Beautiful south

When it comes to finding new outlets for their technical skills, northern European fine chemical producers are missing out. Dr Rob Bryant explores the unbranded sector and the vagaries of the north-south divide

Fine chemical companies will find sunnier business climes in the south.
Illustration by Rob Wilcockson

During the 1970s and 1980s the European fine chemical industry could be divided by its pharmaceutical customer-base into two sectors: innovative (also known as the branded sector) and generic (the unbranded sector). This classification coincided with a division along geographic lines: 'the North' (UK, Germany, the Netherlands and Switzerland) and 'the South' (Italy and Spain). Enjoying a presence in the north and south, France participated in both sectors.

It became received wisdom among northern European companies that the valuable business was to be found in the supply of novel intermediates to the major drug developers, and the southern Europeans could be left to supply the generic industry. Italy developed an early lead in active pharmaceutical ingredient (API) manufacture by taking advantage of a privileged patent regime. But, canny operators that they were, both the Italian and Spanish API producers could be heard complaining about the terrible prices and cut-throat competition that afflicted their businesses. And the more sober northerners accepted that their greater technical skills were better adapted to the ever-changing demands of the innovative pharma industry. At the time, this division of labour made sense and it was possible to make a good living in both sectors.

Looking at today's landscape, it is clear the companies that 'hitched themselves to the new chemistry bandwagon' are suffering miserable profits and an ever-decreasing supply of new projects. And the southerners continue to 'cry all the way to the bank'.

Market breakdown

As the pharma industry has matured and its size increased, the unbranded sector has become increasingly important, particularly in terms of volume of scrips. But what are the relative sizes of these market sectors at the level of the pharmaceutical fine chemical (PFC) industry?

It depends on who one believes. For many years, Switzerland-based industry expert Peter Pollak has published estimates of the global value of PFC sales. These support the commonly held thesis that the global value of sales at this level is around US$50 billion, of which US$12-15 billion is available to third-party suppliers, ie outsourced. Other industry commentators have published similar figures, although many have preferred to avoid making valuations because of the many uncertainties inherent in such calculations – a fact implicitly acknowledged by Pollak's intentionally approximate estimates.

But from the perspective of fine chemical business development, what may be more useful is a detailed estimate of the real level of captive versus third-party sales in all sectors of the pharma industry. In examining the whole issue of the value of the various sub-sectors of the PFC industry, the results of a relatively simple analysis are surprising.

The key factor that changes the accepted picture is the significantly higher contribution to end-user sales made by PFCs in the unbranded sector, both for the US and European generic markets and in particular in the developing world (estimated at US$20 billion). The results of such an analysis are shown in the Figure 1. From the global pharma sales in 2002 in four regions of the world (Western Europe, the US, Asia and 'rest of world'), estimates are made for the corresponding value at the API level, and these are further split by outsourced and captive market shares.

Analysis shows that the third-party value of PFC sales in 2002 to the unbranded sector was US$30 billion, compared with barely US$5 billion for the branded sector. This offers some insight into why the northern European fine chemical industry is looking a little sick, while the southern European and Asian industries enjoy far greater success.

Even if this approximate method of calculation is open to argument, the results are sufficiently dramatic that the essential message is clear: generics account for a very substantial sector of the global fine chemical market. It seems that many fine chemical companies have a false view of

the value of the available market and, at a time when they are struggling to find new outlets for their technical skills, this unnecessarily limits their ability to sustain and develop their businesses.

There are several important conclusions to be drawn from this fresh view of the PFC business, some of which can be examined in greater detail, including:

•Business conduct. It is commonly stated that when a company supplies services to a brand-holder, this prohibits participation in the unbranded sector. This position is both untrue and logically unsustainable. Untrue, because many successful companies generate sales across the whole industry. Cambrex, for example, offers a wide range of APIs via its Profarmaco division, as well as supplying toll-manufacturing and custom synthesis services to the multinational innovative sector. Orgamol, Omnichem and Helsinn are other well-respected companies that benefit from this marketing flexibility. And the logic can't be sustained because PFC suppliers cannot make any impact on a pharma company's ability to compete effectively within its business sector, whoever they supply. Pharma companies compete on the basis of whether they are able to develop and sell effective medicines. In a business where there are no shortages of suppliers, the source of chemical intermediates or even APIs is immaterial to their success. When was the last time anyone heard a pharma executive state that, through its excellent relationship with its loyal PFC suppliers, its business grew by 15% in the last financial year?

