Winning franchise strategies

Market leaders are no longer companies launching the next blockbuster, but those that can provide the most comprehensive offering in the treatment of a disease, or a therapy area.

For any given diagnoses, doctors must make complicated choices between different classes of drugs, devices, surgical or lifestyle interventions or a combination of these. These choices are likely to be regimented by local or national guidelines or guided by established treatment algorithms. To add to the complexity of this landscape patients, regulators and payers are also able to influence a doctor’s choice (see Figure 1, overleaf).

One or two strategically positioned products, even those which offer significant therapeutic improvement, are not going to catapult a company into pole position within a therapeutic area. The changing environment has revolutionised today’s business models and it appears that the whole exceeds the sum of the parts.

If a company is able to provide a number of treatment options for one indication both now and in the future, then it is likely to establish itself as one of the key providers in that area with the potential to become a franchise winner in time. Franchise building begins in earnest at a strategic level, often stemming from the desire to reinvigorate growth in
one key therapeutic area, or while preparing to protect against the upcoming loss of exclusivity (LOE) and/or generic competition. It is vital that a company keeps its goals and objectives in focus and possesses a thorough understanding of what exactly is required in order to be successful, both from an investment and an organisational perspective.

The most common way to build a franchise is to base it around one or more existing internal assets. It is also possible to start a franchise opportunistically, although this presents more of a challenge. Indeed, when the franchise is built around one or more existing in-line products, the company benefits from an established knowledge base of the therapeutic options and the patient population, as well as the existing competition in that area. The company will also have a recognised sales organisation already calling on target prescribers with access to payers where necessary.

Many companies face life cycle management issues at the franchise level [see Figure 2]. Within the traditional franchise model, a follow-up compound of the lead molecule would be developed and patients and physicians converted before LOE. This was usually done by active cannibalisation or with a co-positioning strategy. It ensured consistent therapy area market share and share of voice and maintained Key opinion leader relationships. It also ensured a continuous sales force and promotion infrastructure.

With the maturing franchise model, or if an expected new product faces delay for approval, a gap opens that needs to be filled with co-promote, co-market, L&A, or the franchise must even be exited temporarily. This is not ideal and leads to loss of capabilities and key stakeholder relationships. In addition, the sales force and likely commercial and R&D structure will need to be re-organised. It also often results in high manufacturing and distribution switching costs.

A merger can also lead to franchise strategy optimisation or review. In this instance, it becomes crucial for the new entity to maximise its new mix of assets, either in development or in-line, within a particular area or indication.

A franchise strategy can also be actioned at local level, even if the option and scope for change is somewhat more limited than that of a strategic headquarter approach. But it can also be extremely successful. (See page 6.)

Typically, franchise building addresses multiple products, including external opportunities, as well as questions of footprint and directions. Portfolio optimisation efforts look to ensure that therapeutic franchises are prioritised...
in order to allocate resources effectively and efficiently. It should also be noted that portfolio management issues exist between and within therapeutic franchises.

The franchise building process involves multiple steps and various capabilities, some of which are not always available or resourced sufficiently within an organisation. More often than not, there are multiple stakeholders involved which can present obstacles when trying to reach agreement. Future assets may also be difficult to value and assessing risk can be complex. The process described in Figure 3 (above) produces multiple alternatives or scenarios. Clarity is indispensable in managing a complex mix of decisions at the end and to reach agreement on the strategy to follow.

THE PROCESS

A description of the complete process is provided in Figure 3. A good place to start is to produce an in-depth review of all the internal assets in or around the franchise, ranging from discovery to in-line products. This should include elements such as capabilities, technology platforms, toxicology and biology models.

In parallel, and if not determined by the existing portfolio, the company needs to identify the highest priority disease areas, based on market and strategic attractiveness and feasibility, and in line with internal strengths, goals and objectives. For example, a company is trying to identify which disease to concentrate on within the cardiovascular area (Figure 4, cardiovascular overview map, overleaf).

It is key to understand the competitive landscape and the treatment guidelines for the chosen franchise areas. Market intelligence is also required at this stage in order to achieve a meaningful understanding of patient segmentation, current and future treatment regimens/combinations as well as of the various national guidelines. Both market research and the input from thought leaders in the form of advisory boards will ensure there is a thorough understanding of the customers’ needs.

- What type and breadth of products do you need to improve medical outcome?
- What will you develop to affect the management of a particular disease for an increasingly narrowly defined patient population?

- What products, technologies and capabilities do you need to acquire or license to complete your franchise objectives?
- How does your product selection compare to that of the competition?

These are some of the questions that are currently defining the competitive landscape in various therapies including oncology, cardiovascular and anti-infectives. The answers will result in a clear representation of the chosen franchise. Superimposing the internal assets on the disease map should allow for the identification of white space in the area.

