Generics' appeal to innovative pharma

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Abstract Selling innovative drugs and generic drugs is as different as selling rockets and sneakers. It is, therefore, not surprising that innovative pharma companies have difficulties in developing strategies for entering and exploiting selected generic markets. In spite of barriers to entry, their interest in specific generic segments is definitely high. And we do believe that this interest will result in increasing generic activity of innovative pharma players — even if selling sneakers requires building new capabilities for rocket traders.

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OF ROCKETS AND SNEAKERS

R&D ('innovative') pharma and generic pharma growth rates are high in comparison with other industry sectors and both are in the business of marketing drugs — this is pretty much where the similarities end. For people not familiar with the pharmaceutical industry, it is hard to understand how different the go-to-market strategies are. Different product development times, portfolios of between 10 and 100 times more products and more aggressive, often cost-based, competition in the generic sector explain the faster pace that generic players are forced to maintain as compared to their innovative counterparts. These differences manifest themselves in very different cultures in both worlds.

As a result of the difficulties in differentiating their portfolios, generic companies have to manage cost more aggressively in order to be prepared to comply with reimbursement changes and aggressive moves of competitors. Sourcing and production are notoriously neglected areas in R&D pharma, as high gross margins do not leave as much room for value creation in production as in other parts of their operations. Generic R&D is focused on achieving numerous product approvals ready for launch on the day of patent expiry at low risk, that is, with high-quality registration files that may be used in various jurisdictions. While timely launches are also commercially important for R&D pharma companies, launching new products is a comparatively rare event for innovative sales forces and there have been cases whereby mid-sized R&D pharma companies had 'forgotten' how to launch a new product. In International Non-proprietary Name (INN) or substitution markets, generic companies aggressively promote substitution at dispensers. In branded markets, generic sales forces are, in many cases, known to be more aggressive than R&D pharma sales lines that have historically placed more emphasis on relationship building with

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prescribers. In many countries, generic sales forces have higher detailing frequencies as they need to promote to pharmacies in addition to prescribers and have to detail far greater portfolios.

Innovative companies, in general, recognise that exploiting opportunities in the generic market is a major challenge to them. At the same time, they recognise with frustration that, by not exploiting the generic opportunity in their core therapeutic areas, they have strategically decided to give up on more than 50 per cent of all prescriptions — written by 'their' prescribers in the therapeutic areas that they believe to understand particularly well, sometimes for the active principles that they originally discovered. It is as intriguing as it is deceptive to believe that the party that has 10 years of experience in detailing a patent-protected drug and managing its lifecycle should be able to more effectively exploit that experience post patent expiry.

For some R&D companies, this vision takes shape when existing innovative marketing and sales entities or operations become available due to either the lack of new products or subsequently major adverse healthcare reforms resulting in excessive sales resources, as they have been the trigger for the recent restructuring efforts in R&D pharma. Such a situation often resurfaces the discussion about selectively exploiting generic market opportunities. The subsequent process in agreeing on the strategy and role of 'our first generic business' can prove tedious:

- Generic business models are more complex than those in R&D pharma — especially if one includes some of the specialty pharma models — as generic players are looking for ways to differentiate from (generic) competition (Figure 1).
- The scope of the business requires decisions about geographies covered, range of general and specialist practitioners targeted and degree of integration along the generic value chain planned. The composition of the generic portfolio

