INQUIRY INTO PRIMARY PRODUCER ACCESS TO GENE TECHNOLOGY SUBMISSION BY IP AUSTRALIA

The appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms

Please note that we are reading "current variety protection rights" to encompass rights available for genetically modified organisms generally, not just those which are varieties.

PURPOSE OF THIS SUBMISSION

Australia's current protection regime is consistent with the international agreements to which we are a party and similar to those of our major trading partners. Adequate protection for intellectual property (IP) is crucial in encouraging innovation and investment. This submission sets out the rationale behind the patent system, the background to our existing domestic policy position and gives an overview of the relationship between IP rights and competition law.

BACKGROUND

IP Australia is responsible inter alia for the administration of the Patents Act 1990.

The purpose of the patent system is to reward innovation by providing the patent holder with exclusive rights to exploit his or her invention in Australia for a fixed term (generally up to twenty years). In return, the patent holder makes available the details of the patented invention for publication, thereby increasing public knowledge and encouraging further innovation.

Australia allows patenting across all technologies. The only exclusions are:

- subsection 18(2) of the Act which prohibits patenting of "human beings and the biological processes for their generation"; and
- "an invention the use of which would be contrary to law" (s51(1)(a)).

The range of patentable inventions involving genetic manipulation found in Australian patent applications includes:

- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;
- the DNA coding sequence for a gene (in either the isolated or recombinant form);
- the protein expressed by the gene;
- vectors (such as plasmids or bacteriophage vectors or viruses) containing the gene;
- methods of transformation using the gene;
- host cells carrying the gene;
- higher plants/animals carrying the gene;

- organisms for expression of the gene (making the protein from the DNA). There are many types of expression systems:
 - bacterial, yeast, viral;
 - plant or animal cell cultures;
 - higher plants or animals *per se*.

There are two ways of claiming protection for plants:

- patents for plants in general and for specific cultivars, and
- plant breeder's rights (or PBR) for plant cultivars only (This legislation is administered by Plant Breeders Rights Australia).

The range of patentable subject matter for plants includes:

- new plant varieties;
- plant components, for example, genes or chromosomes;
- reproductive material, for example, seeds, whole plants, cuttings, cells or protoplasts;
- products from plants, for example, fruit, flowers, oils, starches, chemicals or pharmaceuticals;
- plant material used in industrial processes, for example, cell lines to produce processes relating to plants, genetic engineering techniques, plant tissue culture, cell and protoplast culture, mutagenesis and breeding and cultivation methods.

INTERNATIONAL OBLIGATIONS

As a signatory to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Australia is obliged to provide certain minimum intellectual property rights.

For the purposes of this inquiry, the most relevant provision is Article 27 which provides that:

"... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

Article 27.3(b) provides that:

"Members may also exclude from patentability:

plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

That is, we must provide patent protection for micro-organisms and some form of protection for plant varieties.

Additionally, if Australian protection regimes were to be significantly out of step with our major trading partners, it would likely make us a less desirable market for innovation than our overseas competitors. Without protection, Australian innovators will not develop and manufacture the latest innovations for the domestic and export markets.

DOMESTIC POLICY

The Australian position to allow patenting of genetically modified organisms (GMOs), stems from a House of Representatives Standing Committee on Industry, Science and Technology report entitled *Genetic Manipulation: The Threat or the Glory?* published in February 1992. This report was the result of an extensive consultation process involving submissions, exhibits and public hearings.

The report is much broader than the issue of patentability of GMOs. However, the Committee considered a number of concerns raised about allowing patenting of GMOs including:

- patenting of animals will lead to the demise of traditional breeders;
- patents will advantage agribusiness;
- patents will restrict competition and keep up costs; and
- patenting will adversely affect farmers.

The Committee did not agree with these arguments and the following findings were set out in their report:

- The Committee was not persuaded that allowing patents would disadvantage traditional breeders;¹
- It is likely that larger corporations are in a better position to secure and enforce patent protection for their discoveries. However, this prospect of gain is not a valid reason against the patenting of genetically modified organisms.² It should also be noted in this regard that patents may also help protect small inventors from having their innovations usurped by others;³
- The Committee concludes that any possible reduction in competition resulting from allowing the patents system to continue would be temporary and justified by the incentive it provides to investment and development of new products;⁴ and
- The Committee does not consider that the patenting of genetically modified animals or crops will cause hardship to farmers. Any increase in cost which may result from royalty payments would have to be at least matched by an increase in return to farmers from using the genetically modified product or it would not be an economic proposition and would not be competitive against the more traditional source of animal or crops stocks.⁵

¹ paragraph 7.60, page 234

² paragraph 7.63, page 234

³ paragraph 7.62, page 234

⁴ paragraph 7.77, page 237

⁵ paragraph 7.82, page 238

PATENT LAWS AND COMPETITION⁶

Competition law and IP law are sometimes viewed as standing in diametrical opposition. But in terms of the *economic goals* sought, the supposed opposition between these laws does not exist. Both competition law and IP law have a common central economic goal: *to maximise wealth by producing what consumers want in a more efficient manner*.

IP law pursues this goal by encouraging the innovation of new and better products. But innovation, like other forms of productive activity, is not without cost. Individuals and companies, who are subject to market forces, therefore need to earn financial rewards to undertake innovative activities. However, inventions and ideas are susceptible to being freely appropriated by others. Patent protection is one of a range of legal devices to insure that there can be property rights in ideas. These temporary property rights to exclude others are a means of preventing 'free riding' so that the employment of resources and taking of risk may be rewarded. Only the ability to keep secrets and to enforce private 'know-how' contracts would, without patent law, provide inventors limited protection for their work. Unlike patent law, such information is not publicly available, which may hinder further developments in the relevant technology and some information may never become generally available.

Therefore, central to the economic justification of an IP system is that without the IP right, too few resources would be invested in innovation. A trade-off (some 'monopoly' restraint in the short term for greater, more efficient output in the long run) is in the interest of socially desirable resource allocation. As well as the direct benefit of the innovation to consumer choice and production efficiency, the general pool of knowledge is increased by public disclosure. Although IP rights involve some costs, other ways of encouraging innovation, such as subsidising inputs through grants or tax concessions, are less satisfactory – they either involve indiscriminate subsidies of both winners and losers or involve trying to pick winners. IP rights reward success by an amount that is determined by the market place.

It is important not to think of patents as a 'monopoly' in the everyday meaning of conferring absolute market dominance since there are normally alternative substitutes. If there is a demand for a patented product, it not only provides reward to the patent holder but encourages competitors to develop improved alternatives. Rather, it is a 'temporary exclusive right' to only part of the commercialisation process, but a part which can be crucial to success by giving the necessary competitive edge.

SUMMARY

Regardless of whether an innovator is a multinational organisation or a backyard inventor, they can obtain patent rights for their inventions. IP Australia believes that by allowing patents across all fields of technology, including GMOs, Australia encourages innovation and investment. No strong grounds exist which justify treating biotechnology differently from other fields of technology under the patent system. It

⁶ IP Australia made a detailed submission to the National Competition Council's Review of Sections 51(2) and 51(3) of the Trade Practices Act. The submission addresses issues of licensing and assignment of IP rights generally.

is also important to remember that many of our major trading partners have similar protection regimes. Denying the right to patent, allowed in many other countries, may adversely affect the biotechnology industry in Australia. Without patent protection, neither foreign nor Australian enterprises will be encouraged to manufacture the latest innovations and make them available in Australia.

Vivienne Thom Acting Deputy Director General Corporate Strategy IP Australia

> PO Box 200 WODEN ACT 2606 Ph: 6283 2008

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