Researched Medicines Industry Association of New Zealand Incorporated

Submission on Patents Bill to the Commerce Select Committee

July 2009

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1. Introduction

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

The full members of the RMI are:
Abbott Laboratories NZ Limited
Alcon New Zealand Limited
AstraZeneca Limited
Bayer Schering Pharma
Boehringer Ingelheim NZ Limited
CSL Biotherapies (NZ) Limited
Dr Reddy's New Zealand Limited
Eli Lilly and Company (NZ) Limited
GlaxoSmithKline NZ Limited (effective from 1 January 2009)
Janssen-Cilag (New Zealand) Limited
Merck Sharp & Dohme (New Zealand) Limited
Mundipharma New Zealand Limited
Novartis New Zealand Limited
Pfizer New Zealand
Roche Products (New Zealand) Limited
sanofi aventis new zealand limited
Wyeth Pharmaceuticals New Zealand

While all of the members operate in New Zealand they are all affiliated to very large international companies.

We request to be heard by presenting our submission to the Commerce Select Committee. Please contact the Secretariat on 04 499 4277.

2. General Comments on the Bill

The RMI is very supportive of the following General Policy Statement contained in the Explanatory Note to the Bill:

> *"The provision of this exclusive right [patent] is to provide inventors with an opportunity to make a return on their investment in innovation by preventing others from copying this invention. This provides an incentive for innovation and its dissemination that might not otherwise occur. The grant of patent rights for foreign innovators to transfer their innovations to New Zealand."*

It is acknowledged that the Bill provides a much needed update to current New Zealand practice, by bringing it more into line with modern international practice. However the mindset behind the more controversial changes appears to be that the

public need protecting from the potential social costs of patents. This emphasis seems to be at the expense of upholding and protecting property rights which we contend should be the prime focus of this legislation.

The following aspects of this Bill fail to create a patenting environment that is friendly towards or supportive of biotech or the pharmaceutical industries:

(a) no patent term extensions
(b) expansion of the "contrary to morality" exceptions to patentability
(c) the status of Swiss-type claims must be clarified in the content of "methods of treatment, diagnosis and surgery on humans" being non patentable
(d) an experimental use exception to patent infringement

3. The Importance of Research and Development and Property Rights to the Pharmaceutical Industry

Patent protection provides a legal means whereby innovators may earn a reasonable return on their substantial research and development investments.

Globally the bio-pharmaceutical industry is the most research intensive and research dependant of all industry sectors. Research and development as a percentage of sales revenues is typically 15-18%. This is significantly more than that of the defence, aero space and automotive industries.

Even allowing for inflation, the pharmaceutical industry is investing twice as much in research and development as it did a decade ago to produce two fifths of the new medicines it then produced[1].

The typical cost of bringing a new chemical entity to the market is now exceeding US$1 billion. Furthermore average lead times between the synthesis of a new medicine and its final marketing have extended from six years in the 1960s/70s to 8-10 years today but often longer, for example, in CNS treatments. In most cases this results in a severe erosion of the EPL. Most new medicines are not introduced to New Zealand until they have been marketed elsewhere and therefore the EPL is further eroded in New Zealand. In many cases it is approaching zero.

It is interesting to note that the Herceptin debate during last year's general election focused public attention on access to innovative new medicines for New Zealand patients. The reality is that the 20 year patent on this "new medicine" expires in 2009.

In New Zealand many health care services including prescription medicines and vaccines are predominantly funded by the state. A low patient co-payment ($3.00 for those enrolled in a Primary Health Organisations) that is universally available reinforces

[1] Pharma 2020 : The Vision *which path will you take – 2007 PricewaterhouseCoopers*

an expectation of public funding. There is a limited market for privately funded prescription medicines whether based on out of pocket payments or private insurance.

The Pharmaceutical Management Agency (PHARMAC) operates as a crown entity, with monopsony powers to acquire medicines for eligible New Zealanders within the public funding provided through the 21 District Health Boards.

The RMI recognises that following the inception of PHARMAC in 1993 New Zealand has developed one of the lowest pharmaceutical cost structures in the developed world. This has largely been achieved by procuring older and cheaper generic medicines with little corresponding re-investment in new technology. The adopted cost reducing strategy is to "wait out" patents and fund the generic substitutes.