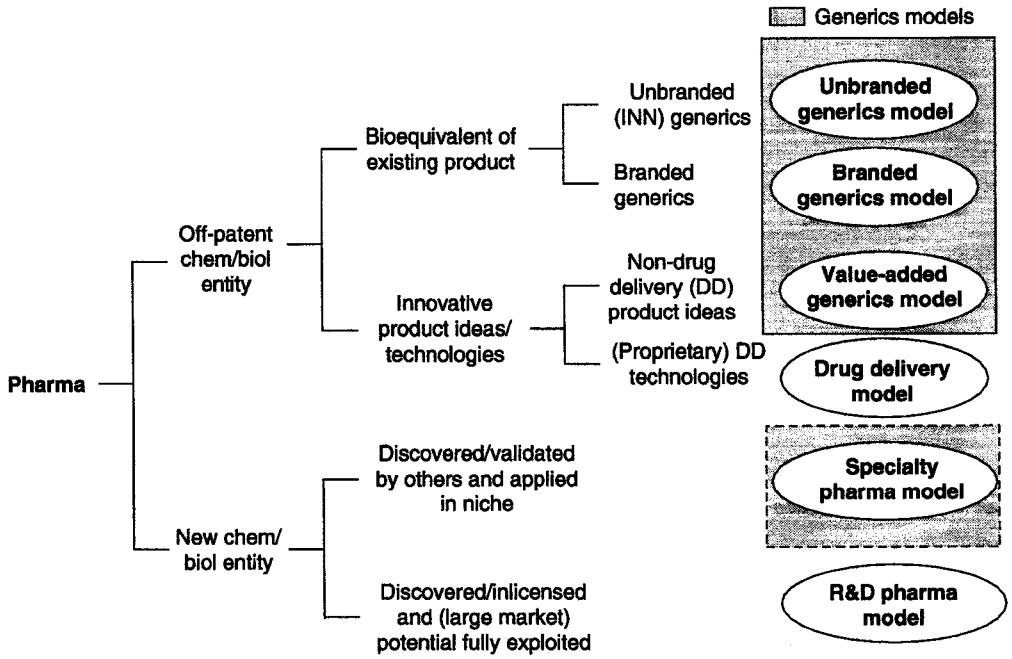

Figure 1: Selected pharma business models
Source: Abolon Limited.

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offered to prescribers is more strategic than in the innovative pharma world: A greenfield generic portfolio may be structured according to the prescribing habits of the target practitioners — product availability is comparatively less of an issue. The shock to the assigned R&D pharma team: Prescribing patterns of 'their' specialists have never been looked at before — for example, a urologist does prescribe pain products, anti-infectives, incontinence and erectile dysfunction products, dermatology products (eg, haemorrhoids), Rx vitamins and a range of (often not reimbursed) OTC products. Most innovative companies would not try to address these prescribing needs as 'one-stop shops'. It is still more complex as physicians in different countries widely vary in their prescribing mix, often due to regulatory differences.

- Governance questions quickly turn political: Is the generic business to report to the most senior board or to the head of Marketing & Sales? Which body should decide whether a generic product opportunity should be exploited or not? The former questions results from the misconception that functions other than Marketing & Sales are less critical for successful generic businesses, and the latter from the conviction that there are a range of important reasons other than lack of commercial appeal as to why products should *not* be launched.

Given these difficulties, it would be helpful to have a few case examples for successful transformations of R&D pharma companies into generic operations and vice versa: But there is no good example! Novartis never 'turned into' a generic company and pursued with its generic subsidiary what financial investors would call a 'buy and build' strategy. One could argue that the commercial success of Schwarz Pharma, as recently as in 2003 the fifth largest generic company globally by sales after the company had just re-entered the generic market, with its US omeprazole generics was the end of their generic success since, as R&D pharma companies do, they focused marketing and sales activities on one product with outstanding sales potential, neglecting the need for a broader generic portfolio. This is particularly true in the highly competitive 'unbranded' US market. US generic players like Barr and Watson have built their specialty pharma operations as separate units. Also, Teva has always strictly separated the development and marketing of its blockbuster Copaxone. No doubt, those transformations have been driven equally by strategic concerns about the sustainability of Teva's impressive margins and the potential for a re-rating by capital markets. Interesting examples for transforming generic companies into R&D operations are some of the Indian companies originally led by Dr Reddy's: After numerous setbacks, Dr Reddy's R&D department has gained international recognition by out-licensing NCEs in diabetes to 'established' R&D companies. Even if these programmes have been discontinued in the meantime, there is no doubt that the vision and persistency of their 'promoters' and superior cost structures should help some Indian players finally manage that transformation — it may just take more time than originally expected. Selling sneakers is not straightforward for rocket manufacturers.

R&D PHARMA'S RATIONALE FOR GENERIC ENTRY

Notwithstanding these difficulties, there are a number of good reasons for R&D pharma to step back and consider in how far ownership of a generic business may create shareholder value.

