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Secretariat
Advisory Council on
Intellectual Property

From Frank Di Giantomasso Email frank.digiantomasso@minterellison.com
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Subject **Submissions in relation to the Advisory Council on Intellectual Property's consideration of patents and experimental use**

Dear Dr Crawford

We act for Epitan Limited (ACN 089 644 119) (**Epitan**).

We refer to the e.mail message that Frank Di Giantomasso sent to you on 15 December 2003 registering our client's interest in connection with the Advisory Council on Intellectual Property's (**ACIP**) review of patents and experimental use, and your e.mail in reply, sent on the same day, confirming receipt of our client's interest in making a submission to this inquiry.

On our client's behalf, we make the following submissions. Please note that the submissions which follow are made solely on our client's behalf, and do not necessarily represent the views of Minter Ellison.

Submission Summary

Our client submits that the formal introduction of an experimental use exception into Australian patent legislation would prejudice the rights of patent owners, and would not be conducive to continued scientific research and development in Australia, nor to the commercial exploitation of such research and development. Accordingly, our client's contention is that an experimental use exception to infringement should not be introduced into Australian patent legislation.

1. Background

1.1 Epitan is an emerging biotechnology company for cancer prevention and therapies, with a focus on reducing skin damage and skin cancer. Since its formation, it has conscientiously worked to establish strong research collaborations with leading researchers in the areas of cancer research, drug delivery and epidemiology.

- 1.2 Epitan is the licensee of a number of Australian patents, and is the applicant under at least one pending Australian patent application.

2. General policy considerations

- 2.1 Some of the general policy considerations regarding, and the reasons for the creation of intellectual property rights are discussed in the *Patents and Experimental Use Issues Paper (Issues Paper)* released by ACIP in February 2004. The Issues Paper makes specific reference to the Intellectual Property and Competition Review Final Report (**IPCR Report**), which states that intellectual property laws ought to provide motivation for efficient outlay in innovation.

- 2.2 The IPCR Report states, in the Executive Summary:

'The creation of intellectual property involves intellectual effort and can entail substantial resource outlays. Private producers will not have an incentive to make these outlays unless they receive an appropriate return.'

Without an intellectual property system which provides economic incentives for research or intellectual property investment, there is likely to be an under-investment in creative effort. In this sense, intellectual property policy has been crafted to address a perceived 'market failure', or at the least, a perceived 'market need'.

- 2.3 Epitan submits that introducing an experimental use exception would considerably reduce economic incentives for investment in the creation and commercialisation of intellectual property. A patent owner's compensation for the disclosure of its inventions is its right to (for the most part) control the use and exploitation of the patented invention for the patent period. This is the 'consideration' given in return for public disclosure of the invention. Introducing an experimental use exception into Australian patent legislation would, to a significant extent, strip patent owners of their right to control the use of their inventions.
- 2.4 Epitan submits that patent owners should be consulted before use is made of their patented inventions, thereby giving them an opportunity to grant licences to interested parties, even in the case of so-called 'experimental use'. Patents are personal property and the use of that property must, at the very least, involve consultation with the owner of the property.
- 2.5 Epitan accepts that a patent system must balance the need to provide incentive for future economic and creative investment against the need to ensure that technological innovations are ultimately disseminated into the public domain. Epitan submits that this balance has already been successfully struck. Indeed, investment decisions of significance have been made within the context of that balance; changing that balance may strike at the foundations of those investment decisions, forcing re-evaluation (if and where possible). A diminution of the property right afforded by a patent may jeopardise many commercial relationships based upon the patent. Moreover, complex commercial relationships involving, for example, licensing and the payment of royalties and milestone payments, and 'read through' royalties have resulted from long and often difficult negotiations. Changing the context and content of those relationships may have dramatic effects upon current and future investment.
- 2.6 The consideration by the ACIP working party on Patent Enforcement and by the Intellectual Property & Competition Review of the pre-grant criteria for patents resulted in a strengthening of those criteria by the Australian government. In our client's submission these amendments to the patent system represented the appropriate

measures aimed at ensuring that access to patented technology is not improperly withheld from the public, and that further measures, particularly those which restrict the rights conferred by patents, are unnecessary and would be unfairly prejudicial to patent owners.

