

**Researched Medicines Industry Association
of New Zealand Incorporated**

**Submission on
Review of the Patents Act 1953 :
Boundaries to Patentability**

July 2002

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 24 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 RMI submission focuses on ensuring NZ has a supportive environment for biotechnology research and development (R&D) investment. Such an environment requires a robust and internationally comparable legal framework that is attractive to overseas interests. Making NZ's IP legislation comparable and therefore competitive is critical for the government's aspirations for NZ to have an innovative infrastructure as a basis for future economic development.

Recommendations

1. That in reviewing its intellectual property legislation (IP) the Government take account of the important links between IP, innovation and commercialisation in achieving its goal to grow the New Zealand economy on the backbone of knowledge intensive industries such as the biotechnology sector.
2. That to improve the competitiveness of New Zealand in attracting domestic and foreign direct investment and associated expertise that New Zealand adopt a supplementary protection certificate (SPC) mechanism to provide for a 15 year effective patent life (EPL) for pharmaceuticals.

This submission is in four parts under the following headings:

- Importance of biotechnology to the government's growth policy
- Role of IP protection for the biotechnology industry (including bio-pharmaceuticals)
- The importance of strong IP protection in NZ as an economic signal
- The importance of patent protection for pharmaceuticals

Importance of biotechnology to the government's growth policy

The Government has singled out the biotechnology industry as critical in promoting growth in the New Zealand economy. Recent statements from three senior ministers (including the Prime Minister) reinforce the importance of biotechnology.

In its 'Growth and Innovative Framework', the government has decided to focus on biotech as one of three areas "which not only have considerable growth potential, but which also have high potential spill over effects for growth in other sectors."¹ This plan is not "yet

¹ Rt Hon Helen Clark, 12 February 2002 Growing an Innovative New Zealand

another bout of theory driven restructuring. It sets out the comprehensive programme aimed at lifting our game and raising our sustainable growth rate through innovation.”²

A Biotechnology Taskforce, established under this framework is charged with “... looking at practical ways of stimulating the growth and international competitiveness of New Zealand’s biotechnology sector. The taskforce will pick international trends on which New Zealand’s biotechnology sector might capitalise, develop strategies for building high value technologies and identify areas where Government action might enhance the sectors development.”³

Effective IP protection is the lifeblood of the biotechnology industry and the Government clearly supports its role in the economy giving strong messages that it will support biotechnology sector development. The Prime Minister’s message to fast-track biotechnology sector development is clear. “Our aim is to speed up development of high growth, high value international competitive sectors which not only create opportunities for well paid and satisfying work, but which also creates the wealth to fund first world public services and infrastructure.”⁴

Role of IP protection for the biotechnology industry (including bio-pharmaceuticals)

Biotechnology is one of the few industries that rely on patents to support the substantial investments in R&D. Effective IP protection is a critical cornerstone to the biotechnology industry. It is a very important piece of the investment jigsaw that businesses factor into their decision making when deciding where to invest their R&D assets.

Of the businesses that are likely to invest in patent related industries, the pharmaceutical industry is the most crucial in terms of dollars invested.⁵ Major pharmaceutical companies regularly make significant investment into R&D. Most major pharmaceutical companies spend between 16 and 20 per cent of sales on R&D. In 2000, Pfizer spent 4,435 US\$ million, GlaxoSmithKline spent US\$3,832, Aventis (US\$2642) and Astra Zeneca (US\$2616)⁶. This year, for the fourth year in a row pharmaceutical companies have had the highest percentage of sales spent on R&D of any industry.⁷

Importantly, a growing percentage of pharmaceutical company research is on biotechnology based pharmaceuticals whose development and increasing importance is underpinned by strong intellectual property protection. Companies are increasingly researching and developing expensive pioneering product research and are responsible for the 369 biotechnology drugs in human clinical testing. Today, approximately one third of the more than 1,000 medicines in human clinical testing are cutting-edge biotechnology treatments. Overseas experts support the importance of IP protection and the role of government as enablers.

² Hon Dr Michael Cullen, Treasurer, Minister of Finance, 23 May 2002 Budget Speech

³ Hon Pete Hodgson, Minister of Research Science and Technology, 10 May 2002 Biotechnology Taskforce Named.

