Overview

Research to realisation: the challenging path for novel pest management products in Australia

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Abstract In this Overview, we explore the linkages between basic research and the commercial development of novel pest management products in Australia. Despite the large volume of research in fundamental and applied aspects of entomology, very few new pest management products are developed and commercialised in Australia. Reasons for this include demanding and expensive regulatory requirements which (as in many other countries) mean that commercial development is the province of large multinational agrochemical companies. We describe the Australian regulatory system and the opportunities and difficulties it can present, using examples from recently registered Australian products, Magnet® moth attractant and the MOOV® range of insect repellents. The science behind these products is described in a series of papers in this issue of Australian Journal of Entomology. We also explore some of the commercial imperatives in novel product development, and aspects of the interactions between researchers and commercial partners. Finally, we discuss potential advantages of Australia as a locale for commercial development of novel products.

Key words commercialisation, Helicoverpa, mosquito, regulation, semiochemical.

INTRODUCTION

Our science should be good, but it should also be good for something. Many entomologists would agree with that sentiment, especially around grant application time. Indeed, to judge by the opening paragraphs of many applications, our crops and livestock would be devastated, our environment ravaged, and our very survival imperilled by hordes of ravenously insatiable insects if not for the dedicated efforts of a small band of entomologists, who are clearly in need of more funding. It would appear, then, that the development of innovative new tools in agricultural and personal pest management should be a frequent occurrence in Australia. However, that is not the case.

Why are so few novel pest management products developed and commercialised in this country? In this issue of Australian Journal of Entomology, four papers describe the commercial development of such products. They are very different – one (Magnet®) is an attractant based on synthetic plant volatiles that can be combined with insecticides and applied to crops as an attracticide for noctuid moths (Del Socorro et al. 2010a,b; Gregg et al. 2010). The other (MOOV®) is a range of personal insect repellents for mosquitoes, the bush fly, Musca vetustissima Walker, and biting midges (sandflies), based on native Australian Melaleuca oil (Greive et al. 2010).

Products such as these, developed, first registered and commercialised within Australia, are notable for their rarity. Following the registration of Magnet®, we asked the Australian Pesticides and Veterinary Medicines Authority (APVMA – the statutory body that regulates pesticide availability and use in Australia) to search their records for similar examples. Registration of new pest management products has been a national responsibility for only 16 years, having previously been a matter for the states. Nevertheless, some APVMA staff recalled registrations from the previous state era. Only seven comparable examples were provided, and on searching the literature we discovered that all but two of these had been previously registered or developed overseas (Table 1). The exceptions were both biological pesticides, the Helicoverpa nuclear polyhedrosis virus Vivus® (Ag Biotech Australia 2009), and the fungus Metarhizium anisopliae (Green Guard®; Hunter et al. 2001). In each case, strain selection and improved formulation methods were used to adapt technologies previously commercialised overseas to Australian conditions. It therefore appears that there is a dearth of Australian developed and commercialised pest management products, at least those that involve the development of new active ingredients.
There is a similar dearth of research aimed at developing new products in Australia. We searched the last five volumes of *Australian Journal of Entomology*, and classified the research papers therein as (1) basic science, including systematics, ecology, behaviour, genetics; (2) applications of science to pest management using existing tools, including sampling methods, thresholds, integrated pest management (IPM; Zalucki *et al.* 2009), biological control and evaluation of new (but already commercialised) insecticides against selected pests, insecticide resistance; and (3) development of new commercial tools for pest management, including novel biopesticides, semiochemicals and new insecticides. We identified 179 papers (73.7%) in category (1), 63 papers (25.9%) in category (2) and only two papers (0.4%; Koul *et al.* 2004; Urech *et al.* 2009) in category (3). In part, this apparent lack of research effort on new tools may be because commercially oriented research is published elsewhere, or not published at all because of commercial-in-confidence considerations. Nevertheless, it is difficult to escape the conclusion that commercially oriented research in pest management is very limited in Australia.

