and/or inventive step resides in the intended medical use.

Non-therapeutic uses

66. Claims directed to non-therapeutic uses that are allowable as a corresponding method claim are not Swiss-type claims. Examples of therapeutic and non-therapeutic methods in the sub-section "Methods of treatment by therapy" of the section 16 page of our Patent Examination Manual.

67. Where a non-therapeutic use cannot be separated from a therapeutic use, a Swiss-type claim will be permissible as the corresponding method will be excluded under section 16. For example, the removal of plaque has both cosmetic and therapeutic effects which cannot be separated. Subsequently, a Swiss-type claim directed to removal of plaque would be permissible, as the corresponding method would be excluded.

68. Where it is possible to separate the non-therapeutic use and the therapeutic use, the non-therapeutic use can be protected by a method claim and the therapeutic use can be protected by a Swiss-type claim. In such situations, Swiss-type claims can be restricted to therapeutic uses in a similar way to methods being restricted to non-therapeutic methods. For example:

(i) A non-therapeutic method for weight loss, comprising administering compound X.

(ii) Use of compound X in the manufacture of a medicament for therapeutic weight loss.

Construction of claims in Swiss-type format that encompass medical uses that are not excluded

69. Where a claim is submitted in the form of a Swiss-type claim and the underlying invention includes matter that is both excluded and non-excluded matter, the claim will be given its broadest construction and relevant objections should be raised as necessary.

70. As an example of this, a claim to:

> The use of a [substance or composition] in the manufacture of a medicament for a [medical use] in a subject, wherein the subject is a human or non-human animal.

71. This claim includes both excluded matter (medical use in humans) and non-excluded matter (medical use in non-human animals).

72. While novelty can be recognized in the medical use in humans, novelty cannot be recognized in the medical use in non-humans. Therefore, the broadest construction relates to the substance or composition, which is merely 'suitable for' that medical use in non-humans.

73. An objection to lack of novelty will be raised if the substance or composition is known. It is noted that in this example a claim to a corresponding method directed to the medical use of non-human animals would be permitted.

Claims relating to a new substance or composition

74. The medical use of a new substance or composition can be claimed in other claim formats. Where the invention resides in the substance or composition, provided there are no other issues, the following examples are notionally allowable.

(i) Example 1: Novel substance X for use in treating medical use Y.

(ii) Example 2: Novel composition X for use in therapy.

(iii) Example 3: Use of novel substance X in the manufacture of a medicament.

(iv) Example 4: Use of novel substance X in the manufacture of a medicament for a medical use Y.

75. Example claims 1 and 2 are construed as substance or composition X **suitable for** the specified use. Example claim 3 is construed as the use of novel substance X to manufacture a medicament that is suitable for any therapeutic purpose. Example claim 4 is construed as a Swiss-type claim.

Comparisons to overseas claim formats

76. In other jurisdictions, claims relating to medical uses take different forms. IPONZ will consider opinions on patentability prepared in other jurisdictions, in light of the appropriate claim construction in New Zealand.

77. Some examples are:

(i) The use of substance X in the treatment of medical condition Y.

(ii) A method of treatment of medical condition Y by administering substance X.

(iii) Substance X when used to treat medical condition Y.

(iv) Substance X for use in the treatment of medical condition Y.

(v) An agent for treating medical condition Y comprising substance X.

78. Examples (i)-(iii) are method of treatment claims. In New Zealand, these forms of claim will attract an objection under section 16(2).

79. Examples (iv)-(v) will be construed in New Zealand as a claim to substance X which is “suitable for” treating the medical condition. While a patentability opinion prepared in another jurisdiction may have taken account of the features relating to the therapy, this will not be the case in New Zealand. If substance X is known, an objection to lack of novelty will be raised.

80. Any of these forms of claim can be converted to a Swiss-type claim. If a disclosure provides support and enablement for a claim in any of these formats, the same disclosure would provide support and enablement for an equivalent claim in the Swiss format in New Zealand.

