The impact of emerging countries – often referred to by the acronym BRIC (Brazil, Russia, India and China) – in the broadly defined pharmaceutical sector has become one of the hottest issues to emerge over the past couple of years. Some analysts confidently predict that the centre of gravity for activities such as pharma, clinical and chemical development, as well as production – both primary (active substance) and secondary (final product) – will undergo a massive shift towards China and India. In this article, we will present a broad-brush overview of the developments occurring in these two countries in terms of pharmaceutical outsourcing.

TWO PROMISING EMERGING COUNTRIES
China and India are largely considered as the two most promising emerging countries. China is increasingly viewed by both industrial and financial investors as the place to be, given that it has:

- A massive population, that is rapidly becoming increasingly affluent.
- An ever-expanding economy – GDP growth having averaged over 7% per annum over the past five years and showing little signs of abatement. Many predict that by 2010, China will have overtaken both Germany and Japan as the world’s second-largest economy.
- Rapid growth fuelled by both domestic consumption and exports. China has emerged as a major manufacturing hub for a number of industries; as an example, half of the world’s shoe production and 70% of the world’s toy output originates from China.

Although India has – until recently – been overshadowed by China, this country is now staging a comeback as an investor’s favourite. This revival is associated with a number of factors, such as:

- A large and growing population – second only to China
- The availability of an educated English-speaking labour pool
- A legal and financial system largely inherited from the British
- The easing of tensions between Pakistan and India
- A gradual liberalisation of the economy and less dirigiste policies adopted by the government.

In the pharmaceutical fine chemicals field, the profile of both countries has continued to increase (see Figure 1). The Chinese fine chemicals industry – whose origins are rooted in government policies aimed at ensuring self-sufficiency in ‘vital’ sectors such as textiles, agriculture...
and health care – has traditionally focused on basic building blocks and commodity types of active ingredient. These are produced by a multitude of state-owned plants – a fragmentation which reflects both the size of the country, as well as logistical hurdles; rivalry among the various provinces also plays a role. While their emphasis was mainly on the domestic market, excess output was often sold through traders in the export markets at rock-bottom prices; witness, for example, the case of fluoraromatics where Chinese competition has prompted a massive shake-out of the supply-base in the West.

Gradually, the supply structure in China has evolved and consolidated as market forces have been allowed to play their role, with privately-owned enterprises now co-existing side-by-side with state companies. Also, the Chinese pharmaceutical fine chemicals industry is increasingly ‘trading up’ – that is, moving into more sophisticated segments such as early phase development services and custom synthesis. In product groups such as beta-lactam antibiotics, for example, the Chinese industry has now achieved a leadership position.

Similarly to China, the Indian fine chemicals industry has its roots in the 1960s as part of the self-sufficiency programmes implemented by the government – the original focus being on off-patent active pharmaceutical ingredients (APIs) for the domestic market. Given the peculiarities of India and its social system, a myriad of small- to medium-sized companies eventually emerged. Several companies also engaged in the production of dosage forms – sheltered from foreign competition by high import duties.

Gradually, the supply structure has started to consolidate, with many players being forced out of the market as a result of factors such as:

- Rivalry among producers – very often the same API can be offered by fifty, if not more, suppliers
- Escalating operating hurdles
- Problematic access to funding sources

Over the years, the Indian industry has scaled back activities in basic building blocks given mounting competition from China, and has shifted more towards custom synthesis and early phase development services, as well as moving downstream into generic dosage forms. Companies like Dr Reddy, Ranbaxy and Cipla have clearly stated their leadership ambitions in these fields.

MAJOR FORCES IN THE GLOBAL PFC SECTOR

Although precise statistics do not exist, it is fair to say that China and India are increasingly becoming major forces in the global pharmaceutical fine chemicals (PFC) sector:

- They have a dominant market share in some product groups where they have outperformed Western suppliers
- They have a de facto monopoly situation in off-patent APIs, where EU-based suppliers (the traditional backbone of the industry) have been forced out of the market given an ill-conceived IP framework
- There is a growing interest, sparked by Chinese and Indian sources, among both Western customers and fine chemicals producers

Indeed, a recent Arthur D. Little industry survey indicated that most large pharmaceutical companies were planning to substantially increase their share of fine chemicals outsourcing out of China and India – this being expected to reach 20-30% by 2006-2007, compared with 5-10% currently (see Figure 2).
Also the focus of outsourcing is evolving; pharmaceutical companies envisage sourcing not just simple basic building blocks or ‘sun-set’ APIs, but also early-phase development services, as well as more advanced intermediates – something that would have been unthinkable only a few years ago. Some companies like Eli Lilly and Merck & Co are even thinking of moving part of their medicinal chemistry activities there, or entering into long-term contractual agreements with local service providers.

Western fine chemicals suppliers are also increasingly jostling for position with respect to China and India. Indeed, the increasingly competitive environment is forcing them to reassess their strategies and take a more realistic view of the threat posed by this set of players – as they now realise that this is both real and here to stay.

