

8 February 2013

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Dear Commissioner

Response to Draft Report on Compulsory Licensing of Patents

Alphapharm appreciates the opportunity to provide the attached response to the Productivity Commission Draft Report on Compulsory Licensing of Patents.

Yours sincerely,

Alphapharm Pty Limited

Dr Martin Cross
Managing Director

RESPONSE TO THE
PRODUCTIVITY COMMISSION DRAFT REPORT
'COMPULSORY LICENSING OF PATENTS'



1. Overview

Although the terms of reference for the inquiry are not directed to any specific industry sector, such as the pharmaceutical industry, there is a clear direction for the scope of the inquiry to consider how the current compulsory licensing and Crown use provisions in the *Patents Act 1990* operate to bring about "affordable healthcare" particularly "where the patentee engages in anti-competitive conduct" in an attempt to prevent it.

While it is important to encourage investment in the research and development of new medicines, it is just as important to maintain an appropriate balance so that generics medicine companies are able to provide *timely access for Australians to quality, safe, efficacious and affordable medicines at a cost the PBS and taxpayers can afford*. However, the practice of 'evergreening' pharmaceutical patents hinders, obstructs and prevents this. The practice is without question an abuse of the Australian patent system and is detrimental to "the wellbeing of the community as a whole". In spite of this, neither the compulsory licensing nor the Crown use provisions have ever been invoked in response.

Evergreening has been aided by weak or very low patentability standards, broadening patentability to include methods of medical treatment, poor patent quality, lack of financial incentives to challenge dubious pharma patents, the readiness of courts to enjoin patent challengers, poorly drafted contributory infringement provisions, too much emphasis on the courts to vet the system and the complete absence of criminal and effective civil sanctions against the misuse of the system. It has also been aided by the complete failure of the compulsory licensing and Crown use provisions to deter this anti-competitive practice.

Unfortunately, the draft report has failed to address the adverse impact that evergreening is having on the Australian economy. It has failed to explain how the compulsory licensing and Crown use provisions should have deterred or will deter evergreening in the future. Indeed, if recommendation 6.2 were to be implemented it is unlikely that the practice of evergreening would amount to anti-competitive conduct under the proposed public interest test. This is a significant oversight.

Another oversight is the continued reliance on the extremely expensive, inefficient and ill-equipped federal court system. It is unacceptable to the generics industry that the Australian Federal Court continue to be the sole arbiter when it is abundantly clear that less than one per cent of the patents granted by IP Australia are ever scrutinised by it. Part of the problem of evergreening is that the complexities, costs and risks of patent litigation are so extraordinarily high that it is simply impractical for the validity of pharmaceutical patents to be comprehensively tested. As a result, even though most of these patents are likely to be invalid, they remain on the Australian Register of Patents. And as such they are enforceable.

The enforceability of patents is powerful. Even the threat of enforcement has the potential to deter competition. The problem is, the more invalid patents remain enforceable, the less genuine competition there is. And the less competition there is, the less choice there is and the higher the price of whatever is the available choice. In the context of the PBS this means less "affordable healthcare".

2. Compulsory licensing

The report acknowledges that there have been only “three applications for a compulsory licence since this became available under Commonwealth legislation in 1903”.¹ This fact is uncontroversial. It is also clear and persuasive evidence of the complete failure of compulsory licensing, as it presently stands, to be an effective and efficient mechanism to deter abuses of Australia’s patent system.

The IPAC report² into the Australian patent system, which led direct to the *Patents Act 1990*, considered compulsory licensing.³ Describing compulsory licensing as “an enigma”, IPAC confirmed that “only 2 cases of petitions for compulsory licences are known to have gone to court in Australia”. IPAC went on to speculate why this was so, providing a number of plausible explanations. However, it concluded that there was simply “insufficient empirical information ... available ... to enable [it] to assess the validity of either of these contrasting possibilities.”⁴ Nonetheless, IPAC recommended the retention of compulsory licensing.⁵ The reason it gave was that the “existing provisions appear to be satisfactory [for the purpose of] ... providing a mechanism by which a patentee can be prevented from *misusing* a patent to *preclude local working* which is economically desirable, in circumstances where, but for the patent, it could and would occur.”⁶ That, however, was 1984.