Common types of Swiss-type claims

81. This section covers common types of medical uses that are seen in Swiss-type claims. Some common considerations that apply to these types of medical uses are discussed in detail below.

Dosage regimens, treatment regimens and modes of administration

82. Dosage or treatment regimens can be covered by Swiss-type claims. These generally relate to treating a known condition by a novel dosage or treatment regimen which results in an improved therapeutic effect.

83. The decision in *Merck & Co. Inc. v Arrow Pharmaceuticals (NZ) Limited* ("*Merck v Arrow*") highlighted that there can be invention in improving existing therapies by way of Swiss-type claims.[19]

84. In order for dosage or treatment regimens to be inventive, it is not enough that they are just novel. Novel dosage or treatment regimens need to provide a means to overcome a problem or provide an advantage over the prior art to be patentable. In other words, it has to have a technical effect that provides a contribution over the art. This was highlighted in *Genentech Inc and Washington University ("Genentech*").[20]

85. While both *Merck v Arrow* and *Genentech* were under the 1953 Act and considered manner of manufacture grounds, *Taiho Pharmaceutical Co., Ltd.* ("*Taiho*") applied the same rationale under inventive step.[21]

86. This is because optimisation and adaptation of dosages and treatment schedules commonly falls within routine practice of a person skilled in the art. The Assistant Commissioner in *Taiho* discussed the level of common general knowledge of a person skilled in the art in the field of oncology.[22] This included discussion that clinical practice guidelines regarding treatment regimens of therapeutics are generally available to the skilled person. Therefore, where the invention involves known therapeutics, the common general knowledge already existing about said therapeutics will be relevant.

87. Similarly, to dosage and treatment regimens, novelty and inventiveness may also rely on the mode of administration of the therapeutic. The same requirements apply in that a technical effect needs to be associated with this novel feature to be inventive. When defining a mode of administration in the claims, care should be taken to avoid use of active language (see paragraphs 45-50 above).

Apparatus and devices

88. Claims directed to the use of an apparatus or device are not Swiss-type claims as they are not directed to the use of a substance or composition (see paragraphs 40-42).

89. Claims directed to the use of a substance or composition may recite an apparatus or device as part of the manufacture of a medicament element, or the medical use element, as appropriate. Care should be taken to avoid active language.

90. Some non-limiting examples are:

> (i) Use of a specific ligand for human immunoglobulin in the manufacture of a column having said ligand coupled thereto for the treatment of a patient suffering from dilated cardiomyopathy, said treatment comprising passing plasma of the patient over the column under conditions which effect the binding of said specific ligand to immunoglobulin in the patient's plasma, thereby removing a significant portion of the immunoglobulin from the patient's plasma, and reinfusing the plasma to the patient.[23]

91. Here, the substance or composition is the specific ligand for human immunoglobulin. The medicament is in the form of a column, and the medical use is treating dilated cardiomyopathy by passing the plasma over the column. The claim sets out how the device is used in the therapy without using active language.

(ii) The use of a local anaesthetic or a pharmaceutically acceptable salt thereof for the manufacture of a pharmaceutically acceptable topical drug formulation contained in a patch for treating pain from a surgically closed wound in a subject, wherein said patch is adapted for administration on or adjacent to an exterior surface of the wound.[24]

92. Here, the substance or composition is the local anaesthetic or pharmaceutically acceptable salt thereof. The medicament is in the form of a patch, and the medical use is treating pain from a surgically closed wound in the subject, wherein said patch is adapted for administration on or adjacent to an exterior surface of the wound.

93. Following *Taiho*, the wording "adapted for administration" will be read as "said patch is suitable for administration on or adjacent to an exterior surface of the wound". If a prior art patch comprising the same substance or composition is known for treating pain and would also be suitable for the recited administration, the claim would lack novelty.

(iii) The use of a substance or composition in the manufacture of a medicament for a medical use, wherein the medical use comprises administering the medicament with a nebulizer.

