

Environment, Sustainability & the Food Supply Challenge

96 pages of insight

Creating an economically, socially and environmentally acceptable future for everyone



INSIDE: How Government, science and business are addressing the major challenges facing us today



- How we address the food supply challenge.
- How business and science are addressing climate change issues.
- How we address a sustainable and environmentally sound future for everyone.

Second chance

Research and development companies spend a lot of money search for new active ingredients they can patent and exploit, a business model that keeps rising in cost as regulations become more restrictive. Less often discussed are the companies that work with ingredients whose patents have expired. Wendy M. Grossman gets redeveloped.

► **Everyone today is familiar with generic drugs. Large pharmaceutical companies adopt the high-risk strategy of pouring funds into research efforts to discover new blockbuster products they can patent.**



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Eric Gussin

They have 20 years after filing for said patent to exclusively exploit those discoveries, after which the chemical compounds are available for anyone to use. Generic drugs are less risky for a company to sell, since their efficacy and safety have already been proven and there's been enough time to discover any unexpected side effects, but they are also less profitable.

The crop protection market works much the same way for many of the same reasons. Today in the EU, developing a new pesticide and achieving regulatory approval for it may take up to ten years and cost €250 million. As older pesticides continue to come out of patent, it's logical that there are companies that take advantage of existing approvals to specialise in the post-patent market.

Research and development

Barclay Chemicals (no relation to the bank) is one of these mid-market companies. Founded in 1979 and privately owned, most of Barclay's 50 employees are based at its west-of-Dublin headquarters, which are home to a regulatory support group, a technical laboratory, a production facility, and the company's back office operations. The regulatory group, explains Barclay technical director Irene McGrath applies to register products in countries throughout Europe.

The technical lab supports both the regulatory group and the production facility. Most of Barclay's products are manufactured on the company's premises, although a small percentage are subcontracted. Overall, the company manages 195 approvals in 18 countries and, in common with other crop protection companies, sells to wholesalers through a distribution network that, says McGrath, can ensure the salesmen handling the company's products are fully trained.

While some post-patent companies, especially those in India and China, do simply sell generics, Barclay and others like it research already known active ingredients seeking to redevelop them by creating their own formulations in the light of today's greater knowledge base. The hope is to boost their effectiveness and efficiency while increasing their safety. McGrath says that the company currently actively sells products based on approximately 12 active ingredients and is working on another six to eight in the short to medium term.

"The gestation period for a post-patent product is about four years," she says. "So what do we think will be appropriate for the marketplace in 2015? We take on board as much information as we can."

In the time since today's post-patent active ingredients were patented, explains Eric Gussin, Barclay's UK area sales

manager, the technology of formulation has "significantly" moved forward. "So it's possible that Barclay can come up with a better formulation today than the original company could."

Cost basis

It is an altogether less risky approach to the crop protection business than the research and development companies that are best-known in this area.

"The active substance itself gets the benefit of what's gone before," says McGrath, "but we still have to produce a large data package on all of our products and that requires a lot of preparation and testing to a very high standard. The key difference is that the business model for research and development companies is all structured around the development of new active ingredients, and the problem with that approach is that the cost of doing that is increasing enormously year on year."

One of the reasons for increasing costs, says Gussin, is that the health and safety regulations are getting more onerous every year. The upshot is that the number of new active ingredients coming onto the market is significantly less than in the 1980s.

"Our business model," Gussin says, "is not research and development – we're not looking for brand-new active ingredients, but trying to boost the market for quality post-patent materials. The market is probably 60% post-patent molecules, and that percentage is increasing as the industry produces fewer new molecules."

How many new ingredients the market needs is a disputed question. McGrath believes that while the market's current needs are met by existing ingredients, developing new products will allow farmers to stay ahead of problems such as resistance. Gussin thinks that it's important for the research and development end of the market to continue to be viable for companies producing new substances.

"We could have a new resistance problem or pest just waiting to show itself," he says. "The weeds and diseases and insects we're trying to control today may be different in five years' time. We need affordable options and different chemistry to give us a mix of choices."

Updating the toolbox

While some ingredients have been discontinued because they've fallen afoul of changing regulations that deem them too hazardous, others, says McGrath, have fallen out of the system because they've become too expensive to support.

Says Gussin, "A product approved in the early 1980s was approved based on the rules of the time, which were based on what we knew. Twenty years on, we know a lot more about a lot more things, and these ingredients come up for renewal and there are new ways of testing, and with new information the amount of work required to get new approval meeting modern standards can be very expensive. So the



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product might still be safe, but without generating the data to prove it... My opinion is that we have lost a number of good active ingredients because the industry can't afford to defend them, not because there are environmental issues around them.

The cost squeeze, he says, is on from all directions. Taking just the UK as an example, you have a finite land mass subject to increasing and conflicting demands: the growing population wants more leisure time and more food, both of

which require land. At the same time, the amount people are prepared to spend on food in Western countries decreases every year. "So," asks Gussin, "how can we help farmers and growers produce food as cheaply, affordably, and safely as possible? We need to make good use of land, good use of crop protection products, and where we think Barclay fits in is to look at the existing molecules in the marketplace and re-present them to growers in an affordable and safe way to complement what the research and development companies are doing."



What's in a label?

No one follows you home from the DIY store to check up, but the label on every can of pesticide sold in the UK, domestic or professional, is a statutory-controlled document whose instructions you are legally required to follow. At the professional level, some compliance schemes do monitor farmers' chemical use to ensure it complies with regulations.

Labels are subject to review and are revised as rules change or new discoveries are made about either the ingredients' effectiveness or their side effects. Only the latest version is approved. Farmers are supposed to send back out-of-date stock for repackaging and replacement. Home and garden versions typically have much lower concentrations and more "user-friendly" labels; it's actually illegal for amateurs to use the professional product.

"Barclay spends a lot of money making sure we have the best label we can find for that particular product for that particular use in terms of efficacy, safety, and environmental protection," says Gussin. "It's a balancing act between making the product as flexible as possible for the user, but safe. Sometimes it's difficult because the farmer wants something he can use every day at all times of the day."

Gussin also calls it a "false belief" to think that just because products seem to have the same active ingredients they're all the same. "The quality and detail on the labels might be very different," he says.

Formulation

The original patent-holder does its research work before filing for a patent on an active ingredient. In the case of glyphosate, the world's most commonly used herbicide, the patent was filed by Monsanto in the 1970s under the brand name "Roundup".

With glyphosate, says Gussin, how it's formulated is extremely important. "If it's just applied on its own without other co-formulants, it's taken up so slowly by plants that it has almost no effect. So the rest of the formulation is crucial." This means including surfactants and wetting agents, and, says, Gussin, the exact percentages can make a big difference to the end product's performance.

The exact original recipe is, of course, the intellectual property of the original patent-holder. A post-patent research department might examine it but not copy it directly.

"In our research we do study the reference product to determine how our product compares to the market leader," says Gussin. "But our idea is not to copy it but to look and see if we can make it more effective and cost-effective for the grower to grow more affordable food. That sort of formulation expertise is in-house at Barclay. We spend a lot of money doing trials to find the right formulation for post-patent products."