Today, Australia is a member of the World Trade Organisation and is subject to TRIPS. It is also a party to AUSFTA. Both agreements contain provisions that have significantly narrowed the grounds upon which Parties may authorise the exploitation of a patented invention without the permission of the patent owner. Importantly, they have removed ‘local working’ as a prerequisite for compulsory licensing. It is fair to suggest therefore, that as the basis of compulsory licensing in the *Patents Act 1990* was ‘local working’, the current provisions are neither TRIPS nor AUSFTA compliant.

Alphapharm therefore agrees that the current provisions must be repealed.

Alphapharm, however, disagrees with Draft Recommendation 6.2.

The Productivity Commission’s draft report, again without any anecdotal or empirical evidence, proceeds to recommend the retention of compulsory licensing by replacing “the current ‘reasonable requirements of the public’ test”, which it concludes “is unlikely to promote efficient outcomes”, with a “new public interest test”⁷ that “focuses on providing access to patented inventions in a way that promotes the wellbeing of the community as a whole.”⁸

In so doing it is critical of the very policy that IPAC, after an exhaustive five-year review of the Australian patent system, believed was both appropriate and necessary to maintain for the benefit of the Australian economy. True it is that IPAC did not have any empirical data to back up its recommendation, but then again, neither does the Productivity Commission.

¹ Box 1.2, 29.

² Industrial Property Advisory Commission (1984), ‘Patents, Innovations and Competition in Australia’.

³ Section 4, 27-35.

⁴ Ibid, 28.

⁵ Ibid, 30.

⁶ Ibid, 29. (Emphasis added).

⁷ Draft Recommendation 6.2.

⁸ Draft Report, 111.

Through what may be best described as speculative evidence, albeit conceded to be “generally anecdotal”, the report attempts to bolster its recommendation with a few selected opinions, elicited from submissions, on how compulsory licensing may be a “deterrent in negotiations”.⁹ Whether the threat of compulsory licences is a credible deterrent can hardly be relied upon on the basis of such flimsy evidence. In any event, the relevant question is this: what conduct is it supposed to deter? It is in answering this question that the most significant problem becomes apparent.

The recommended test for compulsory licensing is not directed to the deterrence of the misuse of the patent system, which is what compulsory licensing was originally designed to do. Instead it is directed towards deterring anti-competitive conduct in the context of traditional antitrust law. And it seeks to rely on European antitrust law as its source of inspiration. Referring to the ‘essential facilities doctrine’, it is suggested that the recommended test may apply “where the intellectual property right is used by the owner to extend its market power *beyond the original scope of the right*”, whatever this may mean. The obtuseness of the proposed test is exacerbated by the additional requirement that the applicant prove that the patentee’s conduct amounts to “an abuse of a dominant position” in the market. This is a very high threshold and one that is unlikely to apply to the many instances of patent abuse that are rife today.¹⁰ The report makes it clear that the recommended ‘public interest’ test should only apply if it is shown that “the patentee is taking advantage of a ‘substantial degree of market power’ as defined in s.46 of the CCA.”¹¹ Significantly lessening the likelihood of this test being effective is the additional requirement that the applicant “must show that it had no economically viable option to produce the relevant goods.” With respect, this is an impossible criterion to satisfy.

Ultimately, Alphapharm accepts that the relevant language in AUSFTA is problematic, however the term “anti-competitive practices” in Art. 17.9.7 appears in the section of the agreement concerning patents. Therefore, it is arguable that the term is directed to conduct that results in the misuse of the patent system, such as the extraction by patentees of an undeserved patent monopoly that unfairly or inappropriately limits competitors or potential competitors. In Alphapharm’s view, the anti-competitive threshold should, therefore, not be linked to market dominance. While it is acknowledged that AUSFTA severely restricts the scope of compulsory licensing, the recommendation contained in this report, in Alphapharm’s view, is made without a sufficient understanding of how the Australian patent system is presently being abused through the grant and enforcement of patents, many of which are probably invalid. In other words, it is made in the absence of evidence about what is actually occurring in the Australian patent system.

Patent evergreening

The prevalence of the practice of patent ‘evergreening’ in the context of pharmaceuticals has been well documented in Europe and is now the subject of a review being conducted by the Pharmaceutical Patents Review Panel. This, however, is merely one example of the kind of patent abuse that has serious implications for the wellbeing of an economy.