3. Commercialisation of experimental use

- 3.1 In Epitan's submission, there is little doubt that the formulation of any experimental use exception to patent infringement introduced into Australian patent legislation would be an extremely difficult task. Epitan submits that it would be impossible to create such an exception without unfairly and adversely altering patent owners' rights and affecting their economic interests; by definition, the creation of such an exception will of its very nature, diminish the rights of patent owners.
- 3.2 In our client's submission, almost all conduct which could be argued to fall within an experimental use exception is commercial in nature. If any promise is shown from the 'experimental use', the experimenter will almost inevitably want to exploit that promise, leading ultimately, to a commercialisation of the 'experiment', its by-products, outcomes or results. Effectively, such an exception may allow third parties to circumvent the exclusive rights of patent owners to exploit the invention, and thereby prejudice patent owners' legitimate economic interests. This is, of course, particularly so in cases where the subject matter of the patent concerned is itself, an experimental technique or product. Such an exception would also increase the costs of surveillance for suspected infringement, as significant detail regarding the use suspected to amount to infringement would be needed in order to evaluate whether or not it was truly 'experimental' in nature.

4. Improved licensing practices

- 4.1 Our client submits that the adoption of an experimental use exception goes beyond what is required to address perceived inadequacies in the current patent system. Epitan believes that improved licensing practices can address any perceived inadequacies more effectively than the introduction of an exception to, and consequent contraction of, the patent owner's exclusive rights.
- 4.2 Licensing is preferable to a formal experimental use exception as it achieves the same end - a wider dissemination of knowledge and use of the invention - without alienating patent owners, as the proposed exception may result in, to the extent that it may have the effect of excluding or marginalising them from having a say in the process of dissemination.
- 4.3 Promotion of improved licensing practices would better balance the interests of patent owners against the interests of the wider community, as more interested parties would have access to the benefits of patented inventions, and patent owners would be given an opportunity to be involved in on-going research and development of their technology.
- 4.4 Licensing additionally allows the inventor to be involved in the use of his or her invention by others. For many inventors, it is not only any financial benefits associated with their inventions that are of primary importance, but a continuing involvement in the evolution of the invention. For many inventors, involvement in these developments is an important consideration.
- 4.5 By promoting licensing over and above a legislative infringement exception, patent owners will not feel marginalised and hence will be unlikely to see an incentive to move their research and development programs to other jurisdictions in which such exceptions

do not exist. Clearly it is in Australia's economic interest to maintain and build its domestic research and development base, rather than encouraging its export to other jurisdictions.

- 4.6 As noted above, a formal experimental use exception may undermine existing licensing arrangements, thereby devaluing or even possibly defeating important investment decisions and commercial relationships between patent owners and licensees.

5. International Treaty Obligations

- 5.1 The Issues Paper makes reference to Australia's international treaty obligations, in particular to Australia's obligations under the Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) Agreement.

- 5.2 Article 30 of the TRIPS Agreement states:

'Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'

- 5.3 As outlined above, our client submits that an experimental use exception would unreasonably prejudice the legitimate interests of patent owners. Therefore, the introduction of such an exception may see Australia breaching its obligations under Article 30 of the TRIPS Agreement.

- 5.4 Further, Article 7 of the TRIPS Agreement provides

'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'

- 5.5 Our client submits that the appropriate balance between the rights of patent owners and others has already been achieved in Australia. An experimental use exception is not necessary, nor conducive to attaining nor maintaining this balance. If anything, the introduction of such an exception will give rise to uncertainty.

6. Clarification of patent rights

- 6.1 The current lack of clarity as to the state of the law in relation to the existence of an experimental use exception highlights an undesirable uncertainty in Australia's current patent laws. In addition to resisting the introduction of an express, legislative experimental use exception, our client seeks to clarify the exclusivity and strength of patent rights in Australia.

- 6.2 It is important that patent owners, and other stakeholders in the community know of the extent and limits of the rights afforded by patent ownership. This is imperative so that patent owners are not mistaken as to the limits of their rights, and do not incorrectly assert that third parties are infringing their patents. Clarification is also essential so that others do not mistakenly infringe a patent, by performing acts that are within the exclusive rights of the patent owner.

6.3 Our client requests that in considering the adequacy of the current law, and entertaining the possibility of changes to the law, ACIP also clarify the strength and exclusivity of patents in Australia.

We would be pleased to comment further on these matters on our client's behalf, should you wish to discuss any aspect of this submission with us. Please contact Gus Hazel on (03) 8608 2188 if you would like us to clarify, or amplify any aspect of Epitan's submission.

On our client's behalf, we thank you for considering these submissions.

Yours faithfully

MINTER ELLISON