Prices for generic pharmaceuticals have dropped dramatically world wide over the past 15 years. PHARMAC's cost containment success has largely been achieved by delaying and restricting subsidised access to new and innovative medicines. Insufficient consideration has been given to the adverse health outcomes resulting from this strategy.

There has been a tendency for PHARMAC to move towards funding a single agent for each class of medicines and to engage in sole supply contracts. This practice restricts clinical choices based on using the most appropriate agent for the individual needs of patients. With medicines "one size does not fit all".

Reference pricing mechanisms have been introduced in several jurisdictions including Germany, the Netherlands, Denmark, New Zealand and British Columbia.

Under reference pricing medicines are grouped into clusters with therapeutically similar properties. The funder sets a single reimbursement price (reference price) for all products in a cluster.

In order for a product to receive a subsidy the price of the product must equal the subsidy; hence PHARMAC effectively dictates the price.

In theory, where already funded products have their subsidy reduced as a result of reference pricing, the supplier is free to charge a price above the reference price but in that case the patient must pay the difference as an excess out of pocket charge. In practice demand becomes highly elastic at prices above the reference price because of time requirements for prescribing physicians and because of patients reluctance to pay excess co-payments.

Under reference pricing when a supplier introduces a new product with enhanced safety or efficacy attributes there is no payment recognition for the superior product even when the benefits of the new medicine are significant.

PHARMAC's aggressive reference pricing models have acted to erode the intellectual property rights of innovative medicine suppliers. Market exclusivity is protected by the patent, but the commercial value of the patent is significantly undermined by reference pricing to competing off-patent products, effectively extinguishing the patent holders economic return.

"The pharmaceutical industry's high ratio of globally joint sunk costs – mostly R&D – to user-specific marginal costs creates the temptation and leverage for regulators and major purchasers to force prices down to a marginal cost level. Pure marginal cost pricing would cover roughly 30% or less of total cost[2]

The price regulation of medicines controls through one branch of Government the value of the patents that are granted through another branch of Government. PHARMAC's policies are based on delaying and limiting access to more expensive innovative medicines and concentrating on the purchase of marginally priced generic substitutes. There is a credible claim that New Zealand is "free riding" on other markets which bear the cost of paying above the marginal price for innovative medicines. In addition existing delays are eroding the patent life of medicines. A recent collation of data from 63 medicines supplied by RMI members shows that the patent life remaining at the time of listing on the Pharmaceutical Schedule has fallen from 14 to 6 years.

Obviously if all markets only paid the marginal price there would be no incentive for continuing innovation and the supply of new innovative products would cease. This has become a global issue for the international pharmaceutical industry facing increasing cost pressures in developing and manufacturing new innovative products.

Many people world-wide regard the pharmaceutical industry as highly profitable and this perception pervades decision makers, health funders and the general public. While this may have been the case historically, it certainly is not correct today.

The Harvard Business Review May 2008[3] compares the average annual return to shareholders (stock appreciation plus dividends) of various industries, weighted by marked capitalisations and expressed as percentages. The global pharmaceutical industry led all sectors in the creation of shareholder value throughout the 1980's and 1990's. Since 2000 however the pharmaceutical industry has gone from 'leaders' to 'laggards' and is today the poorest performing sector of the 10 industry sectors considered in the comparison undertaken by the Harvard Business Review.

[2] Ibid, p19.

[3] Rebuilding the R&D Engine in Big Pharma, Jean-Pierre Garnier, May 2008 Harvard Business School

4. Clause by Clause Issues of Concern to RMI

4.1 Part 2. Clause 15 (p29-30). Exclusivity from patentability.

Clause 15

(2) An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention.

(3) An invention of a method of diagnosis practiced on human beings is not a patentable invention.

Comment:

Method of treatment claims are not patentable under existing New Zealand patent law. However it is not clear whether or not this intends to exclude "**swiss-type**" method of use claims which have been allowed under existing legislation following court rulings.

The Intellectual Property Office published an updated version of the examination guidelines for Swiss-type claims on 8 April 2009.

Swiss-type claims provide patent protection for new second therapeutic uses of known pharmaceuticals. Swiss-type claims have been allowable in New Zealand for some time, the allowability being confirmed by the Court of Appeal *Pharmaceutical Management Agency Limited v commissioner of Patents & Others* [2002] 2 NZLR 529 *(Pharmac)*. Since the decision in *Pharmac* there has been uncertainty regarding the boundaries of what constitutes a new therapeutic use patentable by way of a Swiss-type claim.

