



SUBMISSION IN RESPONSE TO

PRODUCTIVITY COMMISSION INQUIRY INTO THE

COMPULSORY LICENSING OF PATENTS

27 SEPTEMBER 2012

1. INTRODUCTION AND PURPOSE OF THE PATENT SYSTEM

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than \$1.5 billion a year to the Australian economy and directly employs thousands of people across the country.

CropLife welcomes the opportunity to make a submission to the Productivity Commission Inquiry into the Compulsory Licensing of Patents. Patents are central to the system of innovation in Australia. Changes made to the system need to be well considered as they may have implications that reach far beyond the initial intent of the reform. CropLife's fundamental position is that the status quo is working and that the existing compulsory licensing provisions of the *Patents Act 1990* provide an efficacious remedy where a patentee is abusing their exclusive rights to exploit a patent, or where the reasonable requirements of the public are not being met. Perhaps even more significant is that the minimal or negligible need to use these provisions is testament to the effectiveness of Australia's current legal framework for patents.

The current incentive for the market to maximise profit and the ability to profit from licensing dictates against systemic anti-competitive conduct. Isolated incidents of abuse cannot justify transforming a remedial mechanism into a tool of general market regulation. Any amendment to the threshold test for compulsory licensing will significantly undermine the efficacy of the system.

Lowering the current threshold test for compulsory licensing will have several unintended and very significant negative effects on innovation in many industries that are completely unrelated to human healthcare, including and in particular the agricultural biotechnology and crop protection industries. It would also lessen the similarity of Australia's national patent system to those of our trading partners and it is highly likely that it may contravene international agreements that Australia is a Party to including the Agreement on Trade Related Intellectual Property Rights and the Australian United States Free Trade Agreement.

Patent ownership does not imply freedom to operate. Historically, the patent system evolved due to the need to address a significant market failure namely, the significant externalities of innovation (which act to depress investment in inventive activity) coupled with the self-evident social benefit of those externalities. Patents provide the economic incentives necessary to stimulate investment in innovative technologies, thereby spurring productivity growth economy wide.

Patent systems have traditionally been used by nation states as a means of encouraging inward flows of technology, increasing innovation and ultimately, economic productivity and growth. The major technological innovations of the last 500 years have all been the subject of patents that operated to ensure the risk of investment in research and development could be justified by the benefits granted to those who developed an invention that was of use to the public.

Many industries, including the agricultural biotechnology and crop protection industries that CropLife represents, face substantial costs and delays in order to satisfy regulators that their products are safe. Genetically modified crops and pesticides are regulated differently, but both systems involve multiple regulatory agencies who give pre-market approval. This high level of regulatory intervention in the market leads to elevated product development costs that would not be able to be recouped without a period of exclusive market access. As these products are often simple to copy through reverse engineering, this exclusive market access period relies on protection of the intellectual property through patents. Without robust patent protection, it is unlikely these products would be released in Australia.

Importantly, contemporary patents do not vest in the patentee an unlimited monopoly for the life of the patent. Market forces interact with statutory check and balances to promote the socially optimal exploitation of patented inventions. The grant of patent rights under s13(1) of the Act effectively arm the innovator with the capacity, and in certain circumstances the obligation to derive profit from the patented invention by exposing their invention to the market.

Section 13(1) of the Act grants two exclusive rights to the patentee namely, the right to exploit the patented invention and the right to authorise others to do the same (*refer Box 1*). These two aspects of the patentee's rights under s13(1) of the Act operate to reduce the potentially negative effects that an unlimited monopoly would have upon technological innovation and market freedom.

Both aspects of the s13(1) rights represent significant avenues for profit for the patentee who may either themselves exploit the invention, or receive monetary reward for allowing others to do so.

Box 1: Exclusive rights given by patent

“Section 13

- (1) Subject to this Act, a patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention and to authorise another person to use the invention.”

2. OPERATION OF THE EXISTING FRAMEWORK

As noted in the Productivity Commission's *Issues Paper on Compulsory Licensing of Patents*, compulsory licensing provisions are currently embodied in ss133-140 of the *Patents Act* (refer Box 2).

Box 2: Compulsory licensing

"Section 133

- 1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.
 - 1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.
- 2) After hearing the application, the court may, subject to this section, make the order if satisfied that:
 - (a) all the following conditions exist:
 - (i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;
 - (ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;
 - (iii) the patentee has given no satisfactory reason for failing to exploit the patent; or
 - (b) the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* or an application law (as defined in section 150A of that Act) in connection with the patent."