The European Commission Competition Division’s comprehensive investigation into the impact of medicinal patents on generic competition has provided important insights into the impact that evergreening patents have on the provision and cost of healthcare. The period of the Competition Division’s inquiry was 2000 to 2007 and covered all 27 member countries of the European Union. The Commission’s report concluded that healthcare expenditure would have been “about €15 billion higher without generic entry” and found first, that “originator companies apply patent strategies, which may interfere with the development of a competing medicine” and second, “any delay [to generic entry] will have a significant cost/revenue impact [on the cost of healthcare].”¹²

⁹ Ibid, 113.

¹⁰ Issues Paper into the Pharmaceutical Patent Review.

¹¹ Draft Report, 146.

¹² Ibid, 521.

On the basis of the European Commission's report¹³ into this practice and the impact it has had on the level of competition in the European Union's healthcare market, it must be clear to the Productivity Commission that such behaviour should qualify as an anti-competitive practice. Yet, the stringency of the recommended 'public interest' test will likely rule this out.

The Pharmaceutical Patents Review

Alphapharm has recently filed an extensive analytical and confidential submission to the Pharmaceutical Patents Review providing the expert panel members with multiple case studies of patent evergreening. The submission shows that the cumulative cost of this practice to the Commonwealth through the PBS is estimated to be in the billions of dollars. However, the cost to the Australian economy is much more. Indeed, the practice has undermined the effectiveness of policies designed to maintain a strong local pharmaceutical industry. One example is 'spring-boarding', the objective of which has been completely undermined by evergreening of pharmaceutical patents. While the 'spring-boarding' policy¹⁴ was designed to facilitate the entry into the market of generic medicines once a patent expired, the practice of evergreening by extending the relevant expiry date, in some cases to nearly 50 years, has effectively neutralised it.

It is therefore important that the Productivity Commission does not rigidly stick to traditional anti-competitive law concepts by requiring its recommended 'public interest' test to meet a market dominance threshold before the relevant conduct can be considered to be anti-competitive.

A patent monopoly does not necessarily, and generally does not, confer market dominance on a patentee. However, what it does do is confer on the patentee the ability to control others in regard to the exploitation of the invention covered by the patent monopoly. In the case of a medicine this is significant power since the substitutability of medicines is constrained by laws that regulate the marketing of medicines. In Australia this occurs through the Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Scheme (PBS). The TGA and PBS play a crucial role in the availability of quality, safe, efficacious and affordable medicines to Australians.

Substitutability between pharmaceutical products is the key to generic competition under the PBS. For a generic product to be included on the ARTG it must be essentially similar to a pharmaceutical product that (a) is registered on the ARTG or, which from November 2012, (b) was previously registered on the ARTG.¹⁵ Essential similarity means that the generic medicine contains the same qualitative and quantitative amount of active pharmaceutical ingredient, in the same dose form, and is bioequivalent. The generic medicine is then accepted as providing the same safety and efficacy profile of the branded original medicine. Therefore, the sponsor¹⁶ of a generic product must have a reference point against which essential similarity can be assessed by the TGA.

The proper functioning of the PBS depends on the TGA, Australian patent system and the availability of generic medicines, working optimally as they were intended. This is because unless a medicine is placed on the ARTG by the TGA, it is impossible for it to be made available through the PBS to Australians. Therefore, only medicines that are on the ARTG and have been approved for inclusion in the PBS¹⁷ are legally permitted to be dispensed by pharmacists in accordance with a prescription written by a medical practitioner and

¹³ Pharmaceutical Sector Inquiry Final Report, European Commission (8 July 2009). One example mentioned in the Report involved 1,300 European patents around one medicine.

¹⁴ For an explanation of the policy see *Intellectual Property Laws Amendment Bill, 1997 Explanatory memorandum*, 7.

¹⁵ *Therapeutic Goods Amendment Regulation 2012 (No 3)*.

¹⁶ For definition of 'sponsor' go to: <http://www.tga.gov.au/about/glossary.htm>

¹⁷ The Pharmaceutical Benefits Advisory Committee (PBAC) advises the Minister in regard to which medicines should be made available under the PBS. No new medicine can be listed on the PBS unless the PBAC approves. The PBAC's criteria include the cost effectiveness of the new medicine compared to those already listed on the PBS.

reimbursed under the scheme.¹⁸ The price that an Australian pays for a medicine is subsidised through the PBS. In this way, the PBS “provides timely, reliable and affordable medication and related health needs, so that both optimal health outcomes and economic objectives are achieved.”¹⁹ These objectives are enshrined in the National Medicines Policy.²⁰ Unfortunately, the prolongation of patent protection around a medicine undermines these objectives.

