Swiss-type claims explained

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The Intellectual Property Office of New Zealand has issued updated guidelines for the examination of Swiss-type (second medical use) claims. Several topics are covered in the guidelines, including novelty requirements, allowable subject matter and sufficiency requirements. The guidelines are available online at IPONZ's web site.

According to the guidelines, novelty of a Swiss-type claim is assessed using the General Tire test (The General Tire & Rubber Company v The Firestone Tyre and Rubber Company and Others [1972] RPC 457). This test states that a prior art document must provide clear and unmistakeable directions to perform the claimed invention in order to anticipate the later claims. Novelty may derive from treatment of a different condition, a new mode of administration or a novel dosage regime. If novelty resides in the mode of administration or dosage regime, the claimed subject matter must overcome a disadvantage or provide an advantage over the prior art.

A new mechanism of action may be allowed in a Swiss-type claim. However, the guidelines indicate that such claims must relate to a new use. That is, the claim must provide more than “mere information on the mechanistic pathways involved when a known compound is used to treat a disease.” The guidelines lack some clarity on this

point and this is not assisted by the presence of two sections regarding new mechanisms of action.

New patient groups may provide the required novelty for a Swiss-type claim. The patient group should be clearly defined and there should not be any overlap with an existing group in the prior art. In order to determine whether the new group is distinct, the Office will consider whether there is a functional relationship between the physiological/pathological status of the patient group and the therapeutic/physiological effect achieved.

Swiss-type claims directed to the manufacture of a medicament for diagnosis of a disease or condition are allowable where the subject matter would otherwise be excluded as a method of treatment claim. In contrast, Swiss-type claims directed to the use of a medical apparatus will not be accepted.

To meet the sufficiency requirements of Section 10(3) of the Patents Act 1953, the description should do more than merely recite the use of the known compound in the manufacture of a medicament for the new use. Although there is no requirement that a claimed invention be exemplified across its entire scope, “the description should place the skilled person in a position of being capable of putting the invention into effect.”

In addition, a Swiss-type claim that 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.” No further guidance on this point is provided.

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