Pharmaceutical Management Agency Limited v Commissioner of Patents, [1999] (New Zealand Court of Appeal (NZCA) 330)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The Court ruled that New Zealand is bound by the TRIPS Agreement that obliges it to provide patent protection for all inventions, without discrimination. In the view of the Court, claims on the use of a known compound for the manufacture of pharmaceutical compositions in which the compound exhibits previously unknown therapeutic activity are inventions.

The facts

The Pharmaceutical Management Agency (Pharmac) is responsible for managing the subsidisation of medicines in New Zealand. In 1997 the New Zealand Commissioner of Patents issued a "Practice Note" – a form of directive – allowing the grant of patents to inventions in "Swiss claim" form.

The "Swiss claim" form derives from the decision of the Swiss Federal Intellectual Property Office in 1984 to allow patents on the use of a known compound for the manufacture of pharmaceutical compositions for the treatment of an indication, provided the compound exhibits previously unknown therapeutic activity. By emphasizing the manufacturing element of the claim, as opposed to the method of treatment, Swiss claims avoid rejections based on excluded subject matter grounds. Article 27.3(a) of the TRIPS Agreement allows WTO Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

The Commissioner of Patents stated that it would allow the consideration of patent applications in Swiss claims format in light of the continuing international trend to liberalise the definition of "invention." It also stated that claims to therapeutic treatment of humans (methods of treatment) would continue to be disallowed, a practice confirmed by the Court of Appeal in *Commissioner of Patents v Wellcome Foundation Ltd*, 1983. Pharmac applied for judicial review of the decision of the Commissioner of Patents arguing that the grant of patents for inventions in respect of second or subsequent pharmaceutical uses would prevent competition among pharmaceutical suppliers with adverse effects on prices. The High Court disagreed and Pharmac appealed to the New Zealand Court of Appeal (NZCA). The Commissioner of Patents was joined by three research based pharmaceutical manufacturers who submitted evidence on selected examples of the research efforts involved in the identification and testing of new therapeutic indications and the costs of bringing successful results to the market.

The legal issues

The case involves the question of whether the Patents Act of 1953 permits the Commissioner of Patents to recognise as invention and grant a patent to protect the

discovery of a new pharmaceutical use of a substance or composition already known for one or more particular medical uses. The Patents Act says nothing about the patentability of inventions directed to medical uses nor about the form claims must take. The background against which Swiss-type claims are to be considered is to be found in the case law. Following the *Wellcome* case, methods of medical treatment of humans were excluded from patentability. This exclusion was generally understood in New Zealand to not only cover the every-day work of medical practitioners, but to extend to the patenting of new uses of known compounds by the pharmaceutical industry. But the NZCA in its review of subsequent case law observed that

> "More recent decisions referring to the exclusion from patentability of methods of treatment of illness or disease in humans no longer give as the reason that they do not constitute 'invention'.
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> […] it seems that the exclusion from patentability of methods of medical treatment of humans is now supported only on ethical grounds. Yet patents are granted for pharmaceutical and surgical products.
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> […] These developments notwithstanding, we have considerable sympathy for the view that individual medical practitioners should not be constrained in the practice of their art in the treatment of illness and disease by concerns that procedures they might adopt in the interests of their patients might render them vulnerable to proceedings for patent infringement.
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> […] What emerges from this is that it no longer can be said that a method of treating humans cannot be an invention. To the extent that the judgments in *Wellcome* express that view we depart from them. The exclusion from patentability of methods of medical treatment rests on policy (moral) grounds. The purpose of the exclusion is to ensure that medical practitioners are not subject to restraint when treating patients. It does not extend to prevent patents for pharmaceutical inventions and surgical equipment for use in medical treatment. It is against that background that the present issue is to be determined. Can invention in the discovery of a new pharmaceutical use be protected in such a way as to leave unrestrained the medical practitioner in the practice of his or her diagnostic, therapeutic or surgical methods? In Europe the Swiss-type use claim serves as the means of achieving such protection. That has its basis in provisions different from those in our Patents Act."[1]

But despite this difference, the NZCA identified domestic jurisprudence (i.e. the NRDC case) that had an objective similar to the European Swiss claims, i.e. the protection of unknown properties as the end result. While that jurisprudence did not relate to pharmaceutical substances, the NZDA considered that all fields of technology had to be treated equally under the TRIPS Agreement:

> "In the *NRDC* case the inventiveness lay in the discovery of the previously unrecognised property (the selective toxicity) of the known herbicide.
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> […] Just as there can be invention and novelty in the discovery of unrecognised properties in known substances qualifying for patent protection […] under the

[1] NZCA, paragraphs 26-29.

> decision in *NRDC*, so there can be invention and novelty in the discovery of unrecognised properties of known pharmaceutical compounds. […][B]y its accession to the TRIPS Agreement New Zealand has undertaken to make available patents "for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application": (Art 27:1). That obligation, which has been assumed by all parties to the agreement, is not to be set aside on grounds based on circumstances of convenience such as the comparatively low level of medical research undertaken in this country or the particular method by which medicines are funded."[2]

Based on this consideration the NZCA came to the conclusion that the decision by the Pharmac to allow the grant of patents to inventions in "Swiss claim" form was in line with the country's patent law.

Points of significance

1. The TRIPS Agreement in Article 27.3(a) allows Members to exclude from patentability *inter alia* methods of therapeutic or medical treatment. Article 27.2 TRIPS authorizes Members to exclude from patentability inventions the commercial exploitation of which is necessary to protect *ordre public* or morality. Since the TRIPS Agreement does not provide for the definitions of invention or medical treatment, it remains for each country to decide on the difference between discoveries of unknown properties of a known substance and inventions, as well as on the scope of the notion of therapeutic (or medical) treatment.
2. The NZCA established a distinction between methods of medical treatment (excluded from patentable subject matter on moral or ethical grounds) and the use of a compound in the production of a medicine for use in a particular therapeutic indication (patentable Swiss claims).
3. The decision modified previous case law that considered new uses by the industry of a known pharmaceutical compound as methods of treatment excluded from the notion of patentable invention.
4. The NZCA did not respond directly to the concern of Pharmac on the implications of allowing Swiss claims on competition in the marketplace. Unlike the decision in the *Wellcome* case, the NZCA ruled out the specific circumstances of New Zealand as a factor to affect its decision.

Key words: methods of treatment, invention, Swiss-claim, new use, second use

Link: **http://www.nzlii.org/nz/cases/NZCA/1999/330.html**

[2] Ibid, paragraphs 57 and 64.