In Alphapharm's view, the practice of patent evergreening must come within the definition of what is “anti-competitive practices”. Unless this is done, Alphapharm believes that the wellbeing of the Australian economy will continue to be adversely and seriously impacted. Indeed, if the threat of a compulsory licence is to be a deterrent, then it is essential that the practice of patent evergreening be specifically targeted and included in the new ‘public interest’ test. If this were done not only would compulsory licensing be effectively available as a remedy against this form of unfair competition, but also it is possible that it may have a mediating behavioural role.

An intellectual property regulator

That said, it must be recognised that the Australian court system is not an optimal vehicle for the administration of compulsory licensing. This is because Australian courts are very expensive, very slow and lack the necessary powers to mediate quickly and effectively to resolve a patent dispute in the context of meeting the objectives enshrined in the National Medicines Policy. The problem is that very few patents are challenged before the Australian courts because of these very issues. As a result, many patents that would most likely be revoked if they were challenged remain on the Australian Register of Patents. This situation then permits patent thickets to remain around key medicines. And this, in turn, means that competitors in the medicines market are required to either “clear the way” or face the prospect of patent litigation. With the cost of patent litigation running into the millions, the high likelihood of an interim injunction being granted - thereby preventing the marketing of a generic competitive medicine - and the potential exposure to an adverse costs order which confronts patent challengers, either of these options is rapidly diminishing as realistic commercial choices for generic medicines companies.

Accordingly, Alphapharm proposes that an intellectual property industry regulator be established and that the regulator be given extensive powers to intervene and mediate in regard to intellectual property in Australia. The regulator should also be given the power to grant compulsory licences if it is of the view that the patentee is guilty of using anti-competitive practices that relate, concern or involve any form of intellectual property. Specifically, the regulator should be directed through the objects clause of the implementing legislation to ensure that policies, such as the National Medicines Policy, are not undermined by such practices and to use compulsory licensing as a compensatory or corrective measure.

Conclusion

While it has been argued that patents may appropriately encourage invention in the provision of new medicines, it must also be understood that a poorly administered patent system unnecessarily imposes market inefficiencies and costs on the Australian economy. And it may, as already outlined, undermine key policies that are designed to ensure, among other things, the provision of quality, safe, efficacious and affordable medicines to Australians. It is clearly arguable that the practice of patent evergreening does nothing to

¹⁸ To be eligible patients must be holders of a Medicare card. Unless the patient is a concession card holder their maximum contribution to the cost of filling a prescription is \$36.10 (as at January 2013), unless it is a ‘premium’ medicine. (http://www.pbs.gov.au/info/about-the-pbs#What_you_pay_for_PBS_medicines).

¹⁹ PBS website: <http://www.pbs.gov.au/info/about-the-pbs> (as at 28 Nov 2012).

²⁰ According to the *Report to Parliament on barriers to generic medicines entering the market through the inappropriate use of intellectual property rights over product information* (June 2011) the National Medicines Policy “is a broad framework that aims to improve health outcomes for all Australians through access to and appropriate use of medicines. The overall aim of the policy is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved.”

promote “the wellbeing of the community as a whole” and that, accordingly, it should come fairly and squarely within the scope of any proposed new ‘public interest’ test.

3. Crown use

While Alphapharm agrees with Draft Recommendation 7.1 it does not agree with Draft Recommendation 7.2.

AUSFTA provides that “public non-commercial use” of, for example, a patented medicine used in public hospitals operated by State governments, can be made provided that such use does not compel the patent owner to “provide undisclosed information or technical know-how related to a patented invention” and is:

- (i) limited to “the government or third parties authorised by the government”; and
- (ii) the subject of “reasonable compensation” to the patent owner.

Yet, the report’s recommendation goes much further and significantly elevates the obligations on the Commonwealth and State governments above those stipulated in AUSFTA in a number of important ways.