There are some obvious reasons, and some less obvious ones, why research on commercial development of new products is not more widespread in this country. We do not argue that commercialisation is the only way that pest management advances. It is just one pathway to the adoption of novel technology. Some advances such as the introduction of new classical biological control agents are not commercial, because introduction of an effective and self-sustaining natural enemy is intended to eliminate a pest’s economic impact, leaving no scope for ongoing product sales. Other advances not readily amenable to the commercial route include improvements in sampling methods and thresholds, the choice of selective insecticides, and improvements in understanding the ecology of key pests, allowing better implementation of IPM. However, the commercial route to market is generally the most efficient for non-persistent tools such as pesticides (whether of synthetic or natural origin), augmentative or inundative biological control agents such as biopesticides, semiochemicals such as pheromones, kairomones and repellents, and resistant varieties of plants, including genetically transformed ones. The potential of this approach can be estimated by the size of the insecticide market in Australia, which is around $300 million annually for crops, and constitutes an unknown proportion of the approximately $600 million in animal health products (ABARE 2008). Similarly, transgenic cotton has now captured over 80% of the cotton market in Australia, estimated at around 195 000 ha in 2009/2010 (ABARE 2009) despite a license fee of $300/ha. The financial incentives for commercially oriented research appear to be there.

A hint of the reasons why there is not more emphasis on the development of commercial products in Australian entomology can be found in a comment from the regulatory authority in relation to Magnet® (APVMA 2009a): ‘It is rare when all research and development work for an agricultural chemical product – including the sourcing of the necessary funds – occurs exclusively within Australia. . . . given that the development of a new agrochemical is such an enormous task, the registration this new product is the final step of a remarkable achievement.’ CropLife International (the umbrella organisation of major agrochemical manufacturers) estimates that to develop a new chemical from initial discovery to commercial release as a pesticide costs between $A225 million and $A270 million, and requires about a decade of work by a substantial research team (CropLife International 2009). Such resource requirements mean that commercialisation of new active ingredients is generally the province of large multinational companies such as Bayer, Dow, Dupont, Monsanto and Syngenta.

But is the development of new products always such an ‘enormous’ task? Are there certain categories of products, and potential niche markets, that can be exploited by entomologists in Australian public and private research organisations? What are the challenges (and the advantages) of Australia as a location for commercial development of such products? How does such work fit the culture of major public research organisations in Australia, such as universities?

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**Table 1** Novel pest management products identified by staff of APVMA as having been developed entirely within Australia

<table>
<thead>
<tr>
<th>Product</th>
<th>Active ingredient</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>1080</td>
<td>Sodium fluoroacetate</td>
<td>Developed by the Western Australian Agriculture Protection Board for fox and wild dog control in the 1950s, but previously used for rodent control in the USA</td>
</tr>
<tr>
<td>Beat-a-bug</td>
<td>Garlic/chili/pyrethrum/piperonyl butoxide mix</td>
<td>Ingredients known as botanical pesticides or synergists for many years, although the mixture is novel</td>
</tr>
<tr>
<td>Dryacide</td>
<td>amorphous silica</td>
<td>Registered as a stored grain protectant in Australia in 2001, but previously registered for the same purpose in the USA in 1998</td>
</tr>
<tr>
<td>Vapormate</td>
<td>Ethyl formate</td>
<td>Registered as a stored grain protectant in Australia in 2006, but previously registered for the same purpose in India in 1996</td>
</tr>
<tr>
<td>Achieve</td>
<td>Tralkoxydim</td>
<td>Registered as a herbicide in Australia in 2006, but previously registered for the same purpose in the USA in 2006</td>
</tr>
<tr>
<td>Vivus</td>
<td><em>Helicoverpa</em> nuclear polyhedrosis virus</td>
<td>Registered in 2002 for control of <em>Helicoverpa armigera</em>. An Australian strain selection of a pathogen previously developed for control of American <em>Helicoverpa</em> species</td>
</tr>
<tr>
<td>Green guard</td>
<td><em>Metarhizium anisopliae</em></td>
<td>Registered in 2007 in Australia for control of grasshoppers and locusts. Other strains of the pathogen have been developed overseas for a range of pests</td>
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</tbody>
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THE PROCESS FOR REGISTERING AGRICULTURAL CHEMICALS IN AUSTRALIA