The arguments fall into six categories (Table 1):

1. *Generic defence through authorised generics:* Controlling the timing and pricing of the launches of authorised generic versions of patent-protected drugs limits the pie remaining for other generic players after

Table 1: Benefits of generic businesses to innovative pharma

	Key aspects
Generic defense through authorised generics	Generic deterrence by allocating the available generic pie to affiliated organisation ('authorised generics') Capturing undiluted value of generic pie (as opposed to partnering with a preferred generic partner)
Additional EBIT from new business opportunities	Growing into new business areas (additional EBIT and EPS contribution) Establishing new fast-growing business areas (EPS growth)
Negotiation advantage with regulatory authorities	Goal of freeing up resources within national healthcare budgets to allow higher pricing and reimbursement of innovative medicines
Stabilisation of industry/price structure	Launching branded (supergeneric) products into the mid-market segment to stabilise the innovative high-price segment rather than widening price gap between innovative high-price and (generic) low-price products
Synergies between innovative and generic businesses	Exploiting the available therapeutic area expertise (R&D pharma) and market intelligence about emerging generic threat (generic pharma) Applying (generic pharma's) cost consciousness in R&D pharma and increase capacity utilisation in production
Transfer of growth-limiting 'tail-end' products	Increasing the innovative business's focus and top-line growth by transferring selected low-growth tail end products to generic subsidiary

Source: Abolon Limited

patent expiry. Pfizer has launched generic versions of blockbusters Diflucan, Neurontin, Zoloft and recently Norvasc through its US generic company Greenstone and, supported by recent jurisdiction on authorised generics, will probably launch Lipitor generics in 2009. Although difficult to prove given limited available data, especially the lucrative 180-day generic exclusivity for successfully challenging US patents can be severely impacted by the launch of authorised generics. Building generic businesses only to fend off generic competition to proprietary NCEs, however, falls short of the real potential in generics.

2. *Additional EBIT from new business opportunities:* Detailing generics in core therapeutic areas may be a more logical business extension and synergistic area than entering unrelated therapeutic areas. Sanofi-aventis has bundled its generic activities under the Winthrop name and is investigating growth opportunities on their likely contribution to value creation case by case, resulting, for example, in the acquisition of an equity stake in Zentiva.
3. *Negotiation advantage with regulatory authorities:* Healthcare spending is highly correlated with the gross domestic products (GDPs) of economies. It is unreasonable to assume that the cost for innovative treatments will outgrow GDP growth forever. Rapidly reducing the cost of older therapies after patent expiry through generic substitution will 'free up' resources that can be used to reimburse innovative treatments. The obvious counter-argument that the low-cost and high-cost drugs do not have to be offered by the same group is clearly weaker under those scenarios in which supply (generic and R&D pharma players) and demand (payors like PBMs, insurances, sickness funds) are increasingly consolidated. For example, Novartis, through its Sandoz generic operations, would be able to negotiate with a buyer representing

numerous payors through key account managers currently representing the 'innovative' portfolio only, after minor changes in organisational responsibilities. One may argue that in highly price-regulated markets, an innovative company might be the preferred owner of the generic business. In France where discounting generics is increasingly restricted by regulatory authorities, bundling innovative drugs or OTC products and generics provides a clear, if not distinctive, advantage to the generic business that a stand-alone entity would not be able to play out.

4. *Stabilisation of industry/price structure:* Innovative treatments launched are increasingly more costly, although this may not always be true in a pharmacoeconomic sense. By contrast, the prices for off-patent products only know one direction: downhill. The idea of establishing a mid-segment between expensive innovative and low-cost generic products has its precedent in the FMCG (fast-moving consumer goods) market, where the various preferences of customers are addressed by offering different packages of product, service and price in order to capture the full surplus of each buyer segment. Due to the regulatory environment, the concept is more difficult to implement in the pharmaceutical practice than in FMCG. In certain (niche) branded markets, however, generic companies themselves have identified and exploit market inefficiencies: Stada, for example, markets certain oral contraceptives under strong brand names at higher prices than the originator. Similarly, in Portugal, the average generic prescription has a higher value than the average innovative prescription. An innovative player occupying the mid-market segment with a branded portfolio of generic and specialty pharma products is likely to achieve a premium positioning as can be observed in Krka's branded target markets. This has helped Krka to achieve valuations that would make some innovative companies envious. This argument is more applicable to branded than to INN or substitution markets.
5. *Synergies between innovative and generic businesses:* It is obvious that, in spite of the differences between their business models, the 'ideal' combined generic/R&D pharma business should be able to realise synergies that are most obvious in production where innovative pharma has been least aggressive. Innovative pharma companies rarely lower the cost of their products to the level of generic entrants by the time of generic entry. Generic companies can teach innovative players to manage their production cost since gross margins play a more meaningful role in highly price-sensitive industries. Sourcing from the most cost-efficient sources available, however, is the reason why Italian marketing partners of innovative originators have in various cases increased their gross margins and market share *simultaneously* after patent expiry by lowering their product prices to the prevailing generic price level. It may, therefore, not come as a surprise to see Southern-European pharma companies enter the generics world only recently. New business opportunities like biogenerics increase the requirements of generic companies to design complex clinical trials and to develop sophisticated clinical marketing strategies, tasks that will be hard to outsource and doubtlessly kick in during the next decade when the wealth of small-molecule patent expiries has come to an end.