First, the recommendation requires “the Crown to attempt to negotiate use of the patented invention *prior to* invoking Crown use.”

Second, it requires the provision of a “statement of reasons no less than 14 days before such use occurs”.

Third, it mandates that the patent owner be “entitled to remuneration determined on the *same basis as that for a compulsory licence.*”

None of these make sense from a policy perspective.

To begin with the Commonwealth and State governments may wish to make available to themselves, and those so authorised, the use of a patented invention without the need to first “attempt to negotiate” such use with the patentee. The circumstances for so doing need not be discussed at length here but clearly include the use of certain technologies that may be necessary for the nation’s security both militarily or otherwise. To require a Commonwealth or State government department, agency or a person so authorised, to be required to first enter into negotiations prior to the invocation of such powers is, with great respect, a concession with very significant consequences that may be little understood without a full and proper consultation across the whole of government. Moreover, this requirement is at odds with Art. 17.9.7, which expressly contemplates the use “of the subject matter of a patent *without* the authorisation of the right holder”. Indeed, not only should it be unnecessary for the Commonwealth and State governments to first “attempt to negotiate”, it should be unnecessary for them to even contemplate the conclusion of an agreement with the patentee relating to such use.

Next, the requirement to furnish a statement of reasons, let alone within 14 days, is merely an invitation for the patentee to seek to delay, hinder or prevent the invocation of these powers through litigation. It is foreseeable that the patentee may seek the intervention of the Australian courts to forestall the invocation of these powers, thereby putting the Commonwealth and State governments reasoning under unnecessary and unwarranted scrutiny. Apart from opening up the government to the expense of litigation, it also opens up the government to an intrusive and investigational process. It is clear that AUSFTA does not require such an intermediate step and it is absurd that such a step be suggested. It must be understood that the patentees that are likely to be the subject of Crown use are most likely to be multi-national, sophisticated and possessed with an enormous capacity to fund complex and protracted litigation.

Finally, while AUSFTA does require some form of “reasonable compensation” to be paid to the patentee, it does not stipulate how that compensation is to be determined, or how much it should be. It seems quite remarkable that the Productivity Commission would venture forth with such a recommendation without some

empirical data and analysis to support it, when the existing provisions already provide a mechanism, namely by agreement or in the absence of an agreement, through the Federal Court.

The existing provisions, in Alphapharm's opinion, meet the requirements under AUSFTA and should not be amended as proposed in Draft Recommendation 7.2.

4. About Alphapharm

Alphapharm is Australia's leading supplier by volume of prescription medicines to the Pharmaceutical Benefits Scheme (PBS). One in seven prescriptions for PBS medicines is dispensed with an Alphapharm product. The company specialises in bringing patent-expired medicines to market, which contributes to the sustainability of the PBS by providing timely access to quality, safe, efficacious and affordable medicines. Alphapharm medicines are made to the highest global quality standards and have the same effect on the body as initial brands.

Alphapharm pioneered generic medicines in Australia in 1982 with twelve staff and four products. Today, we have some 600 employees nationally, including 450 at our state-of-the-art manufacturing plant at Carole Park, Queensland. Almost a quarter of Alphapharm's employees focus on the quality assurance and quality control of our products. This year, the plant will produce 3.1 billion doses of which about 1.7 billion will be exported to some 50 countries around the world.

Alphapharm consistently adheres to strict quality control testing and practices throughout its facility ensuring its products meet its established, documented standards for safety and effectiveness.

Alphapharm's quality control labs test and re-test raw materials, in-process products and finished goods for dissolution, potency, content uniformity and stability. The quality assurance team makes certain the company's products are made to the highest global quality standards. This means satisfying Australian, European Union, United Kingdom, United States, Canadian and New Zealand standards of Good Manufacturing Practice (GMP). This is vital to its business, because apart from supplying the Australian market, Alphapharm exports products to more than 50 countries, including to Europe, South East Asia and the U.S. With methodical documentation, ongoing monitoring procedures, and stringent product testing, Alphapharm is ready for inspection 365 days a year. But quality is more than just processes. It depends on the commitment to excellence of Alphapharm employees - a commitment that is demonstrated every day, by every member of the company.

Alphapharm is part of US-based Mylan.

5. About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service a habit, do what's right, not what's easy and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 150 countries and territories. Our workforce of more than 18,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world.