94. This claim would be considered in a similar way to a treatment regimen or mode of administration. That is, there would need to be a technical effect associated with the novel features to be inventive.

95. Particular attention may be given to any differences in the physical properties that the nebulizer confers on the substance or compositions (such as particle size) and/or in the delivery to the patient. If these differences result in an improvement in the medical use, these would be considered inventive.

Patient groups

96. Patient groups can be covered by Swiss-type claims. These generally relate to treating a known condition in a distinct group or subset of patients.

97. The Assistant Commissioner in *Taiho* refers to *Astrazeneca AB* [2007] ("*Astrazeneca*")[25] and notes the standard Swiss-type claim was adapted to provide protection for an invention where a known treatment is effective in treating a specifically defined group of patients. The Assistant Commissioner highlighted that if this clearly leads to an improvement in an existing therapy, that this should be patentable following *Pharmac.*

98. When considering the allowability of a patient group in *Astrazeneca*, the Assistant Commissioner referred to the test as set out in T 233/96 ("*Medco").*[26] The *Medco* test includes the following steps:[27]

(i) The treatment must be carried out on a novel group of subjects which is clearly distinguished with respect to its physiological or pathological status from, and does not overlap, with the group previously treated; and

(ii) The choice of this new group, if distinguishable from the known one, must not be arbitrary, meaning there must exist a functional relationship between the particular physiological or pathological status of the new group and the therapeutic effect achieved.

99. For the purpose of examination, step (i) considers the novelty of the Swiss-type patient group and step (ii) is considered to relate to the inventiveness of the Swiss-type patient group. This two-step test is used to help assess patentability of Swiss-type patient groups.

100. Selection invention criteria as set out in *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* ("*Dr Reddy's*") may also be considered relevant for Swiss-type patient groups.[28] The criteria for selection inventions are particularly appropriate where the invention relates to a selection of a subgroup of patients.

101. There are multiple ways to distinguish a Swiss-type patient group. A purposive construction should be applied to consider the physiological or pathological status of the patient. Some non-limiting examples of Swiss-type patient groups are:

(i) Treatment resistance, and patients that have not responded to previous treatments.[29]

(ii) Early or late-stage cancers.[25]

(iii) Patient parameters, such as age, biological sex, or other characteristics.

(iv) Genotypes, for example, specific mutations in cancer.

(v) Phenotypes which set out a subset within a disease.

(vi) Specific symptoms.

Combination therapies

102. Combination therapies can be covered by Swiss-type claims. These are generally where novelty and inventiveness resides in the use of two or more therapeutic agents that are individually known for the same medical use. As discussed in more detail below, careful consideration should be given to how a combination therapy is defined in the claims.

Combination therapies that are 'formulated for' or 'adapted for' combination

103. In *Taiho*, the claims were drafted to a use of a known combination chemotherapy which was 'formulated for' co-administration with a known anti-cancer antibody.[21]

104. The Assistant Commissioner found that the 'formulated for' wording in this instance was equivalent to 'suitable for'. The Assistant Commissioner concluded the claim did not relate to a newly discovered purpose.[30] This was because the recommended oral dosage of the known combination chemotherapy was suitable for co-administration with the antibody. As a result, the claims were found to lack support and novelty.

105. A similar construction will apply to the wording 'adapted for' as this similarly reads back on how the medicament is prepared.

106. There are cases where 'formulated for' or 'adapted for' can limit a claim to provide novelty and inventiveness. This will require a physical difference in the substance or composition, or in the medicament that results in the new medical use.

107. The complete specification should provide sufficient disclosure to support the physical difference in the substance or composition, or the medicament. This will need to be assessed on a case-by-case basis.

Examples of combination therapies in Swiss-type claims

108. Examples of combination therapies are included below. The claim construction of each example is discussed, and whether the claims are limiting or not to the combination therapy.

