

Submission

By



to the

**Commerce Select Committee**

on

**Patents Bill**

July 2009

Agcarm  
PO Box 5069  
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**PATENTS BILL  
SUBMISSION BY AGCARM Inc**

This submission is from:

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I am available to appear before the committee to speak to this submission.

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**Key Points In Submission**

- **Agcarm opposes the presence of a springboarding provision (clause 138) for agrichemicals and veterinary medicines.**
- **Agcarm opposes the springboarding provision but submits that a patent term extension should be provided if clause 138 is retained, as per Australian and other overseas legislation.**
- **A carefully drafted experimental use provision that clarifies the extent of experimental use exemptions in New Zealand is supported by Agcarm members (clause 136).**
- **AGCARM members would prefer that opposition proceedings in which the parties can be heard are retained. Currently, the Patents Bill does not provide for this.**

**Introduction**

1. Agcarm welcomes the opportunity to comment on the Patents Bill, currently before the Commerce Select Committee.
2. Agcarm is an industry association of companies which manufacture, distribute and sell agrichemicals (or crop protection products) and veterinary medicines. Member companies are committed to ensuring that these products are used safely, effectively and sustainably. Agcarm represents 30 member companies ranging from global enterprises to small New Zealand-owned companies. More information about Agcarm is available at [www.agcarm.co.nz](http://www.agcarm.co.nz).
3. Many of Agcarm's members are involved in researching and developing

innovative products which bring new technology and greater efficiency to New Zealand agriculture.

4. Agcarm has consulted its 30 members in the preparation of this submission, including circulating a draft submission for comments. One member declined to support the final submission.
5. The Patents Bill represents a significant step forward for New Zealand's intellectual property legislation. Substantial progress will be made in bringing New Zealand into line with current international standards.
6. However, some areas of concern and uncertainty remain. Areas of concern are those provisions that if enacted would place New Zealand's patent legislation at odds with its major trading partners Australia and the United States, and weaken intellectual property protection over registered agrichemical and veterinary medicine products.
7. The Patents Bill is a very large piece of legislation. Agcarm has identified four key areas worthy of comment – springboarding, patent term extension, experimental use exception, and pre-grant opposition.

### **Clause 138: Springboarding**

8. The Patents Bill includes clause 138, a regulatory review exception also known as a springboarding provision.
9. This clause enables a third party that is not the owner or licensee of a patent to use an invention for 'uses reasonably related to the development and submission of information required under New Zealand law, or the law of any country, that regulates the manufacture...[or] sale...of any product'.
10. Clause 138 corresponds to existing section 68B of the Patents Act 1953.
11. Notably, this section was introduced in December 2002 under urgency (i.e. without any consultation with interested parties) for the benefit of Pharmac.
12. Clause 138 and section 68B allow the production, sale or use of a patented product, without the permission of the patent owner (or licensee), for the purpose of obtaining marketing approval prior to the patent term expiry.
13. Clause 138 is intended to reduce the delay in generic human medicines, including generic pharmaceuticals, entering the market after the patent for the product expires. This means that producers of generic products can begin the process of seeking marketing approval (which may take two to three years) before the expiry of the relevant patent.
14. Though targeted at pharmaceuticals, Clause 138 would also apply in other industries, such as the agricultural chemicals and veterinary medicine industries, where regulatory approval of products is also required.
15. Springboarding is a disadvantage to the patent holder as it reduces the effective patent period available to manufacturers of agrichemicals and

veterinary medicines by up to three years. The effective patent period for these products would typically be no more than 10 years under springboarding, given the time it takes to achieve the mandatory marketing approval.

16. Springboarding is a disincentive to bringing new technology into New Zealand, which means farmers and growers do not access the latest technologies available overseas.
17. In the absence of an extension of term provision, the presence of clause 138 in the Patents Bill continues to place New Zealand at odds with its major trading partners, Australia and the United States.
18. **AGCARM opposes the presence of a springboarding provision like clause 138 – especially without the facility for a patentee to apply for a patent term extension (discussed below).**

