



Sean Applegate  
ACIP Secretariat  
PO Box 200  
Woden  
ACT 2606

25 February 2005

Dear Sean,

**Re: Patents and Experimental Use – Options Paper**

Introduction

Acrux is a dynamic Australian specialty pharmaceutical company developing patient-preferred products for global markets. Acrux started operations in 1999, has more than 30 staff located in West Melbourne and has completed 16 clinical studies with 6 different drugs. Acrux currently undertakes all research and development activities in Australia, although it does have partners in USA (Eli Lilly, VIVUS, Connetics and Population Council).

Acrux's business model is based on its patented technology (enhanced delivery of drugs through the skin and mucosal membranes) adding value to drugs which already have regulatory approval, or at least are generally considered safe and effective for use in humans or animals.

The Patents Act 1990 followed from an inquiry by the Industrial Property Advisory Committee which reported in 1984. Two of the stated aims of that report were to encourage technological innovation and to eliminate unnecessary complexity in the statutory regime. It was also stated in this report that “the economic significance of patents has at times been obscured by a haze of assumptions about rights and rewards for inventors”.

Generally speaking, large pharmaceutical companies can take advantage of the differing “experimental use” laws in each jurisdiction around the world by setting up laboratories and clinical trials in jurisdictions that allow them an “experimental use” exemption. Needless to say, smaller pharmaceutical companies, like Acrux and many other Australian pharmaceutical companies, that have laboratories in one jurisdiction (Australia) do not have the capability to utilise such opportunities and would thus be prejudiced in a global market if patent laws pertaining to experimental use were construed too narrowly.

The existence of formulation development, clinical trial manufacture and clinical trial capabilities in Australia generally helps to progress pharmaceutical product development locally, instead of exporting the work, expertise and rewards for these to other countries. It would therefore be detrimental, not only to Acrux and similar Australian companies, but also to the companies providing services to the

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pharmaceutical industry, if barriers to explore patented drugs were implemented in Australia.

Further, we believe that it is important globally that people get access to better and cheaper medicines as soon as they become reasonably available. Given the fact that pharmaceutical product development and approval, even of generic products, takes several years, the repercussions of preventing companies in Australia exploring patented drugs prior to patent expiration could be quite severe.

In addition, such laws could prevent independent research on safety and efficacy of patented drugs, which is clearly a highly undesirable situation and one that would stifle much of our academic medical research.

Therefore, we wish to make the following submission in response to the Options Paper entitled "Patents and Experimental Use".

Options Considered:

*Option A – Expressly preclude experimental use from allowable activity.*

As can be seen in the Options paper itself, the disadvantages of this approach far outweigh the advantages. We believe that this provision would not encourage innovation in Australia and would potentially be very damaging to both businesses and academic institutions. In particular, many academic researchers currently undertaking degrees and projects are currently unaware that they might be infringing a patent. Option A would firstly require an extensive education program and secondly, result in many of these projects and courses having to cease which may ultimately end in the closure of some courses and institutions.

With regards to businesses, as you are aware, the process of drug development through to approval requires that a series of highly regulated stages must be satisfied before a new drug reaches the market. This process places considerable demand on resources and is often drawn out. Even a generic product can take years to progress through clinical and regulatory pathways. Option A would prevent the experiments required to allow others to market a drug that had been the subject of patent protection until after the patent had expired. This would effectively extend the life of the patent beyond the prescribed period and create further barriers to competition in addition to those that already exist in the Patents Act.

Therefore, we consider that this option would significantly hinder innovation and discourage fair competition.

*Option B – No change*

The issue of “experimental use”, and its lack of clarity in the Patents Act 1990, has

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raised considerable confusion with regards to “freedom to operate” and infringement. Since the Issues Paper was released in February 2004, and because Australian courts have yet to consider a common law defence of experimental use, it has been very difficult to obtain a clear legal opinion regarding “freedom to operate”. In addition, in the absence of clarity, any legal advice must err on the side of caution and thus assume that any “use” will constitute infringement.

Generally speaking, a company needs to know where it stands in order to assess the risks. If one does not know if one is infringing or not until the outcome of a litigation action, it becomes increasingly difficult to weigh up the risks. This uncertainty results in substantial cost to Australia, both in the cost of risk management and lost innovation.

Furthermore, allowing the courts to decide on whether infringement has or has not occurred will encourage expensive litigation procedures (which probably favour the deeper pockets of large pharmaceutical companies outside Australia).

Therefore, we do not consider this option would provide sufficient clarification, and is thus of no benefit to the patentee, any subsequent inventor, the competitor or the courts.

#### *Option C1 – Definition of exploitation does not include experimental use*

Whilst we agree that this would perhaps be the simplest way of providing an “experimental use” clause, we believe that this approach would further complicate the issue.

Firstly, this approach would further complicate the meaning of “exploit”, which has already been the subject of interpretation in a number of instances. Secondly, the question would still remain as to what constituted “experimental use”, particularly when considering any commercial orientation. Again, this would necessitate the courts determining the definition of “experimental use”, thus providing little clarity on the matter in at least the short to medium term.

As per option B, this approach would make it difficult to assess the risk and potential outcome of litigation.