(i) Use of compound A and compound B in the manufacture of a medicament for treating condition Y.

109. The claim is limited to the combination of both compounds A and B. This claim may cover a single formulation containing both compounds, or components as separate physical formulations (non-fixed formulations) or both depending on what is supported by the complete specification.

(ii) Use of compound A in the manufacture of a medicament for treating condition Y, wherein the treatment comprises co-administration of compound A in combination with compound B.

110. The claim is directed to the medical use of compound A as a single therapeutic. The medical use includes the co-administration of both compounds A and B. Another independent claim may cover the use of the other therapeutic in a similar manner to be used with compound A.

(iii) Use of compound A in the manufacture of a medicament for the treatment of condition Y wherein compound A is administered with compound B to the subject.

111. This claim is limited to administering compound A and B together to the subject. However, this claim contains active language and will be objected to under s16(2) for extending to a method of treatment of humans by therapy.

(iv) Use of compound A in the manufacture of a medicament for the treatment of condition Y, wherein the medicament is for administration with compound B.

112. The wording 'for administration' is construed as 'suitable for'. The medicament only needs to be suitable for administration with compound B. A novelty objection will be raised if compound A is known for treating Y and would be suitable for combination with compound B.

(v) Use of compound A in the manufacture of a medicament for the treatment of condition Y in a subject that is undergoing treatment with compound B.

113. This claim defines the treatment in a patient that is undergoing treatment with compound B. This will be considered as a Swiss-type patient group. The complete specification will need to support a link between this particular patient group and the therapeutic effect obtained.

Diagnostic uses

114. Diagnostic uses can be covered by Swiss-type claims. Different considerations apply depending on the nature of the diagnostic use, the form of the proposed claims and the technical contribution. Some specific considerations are discussed in detail below.

Method of diagnosis practised on a human being

115. Swiss-type claims can provide an alternative claim format for methods of diagnosis practised on human beings which use a diagnostic substance or composition.

116. A typical example of this is:

Use of diagnostic compound in the manufacture of a medicament for diagnosing a particular condition.

Swiss-type patient groups identified by a diagnostic method

117. Swiss-type claims can define treating a patient with a substance that is known to treat a particular medical use, where the patient is identified by a new method of diagnosing patients. This claim will be considered in the same way as other Swiss-type claims directed to patient groups.

118. An example of this is:

Use of substance X in the manufacture of a medicament for medical use Y wherein the patient has been identified using a defined diagnostic method.

119. This example will only be novel and inventive if it meets the patient group criteria set out above. In other words, the patient group needs to be distinct and linked to the therapeutic effect obtained. An example of this is where the new diagnostic method identifies a subset of patients with a specific genotype or earlier stage of a condition that results in an improvement in treatment efficacy.

Diagnostic steps forming part of a treatment regime

120. Swiss-type claims may also include a diagnostic step as part of a treatment regime.

121. An example of this is:

> Use of substance X in the manufacture of a medicament for treating condition Y, wherein the treatment comprises identifying a patient using a defined diagnostic method and administration of substance X to the patient.

122. As the diagnostic steps reads back on the intended treatment, the diagnostic steps could provide novelty and inventiveness to the claim. The usual construction rules for Swiss-type claims and treatment regimens are applicable.

Other sections as they relate to Swiss-type claims

Manner of Manufacture

123. Section 14 defines a patentable invention as being a manner of manufacture within the meaning of section 6 of the Statute of Monopolies. The Court in *Pharmac* referred to *National Research Development Corporation v Commissioner of Patents* ("*NRDC*")[31] and held that Swiss-type claims are for a manner of manufacture based on the discovery of unrecognised properties of known pharmaceutical compounds.[32]

124. In *Vital Food*[7], the Commissioner considered whether the Swiss-type claims at issue were for a manner of manufacture. The Commissioner noted that a mere discovery, or mere information, as to why or how a known substance works is not patentable. There is a distinction between **mere information** about the way a known product works, and information which defines a **new purpose**, made possible by a new and different technical effect.[33]

125. The question of whether a Swiss-type claim relates to a mere discovery must be determined on the balance of probabilities, and with reference to any available evidence.[14]

Novelty and Inventive step

126. Novelty and inventive step in Swiss-type claims can be found in either the substance or composition, or in the medical use.