### **Patent Term Extension**

19. As background, in 1994 the term of a New Zealand patent was changed from 16 years to 20 years, to comply with the TRIPS Agreement that emerged from the GATT Uruguay round of trade talks.
20. At the same time, a provision allowing the term of a New Zealand patent to be extended from 16 years to a maximum of 26 years in cases where regulatory delay had occurred, was repealed.
21. There is no provision for a return to an extension of patent term in the Patents Bill.
22. As outlined above, Agcarm members do not support springboarding, which is disadvantageous to its members who are innovators of agrichemicals and veterinary products.
23. Agcarm believes that if the springboarding provision is retained for agrichemicals and veterinary medicines, a corresponding extension of patent term should be made available to patentees whose rights are affected by the ability of generic manufacturers to gain market approval for generic products in advance of the expiry of a patent for that product.
24. In addition, Agcarm submits that patent term extensions are an appropriate means to compensate owners of patents in the agrichemical, veterinary and pharmaceutical companies for the large cost of pre-market approval.
25. Canada is the only major trading partner of New Zealand that has a springboarding provision without providing an extension of term.
26. **Agcarm opposes the springboarding provision but submits that a patent term extension should be provided if clause 138 is retained.**

## Clause 136: Experimental Use Exception

27. The Patents Bill also includes an experimental use exception (clause 136) which provides that it is not an infringement of a patent for a person 'to do an act for experimental purposes relating to the subject matter of an invention if the act does not unreasonably conflict with the normal exploitation of the invention.'
28. Several activities which will fall within the definition of experimental use are defined in clause 136(2). These include determining how the invention works, determining the scope of the invention, determining the validity of the claims and seeking an improvement of the invention.
29. The experimental use provision included in the Bill attempts to clarify the situation in New Zealand.
30. There is no corresponding section in the current legislation. Experimental use of a patented invention has been covered by case law. The relevant decision is *Smith Kline & French Laboratories Ltd v Attorney General* (1991) 4 TCLR 199. In this case, the Court held that experimentation was non-infringing if it did not serve to advance the experimenter in the actual marketplace. It may be difficult to determine where a given activity falls (i.e. whether it is infringing or non-infringing) as this is often a matter of degree.
31. Therefore, the inclusion of the experimental use provision may be considered as providing clarity and certainty regarding the boundaries of this exemption. The proposed clause may encourage innovation by allowing experimenters to, for example, determine new uses for an invention without infringing a patent.
32. The question of an experimental use exception has been considered in Australia through consultation by the Australian Law Reform Commission and the Australian Advisory Council on Intellectual Property. These bodies recommended that an experimental use exception be included in the Australian Patents Act. This has been accepted by the Government. The wording of the suggested experimental use exception in Australia is the same as the wording used in clause 136 of the Patents Bill.
33. An experimental use exception is considered to encourage innovation.
34. **A carefully drafted experimental use provision that clarifies the extent of experimental use exemptions in New Zealand is supported by Agcarm members.**

## Pre-grant Opposition

35. The Patents Act 1953 provides the ability for a third party to oppose the grant of a patent for certain reasons by way of a hearing before the Commissioner of Patents. Since opposition is a proceeding that takes place prior to grant, it can delay the ability of the applicant/patentee to issue infringement proceedings until the opposition process is finalised.

36. The Patents Bill does not provide for pre-grant opposition procedures. Rather, the opposition procedures are replaced by a re-examination procedure (clauses 88 to 92). These re-examination procedures do not provide the opportunity for either the applicant or the person requesting re-examination to be heard and the grounds of objection are very limited.
37. The re-examination procedure does not include the objector in the process once the process is initiated. This means that pre-grant *inter partes* proceedings before the Commissioner will no longer be available and objectors will not have a say in what happens in the proceedings.
38. Often the pre-grant *inter partes* opposition proceedings result in a negotiated settlement between the applicant and opponent (in other words, the applicant's claims will often be amended to the satisfaction of the opponent). This interaction will be lost under the new re-examination process.
39. The Australian Patents Act 1990 has a pre-grant opposition provision.
40. The Patents Bill does provide for an inter partes revocation procedure before the Commissioner of Patents (clause 104). However, this is a post-grant procedure. As any patent that is the subject of an application for revocation before the Commissioner will be in force, it will often be at the advantage of the patentee to delay the proceedings for as long as possible. Delay will create uncertainty for third parties and will prevent or delay them from entering the market. With the present pre-grant opposition procedure, it is to the benefit of the patent applicant to have the proceeding resolved quickly and this also provides greater certainty to third parties.
- 41. Agcarm members would prefer that pre-grant opposition proceedings in which the parties are heard be retained. Currently, the Patents Bill does not provide for this.**

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For further information:

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