Therefore, we are of the opinion that this option does not go far enough to clarify the situation.

#### *Option C5 – Exemption for exclusive permitted uses*

We believe that a company like ours essentially needs clarity as to what we can do and what we can’t do. Limiting an “experimental use” exemption to specific acts

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would minimise any ambiguity, and thus provide the clarity sought.

The uses that may attract exemption potentially include a wide variety of controversial uses such as clinical trials, which we also believe should be addressed. By excluding trials (for both investigational and regulatory purposes), we believe that Australian companies will be severely disadvantaged and thus development in Australia will be limited, and Australian companies encouraged to develop products overseas. Encouraging companies to conduct trials overseas would result in a loss to the Australian economy, including both jobs and revenue.

For the majority of Australian biotech and pharmaceutical companies, the United States is considered the biggest market, and thus the main target for product launch. Australian companies already struggle to compete in such a market. It is unlikely that, by allowing clinical trials, Australian patentees would be disadvantaged since the developed product is likely to be launched by them overseas where, generally, such clinical trials are allowed.

The United States Waxman-Hatch Act provides that the patentee may be given an extension of term to compensate for time taken to gain FDA approval, and in return pharmaceutical competitors can develop a product in order to gain FDA approval for an improved or generic drug so that it can be launched immediately after the patent term expires. The problem with the Waxman-Hatch Act is that, in its strictest interpretation, R&D on a drug not yet approved by FDA, or a drug approved but for a different indication than that sought by a competitor, could not be researched. Often, the failure of the drug or problems with approval by FDA are the result of problems with delivery of the drug. It is therefore highly desirable in the interest of patients to be able to explore the delivery of patented drugs by organisations other than the patent holder, with the view to launch a valuable product for the patient once the patent has expired.

The Patents Act 1990 provides for the extension of term of pharmaceutical patents for a period of up to five years. The Act also includes a 'spring-boarding' provision, which enables generic manufacturers, from the date the extension of terms is granted, to undertake pre-marketing regulatory requirements prior to patent expiry. Thus, an experimental use exception to patent infringement does exist for pharmaceutical patents during an extension of term.

We do not believe therefore that this type of exception should be limited to the term of extension, since developing new methods to deliver existing patented compounds is likely to take significantly longer than 5 years and is of general benefit for Australia. Furthermore, we believe that further research, whether investigational or commercial, would not interfere with the monopoly rights provided the invention could not be commercialized until after patent expiry.

Thus, we believe that this option warrants further consideration.

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*Option C7 – Exemption for fair experimentation, with inclusive permitted uses (C4 + C6)*

In determining whether an act is fair experimentation, several factors for consideration were listed, including the commercial effect on the patentee. As mentioned previously, we believe all types of experimentation are “fair” provided there was no commercial gain until after patent expiry. Therefore, we propose that any experimentation, including clinical trials, would not interfere with the patentees’ monopoly, thus would not constitute having a commercial effect and should therefore be permitted.

Acts that may be considered fair experimentation appear to include “developing an improvement to the invention”. Therefore, this may be construed to encompass new technology applied to existing compounds, for example a new method of delivering a patented drug compound. In many instances, the only method of investigating the new method of delivery is to run pharmacokinetic trials in humans.

We believe that in order to advance the technical field of the invention or improve the invention itself will, in some circumstances, require investigation in humans by means of a clinical trial.

Therefore, we agree that this option warrants further consideration and would encourage the broad interpretation of “commercial effect” and “improvement to the invention”.

*Option C8 – Exemption for experimenting “on the subject matter of the invention”, with inclusive permitted uses (C3 + C6)*

We find that this option may be considered contradictory and therefore somewhat ambiguous. On the one hand, the exemption is only available if “experimentation is the sole purpose of the act”, and on the other, permitted acts include “developing an improvement to the invention”. When it comes to a pharmaceutical compound, it is incredibly difficult to establish that any experimentation would be the sole purpose of the act. In other words, investigation into pharmaceutical compounds will eventually constitute a commercial orientation, whether as a potential license transaction or as a marketing opportunity, and usually as an improvement to the existing invention.

Thus, a literal interpretation of this option would result in no exemption existing for pharmaceutical research. We believe this would severely inhibit pharmaceutical development in Australia, and stifle the growth of Australian biotech and pharmaceutical companies.

Therefore, we do not consider that this option strikes a sufficient balance between encouraging innovation and the rights of the patentee.

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### Conclusion

Acrux strongly supports the need for a research exemption clause within the Patents Act, with our preference being to include clinical trials within the exemption as being experimentation. We do not consider that this would impact on the rights of the patentee, provided no financial gain could be made prior to the patent term expiry. Not to do so, we believe, would encourage Australian companies to conduct their investigations overseas and to prevent non-Australian companies conducting investigations in Australia, which would be detrimental to both Australians and the Australian economy. There is no benefit, in our view, to restricting research and development on patented drugs in Australia.

In reaching their recommendation we would like the Council to consider the financial implications for small and medium sized entities and the effect on the Australian economy, as outlined above.

Please feel free to contact us should you have any queries arising from the above submission.

Kind regards

Nina Wilkins Ph.D.  
Intellectual Property Manager  
Acrux DDS Pty. Ltd.

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