The balance between risk and reward in the innovative sector has changed, as customers demand cost-plus pricing and full control of IP rights

•Risks versus rewards. Over the past 5-10 years the balance between risk and reward in the innovative sector has changed as customers demanded greater transparency, cost-plus pricing and full control of intellectual property rights. In the unbranded sector, customers generally have much less interest in how even advanced intermediates are made, so long as they fulfil their quality and patent-infringement criteria. An innovative company can reap higher margins under such circumstances. And, in contrast to the innovative sector, the demand uncertainties are greatly reduced, particularly for suppliers of intermediates.

•Maximising technology strengths. Developing and investing in a technology is easier to justify and more rewarding if a PFC producer can expect to supply its products and services to the entire global industry. It is common to encounter a specialist with only a modest share of a global technology sector simply because it is unable to sell to more than 10-20% of its potential customers. Although many customers will claim this is a necessary consequence of the need for confidentiality, it actually results in both sides losing the benefits of scale and project development experience.

•Value-addition. Contracts to supply PFCs to innovative pharma companies can be divided into two main types: contract or toll manufacture, and custom synthesis. The first category involves the operation of a process that has been largely formulated and developed by the customer. It will often involve the manufacture of an API or an advanced intermediate, rarely a basic intermediate. The price will be set on a cost-plus basis, since the customer will have a good idea of the process economics. Custom synthesis contracts can offer greater scope for innovative thinking by the supplier, but these are rarely offered for advanced intermediates or APIs. Another feature is that Asian competition tends to be fiercer for basic intermediates. Thus margins in either case are more constrained, with gross margins of 20-40% being typical.

In contrast, API production companies serving the unbranded sector tend to demand advanced intermediates and will very often outsource the process development of the API. Generally, therefore, this sector offers far greater scope for technological ingenuity (especially for intermediates suppliers), with concomitant rewards in margins.

Putting concepts into practice

Although the technical challenges involved in supplying the unbranded sector are essentially the same, the commercial side of the business is very different. Anyone with experience in dealing with the southern European or Asian fine chemical industries will understand the contrasting way in which new projects are identified and supply contracts won by API manufacturers from these regions. Companies with a history in contract manufacture will need to sharpen their marketing skills and develop a broader supply base for their intermediates. Access to good advice on the 'ins and outs' of patent law are also important.

	US$ billions Branded	Unbranded	Totals
Captive	22	7	29
Third party	5	30	35
Totals	27	37	64

Figure 1: Breakdown of the PFC market by value sectors in 2002. Source: Brychem, using IMS data for global end-use sales in 2002 (US$401 billion).

A number of companies have chosen to acquire additional competence through partnerships and acquisitions. This is an ideal way for a medium-sized player to extend its business into the unbranded sector. Asian companies are open to such approaches because a Western partner offers improved access to higher value markets, among other things.

Another approach is to buy into the southern European industry, as US-based Cambrex has done, as well as the UK's Yule Cato, which has a successful Spanish PFC operation – Uquifa. A third solution would be to combine with an unbranded PFC specialist from Asia. Although less common, this could be an attractive solution if the terms were right. Certainly, in the unbranded pharma industry itself, this type of acquisition is far from rare.

Moves to independence

More than ever before, fine chemical companies that focus on supplying products and services to the global pharma industry must develop a greater independence in exploiting their precious technological resources. Even though the creation of new products naturally gives the innovative pharma sector the power to control the way in which a novel drug is initially manufactured, it is simply unacceptable to agree that the customer should dictate the PFC industry's conduct, once the period of exclusivity has expired. By exploiting its technologies to the fullest, a confident and independent fine chemical industry will offer a far better resource for the production of pharmaceutical fine chemicals. SM

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