Applying the maxim “if you cannot beat them – join them”, various Western sellers are scrambling to source part of their input requirements (such as starting intermediates) out of India or China – the overall idea being to both suppress raw material costs and avoid investing in own in-house capacity. Others, such as Borregaard, Rhodia and Tessenderlo, have set up their own industrial base in China or India – either alone or in partnership with a local player – as a strategy to consolidate access to low-cost inputs or tap the potential offered by the local domestic market.

The next step would be a full relocation of the production-base to India or China – the vendor keeping only some operations such as R&D or product finishing in the West. This set-up – though not yet implemented for fine chemicals – is similar to those already adopted by various other industries such as toys, footwear and dyestuffs.

This interest in China and India has been sparked by various factors, including:

- Access to an ample, chemically-trained labour pool who respond to motivation and are eager to work hard.
- A receptive climate, even for chemically-related activities. This is a far cry from the opposition increasingly surrounding these types of operations in the West.
- Flexible labour practices.
- Considerable advancements achieved by many players in terms of reliability and quality standards. Many Indian and Chinese suppliers have demonstrated both an eagerness and an ability to learn quickly.
- Last but not least, lower input-costs compared with a Western base.

Within this framework, the general perception by and large is that China and India are way more cost-competitive than Western countries for fine chemicals manufacture, as reflected in the vastly lower prices at which they are able to offer their products (see Figure 3). In China and India, for example, FTEs (Full Time Equivalents at which early phase development work is priced) are only 30-40% compared with those prevailing in the West. Labour costs and investment requirements per unit of installed capacity also represent only a fraction of those in the West.

All of this translates in substantial apparent cost-advantages for Indian and Chinese suppliers, while flexibility and access to a qualified labour pool provides them with additional pluses.

**WHAT FUTURE FOR WESTERN PFC SUPPLIERS?**

Does all of this mean that the days of Western suppliers are numbered? Most probably the answer will need to be treated with a degree of caution as the future may not be as straightforward as expected. Within this framework, three scenarios can be envisaged for the role of China and India as outsourcing centres for pharmaceutical fine chemicals (see Figure 4, page 76).

**The first scenario** calls for a massive and rapid relocation of the pharmaceutical fine chemicals supply structure for both...
development and full-scale production to China and India. In this scenario, pharmaceutical customers continue to insist on the lowest possible cost alternative, while the cost differential between Western and Indian/Chinese suppliers continues to widen.

Another extreme scenario calls for Western suppliers to regain their traditional leadership, while Chinese and Indian competition gradually falls away. Triggering factors behind such a scenario could include:

- Some high-profile setbacks suffered by customers in their dealings with China and India
- The introduction of trade barriers by Western governments in an effort to protect local jobs
- Inconsistencies in the technology or regulatory environment, leading to a major change in the overall competitive environment
- A rapid narrowing of cost differentials – following, for example, massive inflation in China and India

Such a scenario seems highly unlikely.

A more likely scenario calls for an increasing symbiosis between the West and China/India. With such a set-up, we would see a sharing of roles between the two regions in terms of primary pharmaceutical outsourcing. For Western suppliers, this scenario clearly implies a redefinition of their traditional scope of activities and mode of operation, as well as continuous efforts to ‘out-innovate’ in terms of both service and technology.

CONCLUSION

Irrespective of the scenario, some developments can be predicted with a fair degree of confidence:

- Growth of fine chemicals demand in China and India will continue to outpace Western levels
- At least among ‘first-tier’ Chinese and Indian suppliers, technical and commercial sophistication will continue to increase – catching up with best Western standards
- The availability of qualified labour, as well a receptivity for fine chemicals-related investments and activities, will continue to be in favour of China and India
- Consolidation of the overall supply structure will further accelerate in China and India, as the market matures and free market forces are allowed fully to play their role

In this context, it clearly emerges that outsourcing primary development and manufacturing out of China and India is certainly an option worth serious consideration. However, it is important to remember that sourcing out of these countries should not be viewed as a ‘hassle-free’ endeavour.

Therefore, before dropping Western vendors and rushing to China and India, it may be worth considering the following set of principles (which can be abbreviated to THINK™):

- Thoroughly evaluate the opportunity for outsourcing out of these areas compared with alternative options
- Haste is the most deadly trap – avoid jumping to hasty conclusions and applying short-cuts and ‘one-fits-it-all’ solutions
- Be Inquisitive. Check and turn over every stone before taking a decision, carefully taking into account all the various factors and building in possible contingency plans
- Negotiate up-front. Redefining the terms of a cooperation or contract later on may well prove to be extremely difficult
- Keep a firm overview through trusted in-house personnel
- Take ‘extreme caution’ as your policy and guideline
- Manage expectations of a quick pay-off or a smooth ride

Applying these basic principles will greatly enhance your ultimate chances of success.

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