New Zealand allows Swiss-type claims for new therapeutic uses of known pharmaceutical compounds. Method of treatment claims directed to the new use of the known compound are also permitted, provided the treatment of humans is excluded.
Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws. Please number your answers with the same numbers used for the corresponding questions.

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

Yes, Swiss-type claims are allowed for new therapeutic uses of known pharmaceutical compounds.

Method of treatment claims directed to the new use of the known compound are also permitted, provided the treatment of humans is excluded.

If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

2) If the answer to Question 1) is yes, please answer the following sub questions.

a) What is the basis for patent protection?

The protection for Swiss-type claims was allowed in New Zealand by the Commissioner of Patents in a Practice note issued on 7 July 1997. This practice was approved by the Court of Appeal in Pharmaceutical Management Agency Ltd v Commissioner of Patents [2000] 2 NZLR 529.

b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

New medical uses of known compounds can be patented in Swiss-type format. It does not matter how successful the previous use was, or if the previous use was medical, or non-medical. Where the previous disclosure of the compound was for non-medical uses only, it is also possible to claim a 'pharmaceutical composition' comprising that compound.

The new use can be the disease or condition to be treated, a novel patient group, or a novel dosage or administration regime.

The Intellectual Property Office of New Zealand has issued guidelines outlining the approach examiners will take to second medical use claims.

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

The subject matter must be capable of being presented in 'Swiss-type' format, i.e. 'The use of [known compound X] for the manufacture of a medicament for the treatment of [new therapeutic indication Y]. Sometimes there are real therapeutic benefits associated with treatments that can be manufacture as a medicament, for example, new treatments involving radiotherapy. This subject matter is not patentable in New Zealand.
The Intellectual Property Office (IPONZ) will also not accept claims where novelty resides only in a mechanism of action. For example, if the art discloses treating cancer by inhibiting X, a claim to treating cancer by activating Y pathway will be rejected. IPONZ's approach has not been tested in the courts.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

Swiss-type claims in the format: 'The use of [known compound X] for the manufacture of a medicament for the treatment of [new therapeutic indication Y]'.

The particular wording of a Swiss-type claim does not need to be exactly as above, as long as it contains the essential integers.

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

IPONZ guidelines state that the following claim formats are not permissible:

i) Known substance X for use in the treatment of medical condition Y. *This is a claim merely indicating the suitability for use of substance X.*

ii) The use of known substance X in the treatment of disease Y. *This is an unpatentable method of treatment claim.*

iii) Commercial packages containing as an active pharmaceutical agent compound X together with instructions ... for treating condition Y. *If the pharmaceutical use of X is already known, the claim is only distinguished from the prior art by the content of the instructions, and this represents a mere presentation of information and thus not a patentable invention under section 2.*

iv) A process for the manufacture of a medicament for use in the treatment of medical condition Y, characterised by the use of substance X. *This claim does not adequately define the use of substance X, thus is unclear under section 10(4).*

v) The use of known compound X for the manufacture of a medicament for the treatment of new therapeutic indication Y, wherein the medicament is administered orally. *The mode of administration should only indicate the form of the medicament, such as ‘the medicament is formulated for oral administration’, rather than impart a monopoly on the administration of the medicament.*

f) Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of 'treatment', 'treating' or 'use to treat' integers in second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.
The scope of ‘treatment’, ‘treating’ or ‘use to treat’ has not been the subject of a decision by the courts in New Zealand, nor is it discussed in the IPONZ guidelines for Swiss-type claims.

3) If your country permits second medical use claims:

a) Who may be liable for infringement of such claims? For example:
   i) the party marketing the drug with label instructions which describe the patented use;
   ii) the physician prescribing the drug for such use;
   iii) the pharmacist dispensing a drug for such purpose;
   iv) the patient using the drug for such purpose?

   The primary act of infringement in relation to a Swiss-type claim is the act of manufacturing the pharmaceutical or compound for the treatment of a specific condition/disease. Therefore, Swiss-type claims will be considered infringed by manufacturers. Physicians and patients do not manufacture the drug, therefore they will not infringe a Swiss-type claim.

   There are no New Zealand court cases regarding infringement of Swiss-type claims. It is possible that marketers who label a known pharmaceutical with the patented use, or pharmacists who package a known pharmaceutical for a patented purpose would also be held liable for infringement.

b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

   There is no statutory exemption from liability, but the Swiss-type claim format is intended to exclude liability of medical practitioners and patients.

c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

   Direct and indirect infringement of Swiss-type claims is theoretically possible in New Zealand. A manufacturer who makes a pharmaceutical with the intent of selling it for the patented use will directly infringe a Swiss-type claim.