Most, if not all, developed countries have processes for registering new agricultural chemicals, and regulating existing ones. These systems aim to ‘... ensure that the health and safety of people, animals and crops, the environment and trade are protected’ (APVMA 2009a) and that products are shown to be efficacious. Regulatory processes are crucial components of all advanced pest management systems, serving to balance the advantages of new pest management technologies for users such as farmers against the risks to society in general.

Since the federalisation of pesticide regulation in Australia, the APVMA (http://www.apvma.gov.au/index.asp) is the key organisation regulating pesticides and similar products prior to the point of sale. Agricultural chemical products, particularly those relating to pest management, are defined by the Agricultural and Veterinary Chemicals Code Act 1994 (part of the legislation governing APVMA activities) as: ‘... any substance or organism used to: destroy, stupefy, repel, inhibit the feeding of, or prevent pests on plants or other things; destroy a plant or to modify its physiology; modify the effect of another agricultural chemical product; or attract a pest for the purpose of destroying it’. This definition is broader than many entomologists appreciate and encompasses products that may not, at first glance, be considered ‘agricultural chemicals’, requiring regulation.

It is unlawful to apply an agricultural chemical to a crop, or a repellent to a person, unless it has been registered by the APVMA. It is also unlawful to apply a registered pesticide in any way that is inconsistent with the label. Consequently, the label is a legal document, and much attention is devoted during the registration process to ensuring that the details on the label comply with registration requirements. For the researcher interested in developing natural-based insect repellents, the Australian market can be a trap if the regulatory requirements are not recognised. With many small manufacturers producing and selling unlicensed products in health food stores, markets, alternative grocers and some pharmacies, to the casual observer personal insect repellents based on essential oils could appear to be an unregulated arena. All personal insect repellents must be registered with the APVMA whether they use synthetic chemicals such as N,N-diethyl-meta-toluamide (DEET), picaridin or natural essential oils.

The requirements for registration are set out in APVMA’s Registering Agricultural Products: Manual of Requirements and Guidelines (MORAG; APVMA 2009b). They are extensive. There are two versions of MORAG – AgMORAG and VetMORAG, for agricultural and veterinary products, respectively. Each runs to five volumes and over 1200 pages. Coincidentally, one translation of the feminine name Morag is from the Hebrew, meaning ‘Akin to God’.

In AgMORAG there are 25 categories under which a product can be registered. Many of these apply to existing chemicals which are being reformulated (e.g. generic products for which the patent has expired), or to new uses, or to research purposes (permits for field testing). The categories in which genuinely novel pest management technologies are likely to fit, and a decision tree indicating how the appropriate category is determined, are shown in Figure 1. The most relevant categories for our purposes are Biological Agricultural Products, and category 1/category 2 pesticides.

A Biological Agricultural Product is defined as one where the active ingredient(s) comprise or are derived from a living organism, with or without modification. The definition includes materials of particular interest in insect pest management such as pheromones, crude plant extracts, microbial agents and other living organisms such as microscopic insects and some genetically modified organisms. Products that are purified, fully identified and where a residue detection method exists are defined as conventional agricultural chemicals (category 1 or 2), and this includes botanical pesticides such as rotenone and nicotine. Chemicals that are produced synthetically (even if the crude base material is of biological origin) are also treated as conventional chemicals.

