Wellcome Foundation Ltd v Commissioner of Patents
(New Zealand Court of Appeal NZCA 137/81 [1983])

Prepared by UNCTAD's Intellectual Property Unit

Summary: In this decision from 1983, the New Zealand Court of Appeal considered methods of treatment of humans to not constitute patentable inventions.

The facts

In 1976, the New Zealand Patent Commissioner rejected patent claims by Wellcome Foundation for the method of treating or preventing leukemia in the human brain or other mammal by the use of known compounds (such as methodichlorophen and ethodichlorophen) that have been used in the past for treating malaria. The Commissioner refused to grant the patent primarily because the patent claim did not relate to a manner of new manufacture as defined in the Patents Act 1953 and because the methods of treatment of disease or illness in human beings are not considered inventions. The Patent Act defines invention as:

> "Invention" means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention.

In 1979, the lower court rejected the Commissioner's decision and held that at the present day it is reasonably arguable that a patent may be obtained for a process for the medical treatment of human beings. The Court concluded that the new use of known substances was by analogy a manner of new manufacture and the Patents Act (1953) did not prohibit registering a method of medical treatment. The Commissioner appealed against the decision to the New Zealand Court of Appeal (NZCA). The appeal was granted in 1982.

The legal issues

The NZCA considered the definition of "invention" and "manner of new manufacture" under the New Zealand Patent Act 1953 and the Statue of Monopoly (1653) in comparison with recent developments in other jurisdictions. It noted that no court in the Commonwealth treated inventions as extending to method of treatment of human illness or disease. The NZCA sought to clarify the grounds for exclusion of certain subject matter from patentability. It rejected the argument of the Commission claiming that the scope of invention precludes patenting a discovery of a new use for a known product in all cases as an outdated argument.

According to the NZCA, the field of medical or surgical treatment and drugs is one in which special considerations have to be borne in mind, since there remains a sense that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavor or trade and commerce. The history of patent law of the United Kingdom, however, reveals an economic dimension (in addition to

the ethical question) to the development of patent law especially that the national economic interest lies at the heart of patent law. On both humanitarian and economic grounds, the search for medical advance is to be encouraged. The discovery of new properties or uses of known pharmaceutical drugs does merit encouragement. In a broad sense, however, the discovery of a new drug is different from the discovery of new uses for an old one. Hence, in as far as the NZCA is concerned, the resolution of the present issue ultimately requires a balancing exercise.

The NZCA reviewed various national laws and case law and concluded that the variations in national patent laws demonstrate that no particular resolution of the issue is necessarily the right one. Although the NZCA considered the need to advance conformity between the laws of New Zealand and Australia, it found that the acceptance of patentability of methods of medical treatment by Australia itself was not determinative. In all the circumstances, the courts should resist any temptation to break new grounds, and to alter or modify the existing practice of not granting patents for methods of treating human illness or diseases. In the view of the NZCA, this is best left to Parliament, as there must be an economic question of particular importance for a country of the size of New Zealand, dependent to the extent that it is upon overseas manufacturers. Encouraging local innovation should be weighted against any increased costs of importing or manufacturing drugs, which is a broader issue than a court can investigate. The NZCA opined that we could not realistically shut our eyes to the possibility that in the language of the Statute of Monopolies [1623] the change sought by the respondent might result in 'raising prices of commodities at home' or be 'generally inconvenient.' Hence, the NZCA upheld the decision of the Patent Commissioner that under the current New Zealand law the patent claims are nothing more than the discovery of a further use for known pharmaceutical compounds and were thus not patentable, on the grounds of raising prices of commodities at home' or being 'generally inconvenient.'

Points of significance:

1. The Patent Act was amended in 1994 to ensure compliance with the TRIPS Agreement. However, the definition of invention remains unchanged. In 1999, the NZCA in *Pharmaceutical Management Agency Ltd v Commissioner of Patents* upheld that patents for the *manufacture* of known pharmaceutical substances for a new medical indication (Swiss claim) are not methods of medical treatment within the meaning of the *Wellcome* decision and hence patentable.[1] In *Pharmaceutical Management Agency*, Swiss claims were conceived as an exception to the general prohibition of the medical treatment exclusion. They allow the patent holder to prevent others from producing the medicament for the particular indication, but do not interfere with the treatment of humans by medical practitioners (See *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [1999] 2 NZLR 529, para 17). In *Pharmaceutical Management Agency*, the NZCA held that the exclusion of methods of treatment from patentable subject matter is on moral grounds. It established a distinction between methods of medical treatment (excluded from patentable subject matter on moral grounds) and the use of a compound in the production of a medicine for use in a particular therapeutic indication (patentable Swiss claims).
2. Based on *Pharmaceutical Management Agency*, in *Pfizer Inc v Commissioner of Patents* (2005), Pfizer sought for the NZCA to overrule the precedence of

[1] Available in this database.

Wellcome to the extent it is not overruled by *Pharmaceutical Management Agency*. This would have resulted in the patentability of physicians' every-day practice. The NZCA in its decision[2] upheld the decision in *Wellcome* to reject patents for methods of medical treatment based on the Statute of Monopolies. In rejecting Pfizer's demand, the NZCA stated that:

> All of these heads of argument must, of course be addressed in the context of Pfizer's broad contention that patentability of methods of medical treatment was desirable and that we should overrule Wellcome (and Pharmac to the extent that it did not overrule Wellcome) for policy reasons. We accept that it would be open to us to do so, in the same way this Court accepted the patentability of Swiss claims in Pharmac." In saying this, to some extent we have consistency between New Zealand and Australia" (Pfizer Inc v Commissioner of Patents (2005), para 80).

3. Beyond the balancing of interests that is needed for a court to interpret existing law, the NZCA decided to defer broader decisions on patent policy issues to the legislative body, which in the view of the NZCA is better placed to weigh matters of economic and social policy.
4. The court rejected a "one-size fits all" approach: the NZCA observed variations in the laws of other countries on the specific issue of medical treatment and noted that no one solution is the right one.

Key words: invention; "method of treatment"; "new use."

Link: the original decision is not publicly available. It has been widely discussed in secondary literature that is available online.

[2] *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 (CA).