At the same time, a detailed review of external opportunities must be carried out. Companies need to identify opportunities to pursue both today and in the future, not only within the products in-line or in development in the disease area, but also in relation to the mechanisms of action and the available technologies. Will nanotechnology, cell therapy or gene therapy be the next technologies of choice? This would indeed be taking a long-term view for the franchise, but large companies must be visionary to succeed.

Having reviewed existing capabilities, both from a technical and commercial standpoint, companies should be able to answer the following questions:

- Do we have capabilities that can be leveraged?
- Which capabilities need to be built, acquired or licensed in order to create a successful franchise?
- Is there something that can be discontinued?

In oncology for example, the mandatory steps that will establish qualitative ranking of potential programmes based on commercial and technical input include looking at the various treatment combinations, the multiple mechanisms of action, the tumour type and characterisation, and the stage of the disease. This forms a complex picture and will increase the number of potential scenarios at a later stage. Some areas, however, are slightly easier to deal with and clear guidelines, which are generally geographically consistent, exist.
SCENARIO BUILDING
A company will be able to generate the various options that are open to build the franchise only once it has:

1. Identified the priority diseases
2. Obtained clear visibility of the internal assets
3. Achieved an in-depth understanding of the market today, as well as a vision for therapies and of the future market
4. A good knowledge of the competition
5. Mapped out the white space within the chosen franchise.

This will require a considerable amount of data, analytics and resources outside support is often sought. It is a good idea at this stage to conduct a strategy workshop with the stakeholders to ensure their concerns are addressed.

The output of this phase of ‘scenario development’ will be the design of a set of alternative strategies, covering the full range of possibilities, including a qualitative evaluation of the pros and cons of each strategy. During the evaluation phase, it is also important to identify the implications of each alternative to the broader company, not only the franchise.

In order to ensure the establishment of option development, approaches that stimulate creativity (brainstorm, successive ideation) as well as a systematic check with the use of decision trees, strategy tables and dynamic roadmap should be used.

A company will also need to assign a value and cost (profitability), and risk assess the various scenarios. They can then explore specific investment alternatives and produce a detailed evaluation of potential sales and cash flow for the proposed franchise, under different strategic options to ultimately make the best decision.

THE OPTIONS OR SCENARIOS
The options generated will often take various forms and range from starting a new development programme, developing a new combination or a new formulation to looking to partner or acquire a missing element. Examples of potential output for scenario building and evaluation are shown in Figure 5 for metastatic colorectal cancer and Figure 6 for breast cancer.

When one of the goals is to prepare for LOE, it is important to explore life cycle options, such as the creation of a second brand or the acquisition or revival of a generic sister firm.

A good example is combination pharma products, or fixed-dose combinations (FDC’s), which offer benefits to many drug classes due to the additive nature of therapeutic effect and the reduced level of side effects associated with their use. They have been particularly popular in recent times as a powerful tool through which to increase franchise value.

The therapeutic categories below have been notably open to reformulated and fixed combination products:

- Antibiotics
- Psychostimulants
- Bone calcium regulators
- MS therapies
- Migraine
• Antidepressants
• Antipsychotics
• Tranquilisers
• Antihyperlipidaemia
• Antidiabetics
• Anti-acids and anti-ulcers
• HIV
• Opioid-treated pain
• Overactive bladder
• Contraception
• Anti-hypertensive

A good product example of combinations that have helped to create a franchise is the anti-inflammatory family of ibuprofen products from Pfizer. In order to address the various ailments where an anti-inflammatory could be used, Pfizer sells the following in some Latin American markets:
• Ibupirac Flu (ibuprofen + nasal decongestant) for flu symptoms relief
• Ibupirac Migra (ibuprofen + caffeine) for migraine relief
• Ibupirac Fem (ibuprofen + antispasmodic) for pre-menstrual symptoms and pain relief
• Ibupirac Flex (ibuprofen + muscle relaxant) for muscle aches relief

In this way, Pfizer is serving the major segments and OTC indications where anti-inflammatories are used and Ibupirac has reached a prominent place in the OTC pain market. Another tactic is to use the current range of drug delivery technologies, which are plentiful.

In fact, a whole industry has formed around life cycle extension, and is growing at a faster pace than its pharma colleagues. Each firm tends to concentrate on one or two delivery technologies, but it is easy to find specialists in oral, implantable, injectable, pulmonary, topical or transdermal technology to assist in developing more advanced formulations. See Figure 7 for possible delivery mechanisms.

Most large pharma also have in-house reformulation capabilities. Some of these technologies involve adding or removing a part of the original molecule, i.e., pegylation. This will result not only in a different product, but more importantly it will lead to modified pharmacokinetic properties, such as prolonged half-life.