127. Novelty of Swiss-type claims is assessed using the test set out in *The General Tire & Rubber Company v The Firestone Tyre And Rubber Company and others*.[34] 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 other words, the prior art should specifically disclose the use of the substance or composition in the intended medical use recited in the claim.

128. Inventive step of Swiss-type claims can typically be assessed using the test set out in *Pozzoli Spa v BDMO SA* ("*Pozzoli"*).[35] The *Pozzoli* test, discussed in the Patent Examination Manual page Section 7: Meaning of inventive step[36], is a reformulation of the test set out in *Windsurfing International Inc. v Tabur Marine (Great Britain Ltd)* ("*Windsurfing*").[37] Another reformulation of the *Windsurfing* test was set out in *Osmose New Zealand Ltd v Tim Tech Chemicals Ltd*,[38] and was applied in *Taiho.*[39]

129. There are other established tests which may be used to assess novelty and inventiveness of Swiss-type claims.

130. In some cases, it may be appropriate to assess inventive step as a selection invention using the approach set out in *Dr Reddy's.* This test requires that the selection is not arbitrary and makes a hitherto unknown technical contribution. This approach was applied in New Zealand in *GlaxoSmithKline Intellectual Property (No.2) Limited, Anacor Pharmaceuticals, Inc*.[40]

131. The *Medco* test may be used to assess novelty and inventive step of Swiss-type claims relating to patient groups.

Support and Enablement

132. The specification must disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a person skilled in the art (enablement; section 39(1)(a)); and the claims must be supported by the matter disclosed in the complete specification (support; section 39(2)(c)).[41]

133. In *Biogen v Medeva* ("*Biogen*"),[42] the two requirements of support and enablement (referred to as support and sufficiency in *Biogen*) were linked by the general legal principle expressed in T 409/91 ("*Exxon/Fuel Oils"),*[43] that the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified. In post-grant UK case law, the questions of support and enablement are addressed together, under the umbrella of "sufficiency".

134. In New Zealand, the requirements for support and enablement are closely associated with one another, and the general legal principle expressed in *Exxon/Fuel Oils* has been held to be linked to the support requirement of section 39(2)(c).[44] The two grounds are effectively two sides of the same coin: the disclosure needs to enable the claim to be worked across its full range (enablement), and the breadth of the claim must be commensurate with what the disclosure makes available in each case, to the skilled person ~~at the priority date~~ (support).[45]

Support for Swiss-type claims

135. Swiss-type claims should be supported by the disclosure of the specification. The specification as filed should therefore support the new medical use recited in the claim. Typically, support will be established from experimental data, test results, or clinical trials in relation to the new therapeutic activity of the substance or composition.

136. The claimed subject-matter must meet the test for support as set out in *Biogen*, where Lord Hoffmann stated:[46]

> "… the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved its application in every individual instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them."

137. A claim which includes an element stated in general terms meets the support requirement if it would be reasonably expected the invention will work with anything which falls within the general term. However, claims will lack support where they include results that are not enabled, claim all ways of achieving a result where the specification only enables one way of achieving the result, or claim results which make no use of the invention. [47]

Principle of general application

138. If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms.[46]

139. The general approach is to compare the invention described in the claims and the invention described in the specification (the contribution), and assess whether the former is "supported by" the latter. The scope of the claims must not be broader than is justified by the extent of the contribution to the art, as disclosed in the specification. [48]

140. Swiss-type claims which related to classes of compounds using functional terms were considered in *Ardelyx*[9]. The Assistant Commissioner considered whether the functional terms recited in the claims represented a principle of general application which could support the claims.