   Soft synergies like superior competitive intelligence (eg, on the likely entry of generic competition over time), exchange of CRM (customer relationship management) data and increased cost consciousness should

be of commercial interest as well. Depending on the product characteristics, Barr makes a decision on whether a women's health product should be marketed by its generic operations or as part of its specialty women's health business.

6. *Transfer of growth-limiting 'tail-end' products:* R&D pharma portfolios are heavy on older products that are beyond peak sales. New product introductions and key products occupy a large share of sales capacity that the industry has now started to reduce. A generic operation detailing several hundred products by frequently mutating detailing slots is the better owner of such 'legacy' or 'tail-end' products — and may even be able to reinvigorate those products' growth potential.

Several of these arguments are hotly debated by strategists and the industry. Some, however, have received more and more attention and appear very compelling with recent dynamics in various pharma markets. For example, the generic industry's outcry over, and legal action against, the launch of authorised generics, especially through proprietary generic operations, is strong indication that this strategy has the potential of severely hurting the generic industry as a whole. The 'Novartis argument' of better positioning an R&D pharma company against consolidating buyer power springs to mind when learning about the major German (AOK) sickness funds, for the first time as one buying group, negotiating a 37 per cent discount with a number of smaller generic companies in Germany in early 2007, only a few months after the details of the latest healthcare reform have been determined — increasing their negotiating power must be a key goal for generic companies even in what are regarded as branded markets today. The observation of bundling innovative products and generics, mentioned above, to evade legal restriction on generic discounting is another intriguing example.

It is, therefore, not surprising that R&D companies start to appreciate the niche strategic positioning of their generic divisions, for example:

- Pfizer has experienced Greenstone to be a powerful tool in retaining some of the value of its blockbuster drugs, especially since exclusive authorised generic launches provide powerful differentiation in such competitive markets as the US.
- Boehringer Ingelheim's generic subsidiaries Bedford Laboratories and Roxane are active in the injectible and hospital generic markets and are rumoured to be as cash generative as they are well managed.
- Novartis is finally reaping the benefits of the integration of Hexal and EonLabs, with the 2006 operating profit being more than twice the corresponding 2005 figure. A focus on difficult-to-make products is a strategy of differentiating the portfolio that Barr has benefited from historically.

Other large and mid-sized R&D pharma players are considering the generic entry in niche areas. Especially players with strong franchises like dermatology, neurology, women's health, oncology and other hospital products are exploring such opportunities. After successful experiences with generics, it is likely that these players will explore which other generic areas provide growth opportunities and synergies with existing generic and innovative activities.

HOW TO PREPARE FOR SUCCESSFUL ENTRY

The steps for building a generic business follow the established growth strategy processes. We only want to highlight some of the critical challenges that we have come across in our project work:

- *Exploring the potential:*
  - *Challenge: Market potential* — As indicated earlier, R&D pharma teams have difficulties imagining how generic

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sales forces can detail 200–300 products every year — and yet they do. Consequently, there is a tendency to limit the number of products 'to start out with'. After assessing likely price declines and after accounting for generic competition however, expected sales per product are smaller than what R&D pharma executives typically deal with; for example, for Lipitor with 2006 US sales of almost US$8bn and the expected level of competition, Greenstone's business plan would, assuming the launch of an authorised atorvastatin (the active ingredient in Lipitor) generics, be ambitious if it contained meaningfully more than US$120m in 2011, the second year after patent expiry (smaller products obviously suffer from less dramatic price declines and a smaller number of competitors). In short, it is important to highlight the full potential of the applicable franchise rather than to focus on 'key products' only. Also, generic portfolios should be 'enriched' by adding products from other therapeutic areas, specialty pharma products, Rx and OTC vitamins, and legacy products, depending on prescribing patterns of the targeted prescribers in the individual geographies. This is particularly true for branded and substitution markets. Especially areas with restrictions to substitution, for example, CNS and women's health, lend themselves to 'enriching' the portfolio.