In the past few years, there have been several cases heard by Assistant Commissioners regarding the type of subject matter that may be patentable by way of Swiss-type claims. The decisions in recent cases have confirmed the allowability of Swiss-type claims where the novelty lies in a dosage regime and Swiss-type claims where the novelty lies in the patient population to be treated. The decisions have tended to follow European cases.

The examination guidelines have been reviewed in light of the recent Assistant Commissioners' decisions to allow Swiss-type claims where the novelty lies in the dosage regime and Swiss-type claims where the novelty lies in a patient group.

A decision of Assistant Commissioner Popplewell, in the case of *Genentech's Application* (P1/2007), published on 28 March 2007, confirmed that claims in the Swiss-type format where the medical activity of the active ingredient is known, and novelty lies in the dosage regime used for administration, are allowable in New Zealand.

The examination guidelines have been updated to reflect the allowability of Swiss-type claims where the novelty lies in a new mode of administration or treatment regime.

The examination guidelines include a cautionary note that "mere novelty in a dosage regime or mode of administration will not automatically render a Swiss-type claim as a new invention unless the new use is a 'new result'." The guidelines require the new use which is purported to be a new mode of administration or treatment regime to be a new result in that it should be a "new and useful effect", in accordance with *NRDC's Application* [1961 RPC 134].

Two related decisions of Assistant Commissioner Hazlewood, *AstraZeneca AB's Application 533106 (P23/2007)* and *AstraZeneca AB's Application 539603 (P24/2007)*, both published on 28 September 2007. In both *P23/2007* and *P24/2007*, Assistant Commissioner Hazlewood reviewed several decisions of the EPO Technical Board of Appeal relating to the allow ability of Swiss-type claims where the novelty lies in the patient group and indicated that New Zealand law should also hold that such claims are an invention.

The two *AstraZeneca* decisions confirm that claims in the Swiss-type format where the novelty lies in the patient population to be treated are allowable in New Zealand. The examination guidelines have been updated to reflect these decisions.

The examination guidelines state that the patient group should be clearly defined to ensure that there is no overlap with an existing group in the prior art.

A general test for a new patient group, according to the examination guidelines, is that the group must be shown to possess a distinct physiological or pathological difference which is neither arbitrary nor overlapping with a known patient group. To determine whether a difference is arbitrary, the Intellectual Property Office will consider whether there is a functional relationship between the particular physiological or pathological status of the patient group and the therapeutic/physiological effect achieved, following *Medco Research,* T233/96.

The examination guidelines published by the Intellectual Property Office (IPONZ) on 8th April 2009 relate to the existing Patents Act and court rulings based on that legislation.

The RMI contends that the current guidelines apply the law on Swiss-type claims too restrictively and that purpose-limited second and subsequent medical use claims as permitted in the 2007 European patent laws (EPC2000) which provide for "compound for use…" should be included in this Bill. This could avoid this being artificially inherent in the Swiss-type claim format.

4.2 Expansion of the 'contrary to morality' exception to patentability - Part 2 – Clause 14 (p 29).

Comment:

The Bill expands the 'contrary to morality' exception to patentability. Currently the Commissioner may refuse an application where it appears that the use of the invention would be contrary to morality. Under the Bill, an invention is not patentable if the commercial exploitation of it is contrary to public order or morality. 'Public order' is a term borrowed from the TRIPS Agreement, and encompasses concerns about matters threatening the social structures tying society together.

This Bill creates a Maori Advisory Committee. The Bill provides that the Commissioner may seek advice from the committee, or any appropriate person, to decide whether an application should be refused as 'contrary to morality'. This is a concern as morality can be in the eye of the beholder. This committee will advise the Commissioner on inventions that are derived from Maori traditional knowledge or from indigenous plants or animals, and whether the commercial exploitation of the intention is likely to be contrary to Maori values. The Commissioner is not bound by the advice of the Committee, but must consider it.

The contrary to morality provision will allow examiners to object to patents on a range of grounds, including religious or cultural grounds. We are already struggling to have claims covering stem cell technology accepted, and the situation is likely to worsen under the new regime.

Innovation in pharmaceutical products is based on the application of evidential science. The introduction of metaphysical and loosely defined spiritual dimensions has the potential to increase uncertainty and hinder innovation.