   Indirect infringement may be possible where a first party manufacturers the compound, and a second party uses that compound to produce a pharmaceutical labelled with the intended use. If the manufacturer of the compound knew that the second party intended to infringe the claim, then it is likely the first party would be held to indirectly infringe.

4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

   It is unlikely that a product merely being capable of an infringing use would infringe a Swiss-type claim. A Swiss-type claim, in our opinion, has two necessary acts required for infringement of the claim, namely the use of a product in the manufacture of a medicament and that the medicament be for use in a particular treatment. Simply because an item satisfies the manufacture aspect of the claim does not necessary mean that it will in fact infringe the claim. For the manufacture of that medicament to infringe the Swiss-type claim, it is also necessary to show that the medicament was manufactured for use in the treatment of the specific illness/disease set out in the Swiss-type claim.
5) If the answer to Question 4) is yes, please answer the following sub questions in that context.

a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

There have not been any High Court decisions interpreting Swiss-type claims in the infringement/validity environment.

We note that the regulatory regime for medicines in New Zealand means that there is unlikely to be difficulties in identifying the purpose for which manufacture, distribution etc of a medicine is intended.

7) What relief is available for infringement of a second medical use claim:

a) at a preliminary / interim / interlocutory level?

b) by way of final relief?

There are no specific provisions relating to infringement of second medical use claims. The remedies available for infringement are the same as those available to any other kind of patentee, e.g. preliminary injunction, damages, etc.

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

We are unaware of any preliminary / interim / interlocutory injunctions being issued in New Zealand for infringement of second medical use claims. We expect that product packaging would be sufficient to meet the tests for granting of an interim injunction.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

This matter has not yet been considered by the New Zealand courts. It is likely that recent Australian case law would be persuasive.

II. Policy considerations and proposals for improvements to your current law
If your country permits second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind permitting such claims?

Methods of medical treatment are excluded from patentability in New Zealand. Such methods are considered to fall within the 'generally inconvenient' exception set out in the Statute of Monopolies, and are therefore not an invention.

However, New Zealand is a signatory of the TRIPs agreement, and has an obligation to provide protection for novel inventions. Swiss-type claims are considered to strike a balance between these two competing positions.

b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

The current balance is considered an acceptable fallback position in the absence of method of treatment claims. The patent attorney profession would generally prefer it if Swiss-type claims were replaced with either method of treatment claims, or European style 'for use' claims.

c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

The scope of protection offered by method of treatment claims is greater than the scope of Swiss-type claims. Therefore, the current New Zealand position can be seen as favouring the public interest in not restraining physicians.

Although Swiss-type claims restrict the scope of the monopoly in practice, the impact on patentees is limited. Even if the restriction on method of treatment claims was lifted, it is likely that pharmaceutical companies would still sue a competing manufacturer rather than individual doctors or patients.

d) If there is any empirical or anecdotal data available, please address the following.

i) What is the prevalence of second medical use claims in your country?

Second medical use claims are extensively used in New Zealand patent applications.

ii) What is the profile of patentees for second medical use claims in your country?

The majority of pharmaceutical patents (for first and second medical uses) are granted to international pharmaceutical companies. New Zealand does not have a significant domestic pharmaceutical industry.

If your country does not permit second medical use claims, please answer the following sub questions.

a) What are the policy reasons behind not permitting such claims?

b) Would such claims serve the interests of relevant stakeholders?

c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?
12) To what extent does your country's law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

New Zealand is a small market and does not have a large domestic pharmaceutical industry. Any originator companies are likely to focus on larger markets, such as the US or Europe, and are unlikely to be affected by the availability of patent protection in New Zealand. We have a small generic manufacturing sector. The position of generic manufacturers in New Zealand is similar to that in many other jurisdictions.

The range of pharmaceuticals available in New Zealand is largely influenced by the central government funding system, i.e. PHARMAC. The effect of PHARMAC on the pharmaceutical industry would be more significant than the effect from New Zealand's approach to second medical use claims.

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.

13) Is it desirable to permit second medical use claims?

Yes, although method of medical treatment style claims would be preferable to Swiss-type claims.

14) Is harmonisation of laws relating to second medical use claims desirable?

Yes. As a small market, New Zealand would benefit if claims accepted in e.g. Europe could also be filed in New Zealand.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

e) Who may be liable for infringement?

f) Any parties/institutions that should be exempted from infringement or liability for infringement.

g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

h) Relief available upon a finding of infringement:
i) at a preliminary / interim / interlocutory level; and
ii) by way of permanent relief.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

NOTE:

It will be helpful and appreciated if the following points could be taken into consideration when editing the Group Report:

- kindly follow the order of the questions and use the questions and numbers for each answer
- if possible type your answers in a different colour
- please send in a word document
- in case images need to be included high resolution is required for good quality printing.