In brief, s133 requires that a patent cannot be exploited in a manner which violates Part IV of the *Competition and Consumer Act 2010*, effectively setting a statutory bar on restrictive trade practices, with the remedy being a compulsory licence. Additionally, where the patentee is NOT exploiting the patented invention, in the absence of a satisfactory explanation for failing to work their product, and where the reasonable requirements of the public are not being met, there is an effective obligation on the patentee to license their product if a license is being sought.

The remedy of a compulsory licence as embodied in ss133-140 must be read in the broader context of the dual intentions of s13(1), as explained earlier in this submission (refer Box 1). The first limb of s13(1) addresses the depressing effect that the externalities of innovative activity would otherwise have upon investment and technological development by extending to the innovator a benefit for being the first to develop a socially useful invention.

The opportunities for market exchange arise from the interaction of the exclusive right granted to the patentee by the first limb of s13(1) and the second limb, which vests in the patentee the exclusive right to authorise others to use the patented invention. This second part of s13(1) is the basis of the market for licensing of innovative technologies, and operates in conjunction with general market forces to encourage the commercialisation of patented inventions, either by the patentee or by another person who has paid the patentee for the right to work the patent.

In the context of medical biotechnology, Nicol and Nielsen's study provides empirical evidence to support the conclusion that competitive pressure and the pursuit of profit are operating effectively to facilitate voluntary licensing of patented inventions on a commercial basis without judicial intervention¹. A survey of industry participants was conducted in which questions were asked regarding whether they had experienced unilateral refusals to license patented inventions. For the purposes of this submission, CropLife will not enter into the details of their results, however, their conclusion is worth noting:

"To summarise, in line with the survey results a few interview respondents expressed frustration at difficulties in licensing-in enabling technologies, but these were greatly outnumbered by the number of respondents who had not experienced any problems."²

Nicol and Nielsen also interviewed those involved in licensing-out patented inventions. Again, the results demonstrated that the incentive to maximise profit and the ability to profit from licensing agreements dictates against systemic anti-competitive conduct:

"[M]ost respondents engaged in licensing-out their technology (including research tools) appeared to hold the view that it made good business sense to engage in fairly liberal licensing practices."³

A survey of CropLife biotechnology member companies who engage extensively in both licensing-in and licensing-out of innovative technologies did not indicate any issues or concerns with the existing tests or threshold for compulsory licensing. However, members did indicate strong concerns about the effect any potential weakening of the current robust Australian intellectual property regime would have on the plant science industry in Australia. These concerns are discussed further in this submission.

Compulsory licensing provisions also appear in s19 of the *Plant Breeder's Rights Act 1994*. These are explored further in Box 3.

Box 3: Compulsory licensing in the *Plant Breeder's Rights Act 1994* - s19

Plant breeder rights are similar to patent protection except they are granted on an entire variety of a plant. The *Plant Breeder's Rights Act* (the 'PBR Act') provides incentive for innovation in plant breeding by rewarding breeders for the creation of new varieties that are better suited to Australian conditions or to meet market needs. This "leads to an efficient and competitive agricultural sector providing higher yields, using fewer pesticides and developing new and different products."⁴

Section 19 of the PBR Act requires the grantee within two years of the grant of PBR to make sufficient quantities of the variety available to meet public demand. Section 19(1) stipulates the grantee "must take all reasonable steps to ensure reasonable public access to the variety".

This is similar language to the "reasonable requirements of the public" test enunciated in s133(2)(a)(ii) of the *Patents Act*. However, the PBR Act goes on to define (in s19(2)) that "reasonable public access to a plant variety covered by PBR is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand."

As of September 2012, IP Australia indicated to CropLife that there had not been any compulsory licences issued under the PBR Act in Australia.

¹ Nicol and Nielsen J, 2003, 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry'. *Centre for Law and Genetics Occasional Paper*, No 6, p145.

² *Ibid.*

³ *Ibid.*

⁴ Australian Centre for Intellectual Property in Agriculture http://www.acipa.edu.au/PBR/3_9_4.html accessed 17 September 2012.