⁴ Rt Hon Helen Clark, 21 February 2002 Prime Minister’s address to the London School of Economics

⁵ The other key industries are fine chemicals, and agricultural chemicals (Levin et al, 1987 and Cohen et al 2000)

⁶ Scrip Magazine, February 2002, p45

⁷ www.phrma.organisation/

“Intellectual property protection (patents, copyright and trademark), are important in providing the necessary incentives to researching and commercialising products. Supporting central Government laws and policies act as enablers to a world knowledge based economy.”⁸

Intellectual property protection also plays a crucial role in partnering and collaboration between international pharmaceutical companies and academia, biotechnology companies and Government. “Academic researchers and institutions need to take a pro-active global portfolio approach to patent management to capture the full value of IP. IP management is a critical consideration in the establishment of ongoing external alliances and collaboration”⁹

Success in stimulating investment, research, development and the growth of the international competitiveness of New Zealand’s nascent biopharmaceutical sector will be dependent on building sustained long-term relationships and strategic alliances amongst the international pharmaceutical companies, New Zealand’s research community, and the Government.¹⁰

The pharmaceutical industry is a major funder of biopharmaceutical research and development worldwide. If the nascent New Zealand biopharmaceutical industry is to grow significantly – and the NZ economy is to profit - it will need international pharmaceutical company funding.

In addition to R & D investments multinational pharmaceutical companies provide other benefits that New Zealand might capitalise on, including experience in the development and commercialisation of intellectual property and (through strategic worldwide alliances) significant international marketing muscle for New Zealand researchers.

For any long term funding partnership to emerge between pharmaceutical companies and government, an understanding of what the pharmaceutical industry considers as strong intellectual property protection is critical. Important fundamentals to protect intellectual property include:

- a minimum 20 year patent protection term from date of filing.
- limited use of compulsory licensing¹¹
- full implementation of the WTO TRIPs agreement.
- a legislative framework for patent protection to be enforced by an appropriate authority.

⁸ Professor Michael Ryan, Georgetown University, RMI 2002 Knowledge Economy Conference – International Pharmaceutical Research and Development External Relationships and Alliances – A way forward for New Zealand, Auckland 19 March 2002. (Prof Ryan teaches and conducts research regarding international political economy and institutions at the Georgetown University McDonough School of Business where he specialises in international law, business, policy, diplomacy, and public administration regarding intellectual property and trade. He is the author of *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (Brookings Institution Press, 1998).

⁹ “Patents more than just a line item on CVs” presentation by Dr Leigh Farrell, Johnson & Johnson Research, RMI 2002 Knowledge Economy Conference – International Pharmaceutical Research and Development External Relationships and Alliances – A way forward for New Zealand, Auckland 19 March 2002.

¹⁰ NZIER, July 2002 “Bio-pharmaceuticals – A Pathway to Economic Growth?”

¹¹ Governments can compel a patent holder to license rights to a third party to produce, sell, and gather royalties determined by the government. In most countries, compulsory licensing is not permitted unless exceptional circumstances prevail.

- products already patented elsewhere, but not yet marketed in NZ, to be covered in new patent law (pipeline protection).
- the use of a patent term extension to compensate for regulatory delays in the approval process for the development of new medicines

The importance of IP protection in NZ as an economic signal

Results from a large number of different studies demonstrate that patent protection is prominent in just a handful of industries. The most important of these are pharmaceuticals, fine chemicals, and agricultural chemicals ¹²

Biotechnology is one of the few industries that rely on patents to support the substantial investments in R&D that produces innovation. Any review of the Patents Act must therefore consider the effect that IP policy has on R&D and how this would impact on the innovation strategy for NZ set out by Government.

Effective patent protection is particularly important for New Zealand because NZ is competing on the international market for R&D investment dollars. If likely competing nations for R&D investment have stronger intellectual property laws then NZ' s prospects for attracting investment dollars is reduced. (see Table 1).

To signal both domestic and foreign investors that New Zealand is serious about developing the preconditions for a vibrant biotechnology industry, the legislative framework must be as least as good as other countries for investors to have confidence.

Table 1 shows that New Zealand legislation does not go as far as other countries when it comes to intellectual property rights. Korea, Japan, United States, European Union, and Australia are all doing more to provide a strong legislative basis for growth in R&D orientated businesses. The only exception is Canada: but Canada provides a raft of other incentives to R&D orientated businesses that outweighs any patent anomalies (e.g. tax incentives for R&D investment and a pricing deal with government that increases pharmaceutical prices in exchange for R&D investment).

¹² Levin R C, Klevorick AK, Nelson R, Winter SR, Gilbert R, & Griliches Z (1987), Appropriating the Returns to Industrial Research and Development. In *Brookings Papers on Economic Activity*. Washington DC : Brookings 783 – 832. Cohen WM, Nelson R, & Walsh J (2000), Protecting Intellectual Assets : Appropriability conditions and why US Manufacturing firms patent (and don't). In NBR Working paper No 7552. Cambridge MA. National Bureau of Economic Research.

	Pharmaceutical product protection	20-year term	Compulsory licensing limited	Patent extension	term
Korea	✓	✓	✓	✓	
Japan	✓	✓	✓	✓	
New Zealand	✓	✓	✓		
European Union	✓	✓	✓	✓	
Canada	✓	✓	✓		
United States	✓	✓	✓	✓	
Australia	✓	✓	✓	✓	

The Supplementary Protection Certificate procedure which governs and tightly defines the length of any extra patent time up to a maximum of five years for medicinal products is available in all the countries of the European Union by virtue of Council Regulation (EEC) No. 1768/92. The EU countries are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden and the United Kingdom. In addition, the effect of this regulation is extended to countries of the European Economic Area (EEA) which takes in Norway and Iceland.