141. Where a specification demonstrates a new medical use for a single compound, the contribution may lie in the use of that particular compound. However, if the contribution can be generalized to a class of compounds, a claim relating to a new medical use for the class of compounds may be supported.[49]

Plausibility

142. Support for Swiss-type claims requires that the specification provides enough disclosure to enable the person skilled in the art (PSA) to expect that that the medicament will work for the claimed medical use. This means that pure assertion is insufficient. See *Prendergast's Applications*,[50] which is cited in *Lonza Ltd*.[51] The Assistant Commissioner also considered the commentary regarding plausibility in relation to Swiss-type claims in *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan*[52] which is cited in *Gilead Sciences, Inc*.[53]

Enablement for Swiss-type claims

143. The disclosure in the specification should provide a clear enough and complete enough description which would enable the PSA to perform the invention across the breadth of the claims, without requiring them to exercise an undue amount of effort, research, or inventive thinking.

144. The test for enablement was set out by the House of Lords in *Kirin-Amgen v Hoechst Marion Roussel Ltd* ("*Kirin-Amgen*").[54] The first step of the *Kirin-Amgen* test is to identify the invention by construing the relevant claims and decide what it claims to enable the skilled person to do. The second step then asks whether the specification discloses sufficient information to enable the skilled person to perform the claimed invention.

145. Enablement is also discussed in *Biogen* where Lord Hoffmann stated:[55]

> "The disclosure must be such as to enable the invention to be put into practice, i.e. to obtain without undue effort the appropriate range of claimed items. Again, what is appropriate will depend on the facts of each case. It is not accepted that all claims that have any speculative element in them are automatically bad. There is always a question of degree that comes into it."

146. A Swiss-type claim is enabled if the notional person skilled in the art can determine how to manufacture the medicament, using the substance or composition, by referring to the specification in light of their common general knowledge. Since Swiss-type claims are directed to the manufacturing process, the claimed medical use for the medicament is not likely to require the notional skilled person to "do" anything different, as compared to the manufacture of the same medicament for a different purpose.

Unity of invention for Swiss-type claims

147. As for any other claim format, Swiss-type claims will be examined on a case-by-case basis regarding unity of invention. Swiss-type claims are unified where they share at least one special technical feature as per PCT rule 13.2. Special technical features are those features in claims which define a contribution over the prior art.

148. In some circumstances, a mechanism of action in a Swiss-type claim may represent a special technical feature. When an inventor discovers a new mechanism of action relevant to a medical use, the mechanism cannot confer novelty to a previously known medical use of a substance or composition. However, if the discovery itself leads to previously unknown medical uses of the substance or composition, these new medical uses can be unified by the common mechanism of action.

Footnotes:

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, article 27 ("TRIPS agreement").

2. *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] NZCA 330; [2000] 2 NZLR 529 ("*Pharmac*").

3. *Pharmac*, above n 2, at [15].

4. G 05/83 *Eisai/Second medical indication* [1984] Enlarged Board of Appeal, EPO.

5. *John Wyeth & Brother Ltd's application and Schering A.G.'s application* [1985] RPC 545.

6. *Pfizer Inc v The Commissioner of Patents* [2004] NZCA 104; [2005] 1 NZLR 362.

7. *Vital Food Processors Limited v Anagenix Limited* [2015] NZIPOPAT 17("*Vital Food*").

8. *Vital Food*, above n 7, at [193].

9. *Ardelyx, Inc.* [2023] NZIPOPAT 17 ("*Ardelyx*"). Paragraphs [69]-[73] discuss performing routine testing.

10. *Ardelyx*, above n 9, at [159]-[164].

11. T 0241/95 *Eli Lilly and Company/Serotonin receptor* [2000] Technical Board of Appeal, EPO.

12. *The a2 Milk Company Limited* [2022] NZIPOPAT 8 ("*a2 Milk*").