4.3 Clause 19 – Term of Patent (p.31)

19(1) The terms of every patent is 20 years from the patent date

Comment:

As discussed in section 3 of this submission the research and development component which underpins innovation in pharmaceuticals is dependant upon patent protection. With ever increasing thresholds and delays the EPL has been seriously eroded. In New Zealand EPL often approaches zero.

This issue is recognised internationally and most countries now issue patent extensions. These include Australia, Japan, Korea, Israel, and United States.

Switzerland and the States of the European Union do not offer patent extensions but do offer an alternative - supplementary protection certificates (SPC). While a SPC is not

strictly speaking a patent extension as it cannot come into force until the relevant patent has expired, the effect is similar - effectively extending the EPL.

The common features of patent extensions and SPCs include the following:

- Extension is not automatic; the patent owner must make a specific application;
- The length of the extension granted depends on the length of time between the date of filing of the patent application and the date of marketing approval;
- A maximum extension of 5 years is provided for;
- The rights of the patent owner in respect of the patent are usually limited during the extended term compared with the rights available during the original term.

Sections 70-79A of the Australian Patents Act 1990 provide for the terms of patents for pharmaceuticals to be extended by a maximum of five years. To qualify for such an extension, the pharmaceuticals must be included in the Australian Register of Therapeutic Goods, and the period beginning on the filing date of patent and ending on the first regulatory approval date for the substance must be at least 5 years. These provisions were inserted into the Patents Act 1990 by the Intellectual Property Laws Amendment Act 1998.

The effect of these provisions is to provide for an EPL of at least 15 years provided the time taken between the filing date of the patent application and the date of first regulatory approval is less than 10 years. If regulatory approval takes longer than 10 years the EPL will be less than 15 years. The rights of the patent owner are restricted though. The patent owner's rights are not infringed by exploitation of the patented product for non-therapeutic uses, or for the purposes of gaining regulatory approval in Australia or elsewhere.

The RMI contents that New Zealand patent law should provide patent protection for pharmaceutical products that is comparable to other OECD countries. With respect to pharmaceutical products this requires the insertion in the Bill of patent extension mechanism or provisions for the issuing of Supplementary Protection Certificates.

4.4 No pre-grant oppositions

The Bill abolishes the current procedure for opposing a patent before grant. Instead, it allows for re-examination at any time in the life of the patent, including pre-acceptance. However, the Commissioner may only re-examine for novelty and inventiveness. For novelty, the Commissioner may only look at prior published documents—that is, prior use is not relevant.

The pharmaceutical industry welcomes the deletion of provisions for pre-grant oppositions as they can lead to abuses of the system; for example in India we have seen multiple pre-grant oppositions in efforts to delay grant.

The Bill allows for revocation proceedings to be taken before the Commissioner or the court at any time in the life of the patent.

According to the Bill's introductory policy statement, these changes are being made to 'streamline' the grant process by reducing cost and complexity.

Abolishing pre-grant oppositions seems at odds with the Government's concern to keep invalid patents off the register. Perhaps the Government perceives that with the more stringent examination process, manifestly untenable patents (which currently are the only ones refused in an opposition proceeding) will not be accepted. The re-examination process will allow a form of challenge to the patent before acceptance, but only on very limited grounds. Those who object to a patent will not be able to fully argue its invalidity until after grant, at which stage they may already be infringing the patent.

It is also unlikely that challenging a patent will be cheaper under the new regime. Revocation actions before the Commissioner and the court are unlikely to differ significantly in cost, particularly in complex cases. Also, if the patentee brings a counterclaim of infringement the revocation action will have to be transferred to the court.

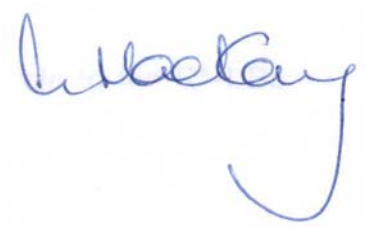
5. Summary

The RMI seeks the following:

1. Provision in the Bill for patent term extensions. This could be achieved by adopting the Australian model or providing for Supplementary Protection Certificates.

2. Greater clarity in the following:

   (a) 'contrary to morality' exceptions in patentability;
   (b) the application of Swiss-type claims;
   (c) the experimental use exception to patent infringement.



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