Once the category has been determined, APVMA requests data in 10 parts (Table 2). Each of these parts may have a number of modules in which data can be requested, and the quantity and type of data required within the modules are determined by the nature of the application, including its category (Table 2). Data requirements are less for category 2 and Biological Agricultural Products. During evaluation the APVMA seeks advice from other authorities, notably the Office of Chemical Safety, Standards Australia, Therapeutic Goods Administration (TGA), Australian Quarantine and Inspection Service, Environment Australia and various other commonwealth, state and overseas regulatory agencies. The target time frame for completion of a category 1 assessment is 15 months, but some recent assessments have taken longer. Though not a category 1 product, the application for the MOOV® range was submitted to the APVMA (then called the National Registration Authority) in September 2002 and received approval in November 2005 – thus taking more than 3 years to achieve registration.

The assessment process is searching. It is unlikely, for example, that beer would pass registration as a category 1 chemical due to the presence of small amounts of carcinogenic nitrosamines (Dorado et al. 2001), not to mention the acute and chronic toxicity of the active ingredient, ethanol. Nor is it likely that it would meet the requirement of a ‘... history of safe use’ for classification as a category 2 chemical. It is fortunate that we do not spray beer on crops. It is, however, sometimes used as a pesticide by home gardeners for the control of slugs (Hagnell et al. 2006). Technically, this could amount to unlawful use of an unregistered pesticide, though the use of a pesticide confined in traps might not be considered to pose the same risks as one that is sprayed on plants, and the level of regulatory assessment might be different.
COMMERCIAL CONSIDERATIONS IN THE REGISTRATION PROCESS

The direct costs of registering an agricultural chemical are relatively modest. The current APVMA fee for assessment of a category 1 application is $A48 860. Category 2 and biological product assessments may be significantly less costly. However, the costs of providing the data required (Table 2) may run into many millions of dollars. In this regard, it is clearly desirable to register a product as a biological product or category 2 chemical. In the latter case, the key phrase is ‘... commonly used household/industrial chemical with a history of safe use’. Unfortunately, it is susceptible to different interpretations, and an example from the development of Magnet® illustrates the complexity and the potential commercial impact of this uncertainty.

In the initial research for Magnet® the compound (Z)-3-hexenyl salicylate was the most attractive single chemical that we tested in olfactometer studies (Gregg et al. 2010). It was also present in most of the best blends we tested, both in laboratory and in field experiments (e.g. Del Socorro et al. 2010b). Although little is known of its natural occurrence in plants, it is readily available from many specialty chemical suppliers, and is apparently a common constituent in perfumes, where it is described as having a ‘... very tenacious, green, woody balsamic odour’ (Interchim 2009). We considered that this would qualify as a history of safe use, and in 2004 submitted a registration application to APVMA for an attractant blend that contained five plant volatile components, one of which was (Z)-3-hexenyl salicylate.

After about a year of assessment, APVMA advised that the other four compounds were acceptable, but (Z)-3-hexenyl salicylate was not considered safe because it was not on the GRAS (Generally Recognised as Safe) list maintained by FEMA (the Flavour and Extract Manufacturer’s Association; FEMA 2009), and had not been evaluated by JECFA (the Joint FAO/WHO Expert Committee on Food Additives; JECFA 2009). APVMA required that either this component of Magnet® be removed or full toxicological and metabolic profiles be supplied (Table 2). As the latter option would have cost many millions of dollars, we opted to reformulate the product and sought acceptable compounds structurally and functionally similar to (Z)-3-hexenyl salicylate as substitutes in the blend. This meant extensive repetition of efficacy testing in the laboratory and in the field, and we eventually settled on two replacement compounds, butyl salicylate and anisyl alcohol, which did have FEMA
GRAS status. In combination they gave equal or slightly better attractiveness to cotton bollworm, *Helicoverpa armigera* (Hübner) when blended with the other four components, compared with the rejected five component blend. This six component blend was submitted in a new registration package in 2006, and registration was granted in February 2009.

