

Swiss-style use claims vs method of treatment claims

A recent patent office decision has held that addition of “method of treatment” claims to a specification that has “Swiss-style use” claims is not an allowable amendment after acceptance of the application.

24 November 2006

FACTS

AU 721477 in the name of Prosidion Limited (“Prosidion”) proceeded to acceptance (allowance) with claims in the form of:

The use of compound X for the preparation of a medicament for the treatment of condition Y.

This type of claim is commonly referred to as a “Swiss-style” claim.

After acceptance, Prosidion sought to amend the specification to include method of treatment claims in the form of:

A method of treating condition Y comprising administering to a mammal, a therapeutically effective amount of compound X.

Novo Nordisk opposed the amendment on two grounds:

- (i) As a result of the amendment, the claims of the specification would not in substance fall within the scope of the claims before amendment; and
- (ii) As a result of the amendment, the specification would not comply with Section 40(2) or (3) as the claims as a whole would be unclear and not succinct.

DECISION

Construction of Swiss-style claims

In order to determine whether method of treatment claims in substance fall within the scope of the claims before amendment, the scope of Swiss-style claims must be construed.

There have been no judicial decisions in Australia that construe the scope of a Swiss-style claim. However, such claims have been judicially considered in Europe, the United Kingdom and New Zealand. After consideration of these authorities, the Delegate concluded that there was general agreement that a Swiss-style claim is construed as directed to the manufacture of a pharmaceutical product for the purpose of carrying out a specified medical treatment but does not extend to the method of treatment itself. The Delegate considered it appropriate to apply this construction in Australia.

In substance within the scope of the claims before amendment

The accepted test for determining whether a claim of the specification in substance falls within the scope of the claims before amendment is the Distiller’s test (*The Distillers Co. Ltd’s application* (1953) 70 RPC 221). The Distiller’s test asks whether a proposed new claim would extend the patent monopoly such that it would make something an infringement that was not an infringement before amendment.



Patents and Designs

Section 13 of the Patents Act 1990 provides the patentee with the exclusive right to exploit a claimed invention or authorise a third party to exploit the claimed invention. A person who exploits the claimed invention, who is not the patentee or their licensee, infringes the patent.

Schedule 1 of the Patents Act 1990 defines “exploit” to include:

- (a) where the invention is a product – make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
- (b) where the invention is a method or process – use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such a use.

The applicant argued that the exclusive right provided by a Swiss-style claim extended not only to the manufacture of the medicament, but also to the product of the process and its use. Accordingly, the medicament itself and the use of the medicament in a method of treatment would infringe the Swiss-style claim. Therefore, the addition of method of treatment claims would not make anything an infringement that was not an infringement before the amendment.

The Delegate was not persuaded by this argument. The Delegate applied the same definition of exploit to method of treatment claims, indicating that a method of treatment claim would be infringed, not only by the treatment of a subject, but by the treated subject (the product of the method) and the use of the treated subject (the use of the product of the method). The Delegate illustrated his point with reference to the treatment of cows, stating that not only would the treatment of a cow infringe the method of treatment claim but also the treated cow as the product of the method and the use of the cow, for example in the production of milk or beef. Since the treated subject and the use of the treated subject would infringe a method of treatment claim and would not infringe the Swiss-style claim as accepted, the addition of method of treatment extends the monopoly of the patent and is therefore not allowable.

Since the Delegate found the amendments not allowable under the first ground alleged by Novo Nordisk, he did not consider the second ground.

COMMENTARY

The Delegate has taken the view that the method of treatment claims give rise to a product, that product being the treated mammal. The requirements for patentability of method or process claims were originally laid out by Morton J. in *GEC's application* [1943, 60 RPC 1], in what are referred to as Morton's Rules. These stated that for a process to be patentable it must result in:

- i) a vendible product;
- ii) improvement or restoration of a vendible product; or
- iii) preservation of a vendible product.

However, these rules were considered and expanded in *National Research and Development Company v Commissioner of Patents* [1959, 102 CLR 252] (“NRDC”) such that a process, to be patentable, must be one that offers an advantage in the useful arts as opposed to the fine arts and is in the field of economic endeavour. In *Anaesthetic Supplies v Rescare* [1994, 28 IPR 383] (“Rescare”) the Full Court stated that NRDC stands for the proposition that it is not essential for a process to produce or improve a product to be patentable. It is enough that the process has a commercial application. In *Rescare*, a case that dealt with the patentability of a method of treatment, it was considered that a method of treatment did not provide a product. It is interesting in the present case that the Delegate was clearly more comfortable illustrating his view that the claimed method of treatment gave rise to a “product” with reference to a treated cow, rather than with reference to a treated human being.

If the decision in *Rescare* is followed and a method of treatment, although patentable, does not provide a product, a method of treatment claim may only be infringed by use of the method of treatment. If the exploitation of a method of treatment claim is limited to the use of the method, then the Delegate has not correctly applied the Distiller's test.



However, although the Delegate may not have correctly applied the Distiller's test to a method of treatment claim, the construction of Swiss-style claims has not yet been considered by an Australian Court. It is therefore not clear that a method of treatment using the medicament manufactured in accordance with the Swiss-style claim should be considered to be an exploitation or infringement of a Swiss-style claim as alleged by the applicant. Accordingly, it is possible that addition of method of treatment claims to the specification may nonetheless extend the patent monopoly and thus not be an allowable amendment.

The decision of the Delegate has been appealed to the Federal Court of Australia.

IMPLICATIONS

Until this decision is reconsidered, it is our recommendation that during examination of an application that relates to a method of medical treatment, the claims are amended to include both method of treatment claims and Swiss-style use claims.

The appeal of this decision will provide the first judicial consideration of the construction of a Swiss-style claim and potentially its validity under Australian law.

MORE INFORMATION

For further information or advice on this article or any other patent matters please contact:

AUTHOR:

Kathryn Morris, Associate:
+ 613 9254 2777 or kmorris@davies.com.au



If you would like to be removed from our mailing list, please send an email to mail@davies.com.au or telephone Melissa McLennan on + 61 3 9254 2777.

The contents of this information sheet are not intended to be, nor are they, a complete statement of the law on the particular subject matter and are for information purposes only. This update is not a substitute for legal advice.

Melbourne

1 Nicholson Street,
Melbourne VIC 3000
Telephone +61 3 9254 2777
Facsimile +61 3 9254 2770

Sydney

255 Elizabeth Street,
Sydney NSW 2000
Telephone +61 2 9293 1000
Facsimile +61 2 9262 1080

Brisbane

Level 3, 303 Coronation Drive,
Milton QLD 4064
Telephone +61 7 3368 2255
Facsimile +61 7 3368 2262

Canberra

Level 11, 60 Marcus Clarke St,
Canberra ACT 2601
Telephone +61 2 6248 8063
Facsimile +61 2 6248 6591

Newcastle

130 University Drive
Callaghan NSW 2308
Telephone +61 2 4960 8366
Facsimile +61 2 9262 1080