13. *Vital Food*, above n 7, at [207].

14. *a2 Milk*, above n 12, at [59].

15. Patents Act 2013, s 16.

16. *Pharmac*, above n 2, at [31].

17. *Pharmac*, above n 2, at [65].

18. Section 16: Other exclusions to patentability – IPONZ Patent Examination Manual.

19. *Merck & Co. Inc. v Arrow Pharmaceuticals (NZ) Limited* [2006] NZIPOPAT 3 ("*Merck v Arrow*").

20. *Genentech Inc and Washington University* [2007] NZIPOPAT 1 *("Genentech*").

21. *Taiho Pharmaceutical Co., Ltd.* [2020] NZIPOPAT 5 ("*Taiho*").

22. *Taiho*, above n 21, at [31]-[43].

23. T 2003/08 *Edwards Lifesciences Corporation/Dilated cardiomyopathy* [2012] Technical Board of Appeal, EPO.

24. *Epicept Corporation* [2007] NZIPOPAT 29.

25. *Astrazeneca AB* [2007] NZIPOPAT 23 ("*Astrazeneca*").

26. T 0233/96 *Medco Research/Adrenaline* [2000] Technical Board of Appeal, EPO ("*Medco*").

27. *Medco*, above n 26, at [8.7].

28. *Dr Reddy's Laboratories (UK) Ltd v Eli Lilly & Co Ltd* [2009] EWCA Civ 1362; [2010] RPC 222 ("*Dr Reddy's*").

29. *Astrazeneca AB* [2007] NZIPOPAT 24.

30. *Taiho*, above n 21, at [101] and [122].

31. *National Research Development Corporation v Commissioner of Patents* [1959] HCA 67; (1959) 102 CLR 252 ("NRDC").

32. *Pharmac*, above n 2, at [64].

33. *Vital Food*, above n 7, at [275-276] and [281].

34. *The General Tire & Rubber Company v The Firestone Tyre And Rubber Company and others* [1972] RPC 457.
35. *Pozzoli Spa v BDMO SA & Anor* [2007] EWCA Civ 588 ("*Pozzoli*").
36. Section 7: Meaning of inventive step - IPONZ Patent Examination Manual.
37. *Windsurfing International Inc. v Tabur Marine (Great Britain Ltd)* [1985] RPC 59 ("*Windsurfing*").
38. *Osmose New Zealand v Tim Tech Chemicals Limited* [2010] NZIPOPAT 22.
39. *Taiho*, above n 21, at [30].
40. *GlaxoSmithKline Intellectual Property (No.2) Limited, Anacor Pharmaceuticals, Inc.* [2022] NZIPOPAT 15.
41. Patents Act 2013, s 39.
42. *Biogen v Medeva* [1997] RPC 1 ("*Biogen*").
43. T 409/91 *Exxon/Fuel Oils* [1993] Technical Board of Appeal, EPO, at [3.3] ("*Exxon/Fuel Oils")*.
44. *Neurim Pharmaceuticals Ltd.* [2022] NZIPOPAT 6, at [14]-[15].
45. *Ardelyx*, above n 9, at [86].
46. *Biogen*, above n 42, at 48.
47. *Ardelyx*, above n 9, at [82]-[83].
48. *Biocon Limited* [2018] NZIPOPAT 2.
49. *Ardelyx*, above n 9, at [175], [190] and [191].
50. *Prendergast's Applications* [2000] RPC 446.
51. *Lonza Ltd* [2020] NZIPOPAT 1.
52. *Warner-Lambert Company LLC v Generics (UK) Ltd t/a Mylan* [2018] UKSC 56; [2018] RPC 21.
53. *Gilead Sciences, Inc.* [2023] NZIPOPAT 8.
54. *Kirin-Amgen v Hoechst Marion Roussel Ltd* [2004] UKHL 46; [2005] RPC 9, at [103] ("*Kirin-Amgen*").
55. *Biogen*, above n 42, at 16.