Similarly, while the three MOOV® repellents described in Greive *et al.* (2010) were successfully registered, another MOOV® repellent application was abandoned because of extra toxicology requirements. The natural essential oil used in this repellent, *Leptospermum petersonii*, was to be used at a level of 0.3% w/w. When developing this formulation we believed that *L. petersonii* was excluded from the requirements of the APVMA. In addition, a competitor repellent was already using *L. petersonii* at a level higher than we were proposing and the TGA allowed its use as an excipient in Listed Medicines at up to 5% w/w. Armed with this information we applied for registration only to find that our product was rejected based on the potential toxicology of the *L. petersonii* oil. The Health Risk Assessment from the Office of Chemical Safety for *L. petersonii* oil concluded that ‘The presence of *L. petersonii* oil in leave-on products at any concentration is not supported.’ Given the evidence of market place use of *L. petersonii* in leave-on products at levels higher than we were proposing, in conjunction with the TGA approval of *L. petersonii* for Listed Medicines, we found the rejection of our usage of *L. petersonii* confusing. Ultimately the registration application was withdrawn as commercial realities outweighed the expense of satisfying the extra toxicological requirements.

Registration requirements can impact in unexpected ways on product formulation, which are often not understood by reviewers for scientific journals. This includes excipient ingredients as well as active ones. An example is provide by the blue dye added to Magnet®, so that moths killed by ingestion of the product can be distinguished from moths that may have died from other causes. We chose commonly used food dyes for research (Del Socorro *et al.* 2010b) even though we knew they persisted poorly on foliage, and in the bodies of dead moths. An anonymous reviewer criticised the uncertainties in our interpretation of the results because of this. We could well have avoided the problem by using more persistent industrial dyes. However, they may have triggered requirements from APVMA for toxicological, metabolic and other data that would have made their use impractical.

Another example concerns the types of insecticides recommended for use with Magnet® as an attracticide. The product itself does not contain any insecticides – they are added by farmers immediately before application. This meant that only insecticides already registered for other purposes (usually cover sprays directed at larvae) on our main target crop (cotton) were considered. The Magnet® label specifies three insecticides (methomyl, thiodicarb and spinosad), and because of the legal status of the label, these are the only ones that can be used with it. They are insecticides we found to be effective

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**Table 2** Summary of registration requirements for category 1 (1) and category 2 (2) chemicals and Biological Agricultural Products (B), as described in AgMORAG (APVMA 2009b). +++, ++ and + are subjective assessments of the extent of data in modules required to meet guidelines under each part

<table>
<thead>
<tr>
<th>Description</th>
<th>Notes</th>
<th>Data required for category:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Application overview</td>
<td>Executive summary, expected use pattern, comparable international registrations, draft label</td>
<td>+++ +++ +++</td>
</tr>
<tr>
<td>2 Chemistry and manufacture</td>
<td>The active constituent, formulated product, manufacturing process, quality control, specifications, batch analysis, storage stability, analytical methods, packaging and labelling</td>
<td>+++ + +++</td>
</tr>
<tr>
<td>3 Toxicology</td>
<td>Acute toxicity: active constituent, the product, short-term toxicity (repeat dose), sub-chronic toxicity, long-term toxicity (repeat dose), carcinogenicity, reproduction, developmental, genotoxicity, toxicity of metabolites and impurities, other adverse effects, toxicity of mixtures, human toxicological data, no-observed-effect level, acceptable daily intake, acute reference dose, poisons scheduling, first aid instructions and safety directions</td>
<td>+++ + +</td>
</tr>
<tr>
<td>4 Metabolism and kinetics</td>
<td>Bioaccumulation, studies in target and non-target animals and plants, pharmacokinetics, biotransformation, target organs</td>
<td>+++ + +</td>
</tr>
<tr>
<td>5 Residues and trade</td>
<td>Establishment of residue definition, maximum residue limits, withholding periods, trade implications including export interval</td>
<td>+++ + +</td>
</tr>
<tr>
<td>6 Occupational health and safety</td>
<td>Hazard, occupational exposure, risk management and workplace information</td>
<td>+++ ++ ++</td>
</tr>
<tr>
<td>7 Environment</td>
<td>Environmental chemistry and fate, environmental toxicology (birds, mammals, aquatic organisms, non-target invertebrates, non-target vegetation)</td>
<td>+++ ++ ++</td>
</tr>
<tr>
<td>8 Efficacy and host crop/animal safety</td>
<td>Assessment of the results of experimental trials for efficacy and safety, effect on following crops or non-target crops, organoleptic tests, effects of residues on subsequent processing of crops; safety to non-target crops pharmacologic studies, compatibility studies</td>
<td>+++ +++ +++</td>
</tr>
<tr>
<td>9 Other trade aspects</td>
<td>Assessment of trade risk relating to non-food residue situations</td>
<td></td>
</tr>
<tr>
<td>10 Special data requirements</td>
<td>Antibiotics and genetically manipulated organisms</td>
<td></td>
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</tbody>
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at the maximum concentrations we tested. Other insecticides (some of which are more selective, and that might have made Magnet® even more compatible with IPM than it is) were not effective at the maximum tested concentrations (Del Socorro et al. 2010b). Why did we not test higher concentrations of these insecticides? It was because their use would have resulted in a higher level of residues in the crop, on a per metre of treated row basis, than applications for which the insecticides were already registered. This would have triggered extensive requirements for toxicological, environmental and trade-related data.