- *Challenge: Competitive landscape* — Heating generic competition and price pressure leads generic companies to look into niche businesses protected by barriers to entry against peer generic competition. The flexibility of generic companies and ephemerality of the sector may change the competitive landscape substantially during the implementation period of the business. The examples of Ratiopharm (oncology) and Pliva (biosimilars) show that within a few months a therapeutic area may be declared 'core' and then discontinued anyway — these timelines are inconceivable by R&D pharma executives. In short, it is important to identify the market characteristics of product portfolios rather than today's generic competition.

- *Defining the business model*:
  - *Challenge: Validation of the model* — It may be intellectually stimulating to develop 'fancy' business models for new activities. 'Direct distribution' models that save sales forces only work in practice if there is a strong generic parent behind, although the bottomline looks fantastic in financial models after eliminating the cost of sales organisations. In short, it is not a bad idea to discard business models for which no successful reference examples can be identified.
  - *Challenge: Value chain* — It is part of the charm of the generic industry that 'collecting' the ideal portfolio is restricted only by the available capital in hand and time available, and not lack of serendipity. A corporate acquisition of one of the numerous generic outfits still available today in many countries provides the basis for detailing to the targeted prescribers. Alternatively, approved products, product registrations, readily formulated products or the active pharmaceutical ingredients are 'products' at various levels of development, available as a basis for building or extending the business. In short, there is an important trade-off to be made between the investment required for buying the components of the generic business and the time required for developing those components in-house.

- *Challenge: Governance* — As soon as the entry into the generic world is perceived as likely within the R&D pharma parent, numerous unfounded claims are made on why one's own business function needs to be represented in the control of the new subsidiary to avoid it turning into an 'untamed beast'. It is important to ensure that the generic management is reporting to the most senior board (unless not personally represented on the board) and to point out how unsubstantiated the fear of unapproved actions damaging the group as a whole is, given basic governance procedures and incentive schemes. It is beyond imagination what reasons are brought forward to prevent the entry into generics.

- *Writing and implementing the business plan*
  - *Challenge: Scope of activities* — Operational execution is of paramount importance for generic business success. The paranoia of R&D pharma teams when it comes to finalising the generic business plan might result from the realisation that lack of serendipity is not an excuse for generic business failure. It is important to focus on the time-critical steps in the business plan that will, in most cases, be building or extending the product portfolio and to leave the surrounding details to the management team in charge.
  - *Challenge: Management team selection* — External experienced generic executives can hit the ground running without the risk of R&D pharma managers learning the trade by doing. An excessive cost structure as a trigger for building a generic business and finding work for excessive management capacity is not a promising start.

If these and similar hurdles can be avoided, then the entry into the generic world is up to a good start.

OUTLOOK

There are high barriers for R&D pharma companies entering the generic industry other than through acquisition. With growing importance to fend off innovative and generic competitors and to exploit customer access and insights, the strategic appeal of addressing the broad range of prescriber needs becomes larger. Also, the less effective the traditional direct sales model in pharma and the more consolidated the decision-making on the buyers' side, the better appears the rationale for offering combined 'packages' of generic and innovative treatments within certain therapeutic areas. Senior executives in innovative pharma companies will need strong leadership to develop generic business ideas into actual profit contributors because the skeptics among their staff knew it all along: 'Selling rockets requires different skills than selling sneakers'. The company-internal political head-wind will be strong and openness to the fast-moving world of generics will remain limited. This is also true because the strategic flexibility will require more frequent strategic adjustments as the Schwarz example shows. In 2003 alone, Schwarz Pharma's omeprazol generics contributed US$800m to gross profits (about two-thirds of the company's total gross profits). Any Schwarz shareholders out there complaining about insufficient value created by Schwarz's foray into generics?

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