



Representing the Plant Science Industry

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13 May 2011

Committee Secretary
Senate Legal and Constitutional Affairs Legislation Committee
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Committee Secretary

On behalf of CropLife Australia, I provide the attached responses to questions taken on notice during the course of the appearance of Mr Daniel Quinn and myself as witnesses at the Senate Legal and Constitutional Affairs Legislation Committee Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 on 29 April 2011.

Please do not hesitate to contact me or CropLife's Policy Manager for Biotechnology and Minor (Mr Quinn) should you require clarification in respect to any aspect of this matter.

Yours sincerely, . .

Matthew Cossey
Chief Executive Officer

Attach:

Patent Amendment (Human Genes and Biological Materials) Bill 2010

**Senate Legal and Constitutional Affairs Legislation Committee Hearing
29 April 2011 - Questions Taken on Notice**

Witness	Hansard Page No.	Senator	Question
CropLife Australia	5	Humphries	<p>Question 1: Senator Humphries: There is an equivalent comment in CropLife submission:</p> <p>The Bill, in its current form, will have a devastating effect not only on the agricultural biotechnology industry, but also on newer chemistries in pesticide science that aim to imitate naturally occurring compounds.</p> <p>Can you describe one of those sorts of pesticides and illustrate how it would be affected by this legislation?</p> <p>Mr Cossey: So that is a new area we think it would capture, and if it occurs in our industry we can see that it must occur in other industries as well. It goes beyond straight biological material. As it stands, we believe it captures anything that even looks to replicate that synthetically or on a chemistry basis. If you like, I am more than happy to provide on notice a more comprehensive list of those new products that are either on the market now and would not be if this bill were law or that are on their way, both in Australia and globally.</p>
CropLife Australia	8	Xenophon	<p>Question 2: Senator Xenophon: I am trying to concertina my questioning. I am just trying to be helpful—as always.</p> <p>Mr Cossey: That EU decision is very specific to what it was regarding. I think Mr Quinn is well placed to put on the record exactly what that matter was with respect to.</p> <p>Mr Quinn: I understand that that case related to a specific trade - namely, herbicide tolerance—in a commodity that was exported from a country that had a very poor knowledge of property protection.</p> <p>Senator Xenophon: Which country was that?</p> <p>Mr Quinn I would have to take that on notice.</p> <p>Senator Xenophon: Sure</p>

Question 1:

An example of a class of chemical compounds that would be affected by the proposed legislation is the synthetic pyrethroids.

Synthetic pyrethroids are synthetic chemical compounds similar to chemicals that are produced by flowers of the pyrethrum family, which includes chrysanthemums. In 2009, synthetic pyrethroids comprised 18.1% of the global insecticide market with sales totalling \$2,078 million. Major active ingredients include:

- Lambda-cyhalothrin
- Deltamethrin
- Cypermethrins (including alpha and zeta cypermethrin)
- Bifenthrin
- Permethrin
- Cyfluthrin

These and a number of other synthetic pyrethroid compounds are used for a range of purposes in Australia, including as household insecticides, sheep and cattle treatments and crop protectants. If the proposed legislation were adopted then synthetic pyrethroids may well have been regarded as being substantially identical to a naturally occurring protein and hence not been able to obtain patent protection. This would have prevented the manufacturer from launching these products in Australia and the loss of an important tool in pest control.

Other compounds that have been developed from naturally occurring chemicals include:

- Compounds derived from Neem trees (azadirachtin)
- Spinosyns (derived from soil bacteria)
- Glufosinate-ammonium - synthetic copy of protein from soil bacteria
- Mectins (macrocyclic lactones) - synthetic copies of streptomycin protein
- Various pheromones
- Various plant hormones

Access to these and other future compounds would also be threatened by the proposed legislation.

Question 2:

Senator Xenophon's question referred to a decision by the European Court of Justice regarding a Monsanto patent on Roundup Ready soybeans. The following information is available on the public record. Further questions around details of the case should be directed to Monsanto.

Argentine growers have benefited from Roundup Ready soybean technology for many years. Approximately 95% of the soybeans grown in Argentina contain the Roundup Ready trait. For many years, Argentine growers used the technology extensively without paying for it. Initial efforts to develop a compensation system there were unsuccessful.

Monsanto simply wanted to be paid for the use of their technology. However, due to a change in Argentine patent law after the introduction of Roundup Ready soybeans, Monsanto's patent was disallowed and their ability to protect their intellectual property was compromised.

Monsanto searched for alternative ways to collect for the use of their technology and obtain a return on its research investment. One such approach was to enforce their intellectual property rights against Argentine exports to European markets. Beginning in 2005, Monsanto initiated several patent infringement actions against imports of Argentine soy meal that contained their technology, which is patented in Europe.

On 11 June 2010, Monsanto and importers Cefetra and Alfred C. Toepfer International signed an agreement settling a patent infringement action brought by Monsanto against those importers in the District Court of The Hague. The District Court accepted the parties' settlement and notified the European Court of Justice (ECJ), to whom the District Court had referred certain issues for interpretation, that answers to those issues were no longer necessary from the ECJ. Nonetheless, on 6 July the ECJ issued its decision on those issues.

In this case, Monsanto brought an action for patent infringement based on the presence of their intellectual property in processed soybean meal imported from Argentina. While the District Court of The Hague found that the gene was in fact present in the meal and infringed Monsanto's European patent, the Court asked the ECJ to rule on the applicability of the European Biotech Directive (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions) that seemed to provide conflicting guidance. The Directive suggests that for a gene patent to be enforceable, the gene needs to be functional in the infringing product. The ECJ decided that the Biotech Directive does not provide protection for soybean meal despite the presence of the gene – as you can't plant soybean meal and grow a soy plant.

The ECJ decision is very limited and does not reflect an international trend of refusing patents on biological materials. The applicability of the Directive to whole soybeans containing Monsanto's Roundup Ready trait, where the gene clearly maintains its functionality, was not at issue.