These examples illustrate the need for early and extensive consideration of the regulatory implications of any novel pest management product, in consultation with potential commercial partners and perhaps some of the numerous consultants who facilitate applications for registration. Failure to do so may result in expensive and delaying complications for the application.

OTHER COMMERCIAL CONSIDERATIONS

Commercial partners are motivated by the potential income from the new product. For them, development and regulatory costs are an investment, similar to a production plant. The return on investment will be decided by the size of the market, and the profit margin of the product. The latter depends on the cost of production and the price. Viable pricing options are likely to be strongly influenced by the cost of alternative technologies, such as conventional pesticides. In the case of Magnet® the alternative technologies consisted of conventional pesticides such as the synthetic pyrethroids and endosulfan, which generally cost less than $20/ha, or the more expensive selective chemicals such as indoxacarb, spinosad and rynaxypyr, which cost around $50/ha. To be cost competitive in such an environment, the plant volatile compounds that were feasible active ingredients had to be ones already used for other purposes such as fragrances, food additives and cleaning products. Apart from the existence of information required for registration, such chemicals are likely to be inexpensive, readily available and of known purity.

Commercial pragmatism may lead to compromising scientifically attractive ideas for developing new products. For example, an interesting volatile for Helicoverpa spp. is the terpenoid (−) germacrene D. Most of the antennal receptors in H. zea, H. virescens and H. armigera are specifically tuned to this compound, and it is known to be attractive to H. virescens (Mozuraitis et al. 2002, Røstelien et al. 2005). We found blends containing a crude preparation of germacrene D were very attractive to H. armigera (Gregg et al. 2010). However, there are no commercial uses for germacrene D, and even crude preparations are expensive. Moreover, antennal receptors respond more strongly to the (−) than the (+) enantiomer, and preparation of enantiomerically pure material is extremely expensive. We were quoted approximately $800 per mL to synthesise this volatile, which is about three orders of magnitude more than the most expensive volatile in the Magnet® formulation. We concluded that while attractants containing (−) germacrene D might prove very effective, they would not be cost-competitive with current conventional insecticides.

Similarly, when developing an insect repellent based on essential oils, the cost of the oil can have a significant impact on the final price of the product. This price is primarily dictated by plantation number and size. For example Eucalyptus oil can be purchased for around $20/kg while L. petersonii oil sells for around $180/kg. Seasonal effects such as drought will also have an impact year to year. When a competitive DEET-based product sells for $5.47 in supermarkets, using rare oils can be commercially detrimental. No matter how effective the product, the consumer only has a certain amount of elasticity in what they are willing to pay for a particular type of insect repellent.

