



Memorandum

Date: 22 June 2010

THE POSITION IN BRIEF

The Patents Bill, if passed in its current form, will provide patent holders with significantly less protection in New Zealand than in comparable jurisdictions, such as the USA, Australia, the UK and the EU.

The pharmaceutical industry is concerned that New Zealand will be used as a safe harbour to exploit patents registered in New Zealand. These concerns are valid for IP developed locally as well as internationally¹.

CAUSES FOR CONCERN WITH THE BILL

The provisions with the most serious implications for our industry are the:

1. Introduction of an “experimental use” exception to patent infringement
2. introduction of an exception to patentability for methods of treatments of humans (without clarifying whether this includes “Swiss-type” claims
3. absence of any patent term restoration
4. expansion of the “contrary to morality” exception to patentability to include inventions that are contrary to public order, without clarifying the boundaries of this
5. allowing “springboarding” without any reciprocal patent term restoration.

¹FRST and NZTE Research investment strategies: Review of the human therapeutics industry's economic value to New Zealand www.frst.govt.nz/library/evaluations/research-investment-strategies/LECG

Experimental use exception

The Bill proposes to introduce the following provision:

1. It is not an infringement of a patent for a person to do an act for experimental purposes relating to the subject matter of an invention.
2. In this section, **act for experimental purposes relating to the subject matter of an invention** includes an act for the purpose of –
 - (a) determining how the invention works;
 - (b) determining the scope of the invention;
 - (c) determining the validity of the claims; seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).

There is no exemption for experimental use under the Patents Act 1953. The issue has been considered in the New Zealand courts, with the Court of Appeal holding that “non-commercial” experimental use would not be a patent infringement, while “commercial” use would.² The scope of the proposed exception in the Bill covers both “non-commercial” and “commercial” experimental use.

Our legal advice is that the broadened exception may no longer comply with the relevant Article of the TRIPS Agreement below.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

New Zealand is obliged to comply with the TRIPS Agreement, and non-compliance is a serious issue, which could lead to action against New Zealand through the World Trade Organisation (*WTO*).

Further, New Zealand is now engaged in negotiations with other WTO countries on an Anti-Counterfeiting Trade Agreement (*ACTA*) which is designed to enforce the intellectual property rights covered by TRIPS. The Bill seems to pull in the opposite direction to that initiative in that it weakens IP protection.

² *Smith Kline & French Laboratories Ltd v Attorney General* (1991) 4 TCLR 199.

Exclusion from patentability of method of treatments

The Bill provides that an “invention of a method of treatment of human beings by surgery or therapy” is not a patentable invention.

This exclusion could create difficulties in protecting a known composition that is useful in treating a disease which it was not previously known to treat. In these cases, neither the composition (being known) nor the method of treatment (being excluded) can be patented. This means that research to define additional uses for medicines to support evidence based practice will need to be funded by Governments, or this research will not be done.

Patent applications for those applications are now claimed for in a form known as a “Swiss-type” claim. For example, “the use of [known compound] for the production of pharmaceutical compositions for the treatment of [a particular medical condition]”. Swiss-type claims have been allowed by the courts in New Zealand for some time.³ It is not clear whether the Bill will allow them or not.

The only other comparable jurisdiction that has an exception to patentability for methods of treatment is the EU (including the UK). However, the EU exception specifically does not apply to “products, in particular substances or compositions, for use in any of these methods.” The New Zealand Bill contains no such clarification.

Lack of patent term extensions

The Bill sets the maximum term of a patent at 20 years from the filing date. No provision is made to extend the term where commercial exploitation of a patented product is delayed due to the need to obtain regulatory approval.

Generating data for regulatory approval currently takes between 12 to 15 years, leaving very reduced patent terms in which to generate a return on the substantial costs of research.

Many comparable countries contain a provision in their patent law that allows an extension of the term of a patent in appropriate circumstances.

The absence of such a provision in the Bill is particularly disappointing for patent holders when read in conjunction with the experimental use exception to infringement. These provisions favour generic manufacturers at the expense of patent holders, as they allow generic manufacturers to commercialise their own products as soon as the patent on the original product expires.

³ *Pharmaceutical Management Agency Limited v Commissioner of Patents & Others* [2000] 2 NZLR 529

“Contrary to public order” exception

An exception to patentability currently exists under New Zealand law for inventions that are “contrary to morality”.

The Bill seeks to expand this exception by providing that an invention is not patentable if it is contrary to morality *or public order*.

In general, the term “public order” expresses concerns about matters threatening the social structures which tie a society together, and is stated in the Bill to have the same meaning that “ordre public” has in Article 27.2 of the TRIPS agreement.

The relevant section of the Bill also includes a list of examples, which reads as follows:

“The commercial exploitation of the following inventions is contrary to public order or morality and, accordingly, those inventions are not patentable:

- 1 an invention that is a process for cloning human beings;
- 2 an invention that is a process for modifying the germ line genetic identity of human beings;
- 3 an invention that involves the use of human embryos for industrial or commercial purposes;
- 4 an invention that is a process for modifying the genetic identity of animals that is likely to cause them suffering without any substantial medical benefit to human beings or animals, or an invention that is an animal resulting from such a process.”

The expansion of this exception may increase uncertainty for applicants as to how the exception will be applied (i.e. what inventions would be contrary to public order in New Zealand).

The Attorney-General’s introductory comments at the first reading of the Bill were that the exception “is intended to be used only in relation to inventions where commercial exploitation is likely to be offensive to a significant section of the community, including Māori.” These comments do not provide significant clarity as to how the exception would be applied. The meaning of “public order” in a New Zealand context will only emerge over time, and clarifying this meaning will be very expensive for the unfortunate patent applicants that challenge the exception.

Springboarding

Where generic companies are able to generate data for regulatory approval a company's effective term for recouping R&D expenses is further eroded. With New Zealand companies beginning to develop human therapeutics and hoping to earn licensing and royalty payments, this springboarding provision is likely to reduce future incomes to New Zealand.

Where springboarding was introduced internationally it was generally in conjunction with provision for patent term extensions to compensate for erosion effective time in which return on investment is recouped.