Furthermore, national SPC legislation exists in a number of countries of non-EU countries including Switzerland, Cyprus, Latvia, Lithuania, Estonia, Slovenia, Czech Republic and Slovak Republic. With the forthcoming extension of the EU, it is expected that other countries, such as Poland, will bring into effect SPC legislation in the not too distant future.

The importance of intellectual property protection should not be underestimated. Recent studies show that IP has a significant impact on foreign direct investment, that lack of adequate IP protection limits the biotechnology industry's potential, and that clearly defined IP encourages biotechnology industry development:

- A 1994 World Bank study¹³ found that the strengths or weakness of a country's intellectual property protection, particularly in high technology goods, had a substantial

¹³ Mansfield E (1994), Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer. *The World Bank*, 1994.

impact on the type of technology transferred by many US firms to that country.

- A 1994 Ernst & Young study¹⁴ found that one of the major impediments to the early development of the European biotechnology industry (relative to the US industry) was the lack of adequate patent protection and the uneven application of intellectual property laws across Europe. For example, in Italy until 1976, patent law did not offer protection for pharmaceutical products. Instead, only process technologies could be patented. As a result, Italian pharmaceutical companies tended to avoid product R&D and concentrated on finding novel processes for making existing molecules.¹⁵
- Establishment of clearly defined property rights has played a major role in making possible the explosion of new firms in the US. These firms have few complementary assets that would allow them to appropriate returns from the new sciences without strong patent rights¹⁶
- As a further sign of the importance of patents in the innovation process, the OECD use co-patenting (between public institutions and private firms) as one of the indicators to explain sources of innovation within an economy¹⁷

The Importance of Patent protection for Pharmaceuticals

The RMI agrees with MORST's view that "funding for R&D alone is not enough. Innovation-driven economic transformation will not happen if regulations and cultural barriers get in the way. That's why we need to identify and remove such barriers, while promoting positive and progressive attitudes to innovation across sectors of society."¹⁸

Effective IP protection also has important public interest implications. First, as IP is the cornerstone of the biotechnology industry, without it biotechnology companies cannot effectively invest and develop new technology e.g. in the form of new bio-technology medicines that will benefit New Zealanders' health.

Secondly, the spillover effects of a vibrant biotechnology sector have growth implications for the NZ economy. The Minister of Finance, Hon Michael Cullen, confirmed this in his 2002 budget which advocated a "reorientation of the role of government from that of simply being a neutral referee disinterested in the outcome. For it is on the outcome that our social and economic fortunes depend."

The current patent term in New Zealand is 20 years from the date of filing of an application. The RMI recommends New Zealand aligns its IP protection with our major trading partners

¹⁴ Ernst & Young (1994), *Biotechnology in Europe*, *Ernst & Young Annual Report*, London, Ernst & Young.

¹⁵ A similar story occurred in Japan, where legislation provided incentives for companies to channel R&D into developing unique process innovations for products that had already been developed.

¹⁶ Teece DJ (1986) *Profiting from Technological Innovation : Implications for Integration. Collaboration, Licensing, and Public Policy. Research Policy* 15(6): 185-219.

¹⁷ Organisation for Economic Cooperation and Development (OECD), Paris, *National Innovation Systems*.

¹⁸ www.morst.govt.nz - Economic goal - overview

through the adoption of a Supplementary Protection Certificate system as currently in use in Australia, USA, Japan and the European Union.

The Supplementary Protection Certificate is an administered rather than a court-based extension procedure. The rules governing the amount of extra patent time are tightly defined and have automatic and non-discretionary elements. An SPC is defined as the difference between the date of the first market authorisation within the country concerned for a new pharmaceutical and the patent filing date less five years. The maximum permitted SPC is five years, which means that for every year above 10 years' development time enhanced EPL is correspondingly reduced. In effect a maximum SPC of five years provides an incentive to curtail development time to 10 years. From the above it is clear that the SPC regime is much more sophisticated than a mere five years' addition to a patent term. It is case-sensitive, with the extra time awarded being dependent on the length of the drug development interval. It penalises companies that take more than 10 years to bring a drug to market.¹⁹

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¹⁹ The SPC was first applied in the European Union in January 1993 and introduced in Australia in 1998. See Council Regulation 1768/92 of June, 18 1992 concerning the creation of a supplementary protection certificate for medicinal products; Supplementary Products, a guide for applicants, UK Patent Office 1992; the Australian Intellectual Property Laws Amendment Act 1998.