3. IMPLICATIONS OF LOWERING THE THRESHOLD FOR INTERFERENCE IN FUNCTIONING MARKETS

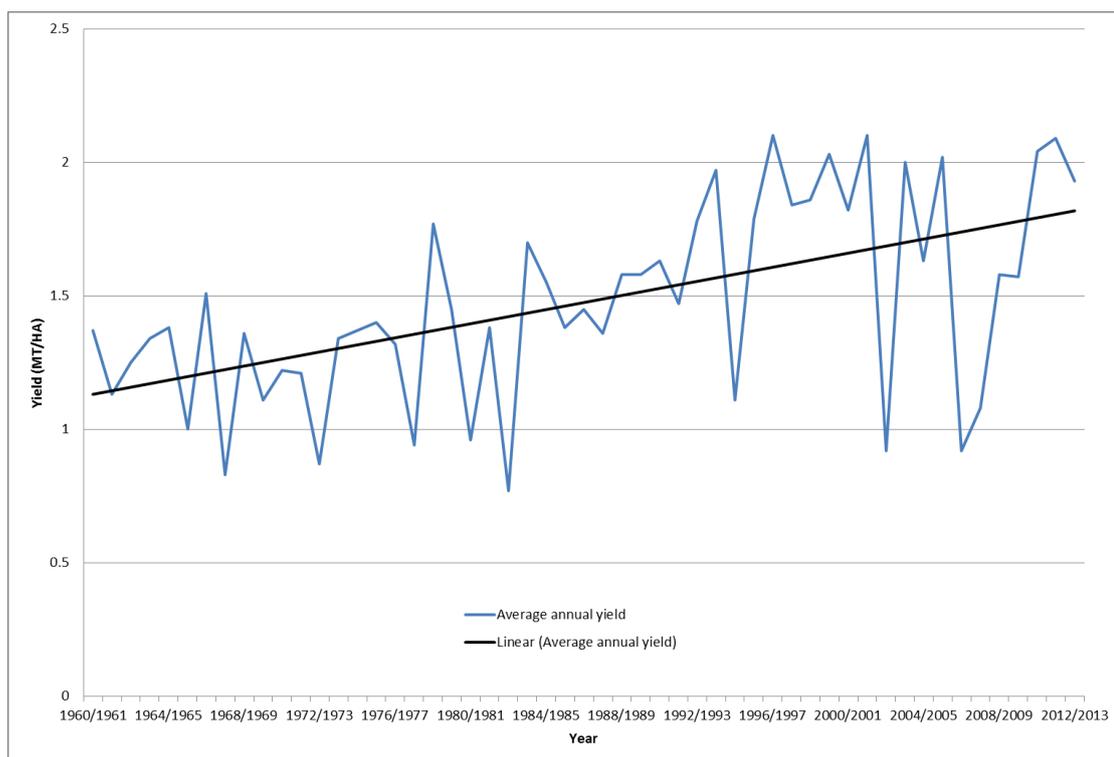
Any amendment to the threshold for judicial interference in the working of what appears to be a functional market for the licensing of patented inventions will risk significantly undermining the efficacy of Australia’s intellectual property regime.

CropLife strongly considers that compulsory licensing ought to be a remedy of last resort, capable of being used in the most serious of circumstances in which a patentee has manifestly abused their exclusive rights granted by s13(1) of the Act. Isolated incidents of abuse, if they have occurred, simply cannot justify transforming what is essentially a remedial mechanism into a tool of general market regulation.

Using the agriculture sector as an example, each Australian farmer produces enough food to feed 600 people, 150 at home and 450 overseas. Australia’s farmers produce 93 per cent of Australia’s domestic food supply⁵. *Figure 1* below shows Australian historical average wheat yield since 1960⁶. The observable trend clearly shows a steady and consistent increase in yield over this 50-year period. Without the support of the Australian government, promoting and protecting innovation and the patent system, it is highly unlikely that Australian agriculture would be the success it is today.

A number of consequences identified by CropLife biotechnology member companies of lowering the compulsory licensing threshold are discussed below.

Figure 1: Average Australian wheat yield 1960 – 2012



(Source: United States Department of Agriculture Foreign Agricultural Service.)

⁵ National Farmers’ Federation, 2012, ‘Farm Facts 2012’ <http://www.nff.org.au/farm-facts.html> accessed 17 September 2012.

⁶ United States Department of Agriculture Foreign Agricultural Service – *Production, Supply and Distribution Online Service*, <http://www.fas.usda.gov/psdonline/psdQuery.aspx> custom query 17 September 2012.