The size of the market is another important consideration for commercial partners. Major pests such as Helicoverpa spp. and mosquitoes represent a potentially large market, but it is still advantageous if a product has activity on a range of species. We have therefore tested Magnet® on a range of other noctuid species such as American horticultural, the Asian soybean looper Thysanoplusia orichalceae (Fabricius), the cotton looper Anomis flava (Fabricius), and various armyworm and cutworm species. We are also investigating its applications for diamondback moth, Plutella xylostella (L.) (Plutellidae). Similarly, MOOV® is registered for repelling not only of mosquitoes, but also the bush fly and biting midges, thereby broadening its market. Conversely, highly specific products such as pheromones may have a very limited market, or be relevant only for a minor pest, and thus not justify significant expenditure on any regulatory costs that may be required, or on commercial production facilities (Jones 2001). The lack of commercial incentive for highly target-specific products is a problem for IPM, because these are precisely the type of products required for selective pest control. The difficulty is analogous to the reluctance of insecticide companies to register products for use in minor crops, which has led APVMA to introduce a category of Minor Use Permits allowing insecticides registered for major crops to be used on minor crops with fewer regulatory requirements than would be the case for a full registration.

THE ‘PUBLISH OR PROTECT’ DICHOTOMY

Entomologists in research institutions where publication in refereed journals is essential for professional advancement are often reluctant to become too involved in product development because they fear that commercial-in-confidence considerations will restrict their ability to publish. The protection of intellectual property can delay publication (often for substantial periods), but does not ultimately prevent it. The work described in the Magnet® and MOOV® publications in this issue was ready for publication more than 5 years ago, but inability to disclose the active ingredients restricted us from doing so. In Australia the Cooperative Research Centres (CRC) program, especially with the emphasis on public-
private collaboration under the previous government, has provided an environment where these limitations are treated sympathetically. Conversely, the renewed emphasis on public good outcomes in the CRC program will work against the commercialisation of novel pest management products. The same is likely with the introduction of the ERA (Excellence in Research for Australia) initiative to universities, with its heavy reliance on metrics-based publication criteria.

Solutions to the ‘publish or protect’ dichotomy could include persuading research institutions to take greater account of impact (in the real world, as distinct from the world of journals) in the promotion of researchers. However, universities will respond to criteria that influence their research funds, and it will be interesting to see how the final ERA guidelines recognise impact at the end-user level. Another change that might be useful is a process whereby refereed journals could accept publications for review, but keep active ingredients confidential (much as many universities allow commercially sensitive post-graduate theses to be examined confidentially).

Ultimately, however, the balance between publication and intellectual property protection is a matter for researchers and their commercial partners, and mutual understanding of each others’ needs is the key. Often, protection of the IP that would be disclosed in publication is less critical than it may seem. Patent protection may be narrow, and not prevent the development of ‘knock-off’ products. It may even facilitate the development of generic equivalents after the period of patent protection ends. A commercial partner that respects the market and competes on the basis of price, technical understanding, service and credibility with the relevant industry may find that patenting is advantageous, but not crucial. The credibility of researchers (not just in science, but in industry too) will help in this regard.

AUSTRALIA AS A LOCALE FOR DEVELOPING NOVEL PRODUCTS

The data-intensive requirements of the Australian regulatory system are not unique. Most developed countries have similar systems. Isman (2006) described the system in the United States and concluded that, despite the existence of concessional requirements for ‘reduced-risk’ insecticides such as botanicals, regulatory costs remained a significant obstacle to the development of new products in that country. He also pointed to the need for botanicals to be cost-competitive with modern selective insecticides. However, he noted that the rapid growth of organic farming in western countries has led to opportunities for products that could be classed as Biological Agricultural Products in the Australian system. Nor are the regulatory obstacles all of recent origin, in Australia or elsewhere. Jones (2001) reviewed the registration procedures for semiochemicals in the UK, and concluded that ‘The regulatory hurdles in the UK for semiochemical-based control products for insect pests are currently so high that it is doubtful that any such products will be put on the market in the near future.’