Consequence 1: Reduction in technology transfer will result in diminished productivity

CropLife member companies indicated that strong patent protection was a significant factor that influenced their investment decisions and innovative activity in Australia. There is a number of published studies that provide empirical surveys to corroborate the anecdotal evidence that decision making of corporate directors relating to investments is influenced by the strength of intellectual property protection.

For example, Levin et al (1987)⁷ surveyed 650 American research and development (R&D) executives across 130 industries and found that for the pharmaceuticals and chemicals industries, the executives placed great emphasis on strong patent protection. This result is supported by Mansfield (1986)⁸, who from a survey of 150 R&D executives found that 60 per cent of inventions in pharmaceuticals and 40 per cent in chemicals would not have been developed had it not been for the availability of patents. Segerstrom (1991)⁹ showed that government incentives to innovation (such as a robust patent system) unambiguously increase inventive intensity.

The potential for reduction in technology transfer could drastically affect Australia's long term economic productivity if innovators consider the regulatory environment to be unfavourable for the deployment (and patenting) of their inventions.

Consequence 2: Increased use of trade secrets

Alternatively, in an unfavourable operating environment innovators may decide against patenting their invention and resort to more frequent use of trade secrets as a mechanism of avoiding exposure to court ordered compulsory licences. The effect of this would be to reduce the degree of disclosure to the public currently enjoyed by virtue of the patent protection system, with potential long term impacts upon the rate of innovation.

If an amended statutory framework were to encourage an industry culture of non-disclosure of proprietary technology, this would unquestionably be a regressive development, with negative consequences in terms of the rate of innovation and the overall efficiency of production. Productivity will decline, because non-disclosure of innovation results in inefficiencies in the market, as all companies will be operating without the benefits of the innovations being used by their rivals, rendering the products of each company at least partially obsolete¹⁰.

Consequence 3: Disincentive for investment in innovation

CropLife strongly considers that licensing fees should be determined by the market, and not the courts. This is because market mechanisms are best suited to arriving at a price that is both economically efficient and profitable for the patentee. Allowing market mechanisms to dictate licence fees is an economic imperative, because failure to do so will have deleterious effects for long term productivity. Baumol (2002) explained¹¹:

"Inadequate fees, which can easily occur if licensing is compulsory, constitute a strong disincentive for investment in innovation. Fees that are excessively low can also lead to the use of the technology by some firms at the expense of other better qualified to do so."

Over the years Australian governments (state and federal) have largely withdrawn their direct funding for agricultural research. The emphasis is now on private and/or public private partnerships. These public private partnerships cannot and will not function without strong patent law that provides an incentive for private investment, as the risk to the private investor is greatly increased. For example, the CSIRO may have excellent research programs in place, but often partners with private industry who provide the necessary investment capital to transform public innovation into a marketable, profitable and socially beneficial product.

⁷ Levin, R.C., A. Klevorick, R.R. Nelson and S.G. Winter 1987, 'Appropriating the Returns from Industrial Research and Development', *Brookings Papers on Economic Activity*, no. 3, Washington, D.C

⁸ Mansfield, E. 1986, 'Patents and Innovation: An Empirical Study', *Management Science*, 32(1), 173-181.

⁹ Segerstrom, P. 1991, 'Innovation, Imitation and Economic Growth', *Journal of Political Economy*, 99(4), 807-827.

¹⁰ Baumol W., 2002, *The Free Market Innovation Machine: Analyzing the Growth Miracle of Capitalism*. Princeton University Press.

¹¹ *Ibid.*

4. CONCLUSION

Statutory schemes for the granting of monopolies of limited duration developed because of the need to address significant market failure. Inventors bear all the cost of an innovation, but all of society benefits (to varying degrees), and therefore there exists the strong incentive to 'free-ride' on the innovations of others. Without robust patent protection, these 'free-rider' effects in a competitive market system will only serve to stifle inventiveness.

CropLife submits that the existing compulsory licensing provisions of the *Patents Act 1990* provide an effective remedy where the patentee has demonstrated a gross abuse of their exclusive rights to exploit a patent, or where the reasonable requirements of the public are not being met.

The current incentive for the market to maximise profit and the ability to profit from licensing dictates against systemic anti-competitive conduct. Isolated incidents of abuse cannot justify transforming a remedial mechanism in to a tool of general market regulation. Any amendment to the threshold test for compulsory licensing will significantly undermine the efficacy of the system.