The silver lining for companies that get products through rigorous regulatory systems such as those of Australia, the UK and the USA is that the products are likely to have substantial credibility in regard to safety and efficacy in countries with lower standards. While we are not aware of any agricultural examples in relation to Australian-developed products, MOOV® is now sold in Asia and the Middle East because its Australian registration, and early discussions in potential markets for Magnet® in south-east Asia have also indicated the value of Australian registration. Another advantage in Australia is the system of permits for research (APVMA 2009b), which (subject to the provision of preliminary data on toxicity and efficacy) will allow products to be trialled over realistic areas. In the case of Magnet®, these trials had to be conducted over many square kilometres, because the product targets the highly mobile adult stage of the pest. The permit system allowed us to discover the potential for area-wide impacts on target moth populations, something that we would never have known from small-plot trials.

A further advantage of Australia is the size of farms, and the level of commercial and technical understanding of farmers and consultants, compared with many other countries. This is particularly so in more recent established and technically demanding (and therefore more scientifically progressive) agricultural industries such as cotton, the main target crop for Magnet®. The development of this product would not have been possible without the enthusiastic support of growers and the consultants they employed. They gave us unfettered access to their properties, and to the data they collected for pest management purposes. Beyond that, they helped us understand what characteristics of the product would be needed to ensure uptake by the industry, and to what uses it could be put. It is hard to imagine this level of support in many other countries.

The development of MOOV® was made particularly easy in regards to field testing for mosquitoes, the bush fly and biting midges as high abundance of these insects frequently occurs in Queensland. It had been hoped that the MOOV® insect repellents would also be indicated for other biting insects such as fleas, and for leeches. However, due to drought conditions sufficient field populations could not be located, and indicative laboratory-based testing was not acceptable for registration.

While it is difficult for Australian research institutions to compete in basic insect chemical ecology with the large teams and impressive facilities and infrastructure of North America and Europe, we have some unique advantages when it comes to working in the field. We believe the particular niche of Australia in the international development of novel pest management products (at least for cotton) is in field testing. Partnerships between Australian and overseas researchers, where the basic work is done overseas and the field testing is done in Australia, would appear to have many potential synergisms.

CONCLUSION – SCIENCE AND ITS APPLICATIONS

As Louis Pasteur famously noted ‘There are no such things as applied sciences, only applications of science.’ We argue here
that the ‘development’ part of ‘research and development’ is no less important, and no less scientific, than the ‘research’ part. Indeed, the application of research may consume more resources and take more time than the basic science. It is often the bulk of the iceberg – hidden under the surface. It requires patience, determination and on occasions the ability to let commercial pragmatism, rather than pure science, drive the process. It can bring particular rewards to its exponents, when they see practices changing for the better when farmers or consumers use their new product. While developmental research can sometimes involve tedious and predictable experiments, conducted primarily to satisfy regulatory requirements, this is not always the case. Sometimes the commercial perspective leads to new insights that are not available from basic research which focuses on the current paradigms of theory.

An example is the selection of volatile chemicals for inclusion in insect attractant blends such as Magnet®. The current paradigm is that, because the chemosensory receptors of insects are narrowly tuned to particular volatiles, we should identify host plants (or primary host plants, for polyphagous species), and mimic their volatile profile. Anonymous reviewers criticised Gregg et al. (2010) for not doing so, and for using a seemingly less structured approach. However, all previous attempts to develop plant volatile-based attractants on the mimicking paradigm have failed, because profiling any plant requires the inclusion of compounds that are either unavailable, too expensive or will encounter regulatory difficulties. This pragmatic difficulty led us to try what we called ‘super-blends’ – combinations of volatiles that may not occur in nature. The fact that some of these were very attractive to naïve \textit{H. armigera} moths suggests that the model of insects recognising host plants by integrating information from specific receptors and comparing it against some kind of innate template may be inadequate, and we have proposed an alternative model. This example illustrates the nexus between applied and basic research that Pasteur envisaged. In this example, we have explored some aspects of this nexus, and the challenges therein, in relation to the development of novel products in pest management. We can only hope this field of our science continues to prosper in step with advances in basic entomology.

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