The chosen options ought then to be refined and compelling support produced for each of the recommended strategies. This would typically include:
• Sales forecasts incorporating synergies and risk
• High level estimates for development costs
• Launch timing
• Probabilities of technical and regulatory success
• Risk-adjusted net present value (NPV) comparisons by options
• Scenario analyses that examine the impacts of specific market events

5. MCCOLORECTAL CANCER TUMOUR STRATEGY COMPARISON

Incremental contributions to expected NPV

- Oral synergy is nearly offset by trade-off in NCT value
- Bet on TT is superior to both ‘synergy’ alternatives
- NCT is potentially the most valuable asset in the portfolio

- New gold standard
- All oral
- Bet on TT
- Bet on NCT

Incremental dev costs – gain/loss
OCT value – gain/loss
TT value – gain/loss
NCT value – gain/loss
This is an area where external experienced support is invaluable, not only to provide unbiased forecasts and probabilities, but also analogues dataset and knowledge of the various markets and therapy areas.

The deliverables at this stage of the exercise are about five fully documented, costed, risk assessed achievable strategic options. Those will clearly articulate the key risks and opportunities of each option, prioritising the most attractive which fit best with the company goals and overall strategy, and potentially identify areas of further work, such as business development/licensing strategy or primary market research.

**DEcision Making**

A decision making strategy map is described on Figure 8. While making the best decision may look simple on paper, there are often many conflicting views and the choices can be hard to make. Managing effectively the decision-making process is almost as important as producing the various scenarios. Here again, external assistance from independent experts can offer great benefits.

Once the decisions on which options to go for have been made, the implementation phase can begin. The development of a clear roadmap, with or without some operational reshuffle will ensure clear directions. This allows the business development sector to pursue targeted opportunities, and leads to improved internal alignment across sales, marketing and R&D. A clear description of roles and responsibilities within accountability centres will also be necessary.

**LOCAL FRANCHISE OPTIMISATION**

Even at a local (affiliate) level, it is possible to have a franchise strategy to increase company presence and competitiveness. Some of the options however, like the acquisition of a new technology platform, are not feasible [see Figure 9]. More often than not, the desire to strengthen a franchise at a local level stems from the need to drive growth and/or to combat a new generic threat.

In essence, the process is similar to the overall franchise strategy review described previously. In this case, the knowledge of the market needs to be more granular due to the complexities of each national healthcare system. Customer needs and a total understanding of the local framework must form the basis of a successful local franchise optimisation exercise.

A non-exhaustive list of the questions that should be addressed include:

- What are the national guidelines for this disease?
- What is the point of care and do we target these?
- What are the distribution channels and are we present in those?
- What are the likely treatments of tomorrow?
- Who are the prescribers? What do they prescribe? Why?
- Patient segmentation and epidemiology?
- Who are the companies actively competing in the area?
- How are they performing and what do they have in their franchise?
- How can I access the missing parts of this franchise?
Once these and other questions are answered, scenario building and an analysis can be carried out and decisions made to identify the best strategy for value creation.

It should be noted that guidelines and gold standards can change and a possible solution in the medium term is to work with the policy makers and the key opinion leaders to modify existing guidelines, or sometimes create them from scratch.

The options open to local companies to strengthen franchises may be restricted but are by no means less effective. Again, alignment of marketing and business development activities is necessary to reach optimal solutions, including alliances, co-promotion, co-marketing or cross-selling.

When it comes to the ominous LOE or the threat of generics to a leading product, one potential option, even at local level, is to consider a second brand or branded generic. This is not always legally possible within the same entity, but there are a few ways this can potentially be overcome.

**COMMON PITFALLS**
Some of these strategic exercises have led to questionable successes, and this is often due to behaviours that are not uncommon in the industry. The most obvious reason is to ignore the market.

Making decisions without taking into consideration the unmet needs of patients, physicians and other
stakeholders, is bound to produce a doomed strategy. Another behaviour that will risk disappointing results is a reactive, rather than proactive approach, such as entertaining life cycle extension as a last resort, very much out of desperation.

This often happens when there is a gap due to delay or failure of a follow-on compound. Similar to the above behaviour, another example of poor timing is to consider product enhancement options too late in the life cycle, less than five years before the entry of generics.

Linked to the timing issue, is the search for quick-fix technology that provides limited levels of improvement, if re-formulation is the chosen option. ‘Off-the-shelf’ controlled-release, or limited in-house reformulation technologies are often chosen but do not bring expected successes.

Sometimes, bad decision criteria, such as focusing solely on exclusivity potential to make go/no-go decisions, are to blame for lacklustre results. And commercial decisions such as an ‘all-or-nothing’ approach to patient conversion will also affect strategies adversely. Equally, relying on low productivity sales and promotion efforts to drive conversion (if this is the strategy chosen) could yield exorbitant DTC spend, massive sampling efforts, rebating and discount for very little rewards.

The fundamental aim of a successful franchise strategy is to increase presence and competitiveness within a chosen market or indication which ultimately leads to generating growth and an increase in revenue. The franchise building/optimising process is complex, but by following a systematic approach, ensuring all scenarios are taken into consideration and evaluated rigorously, the exercise will be very successful.

The market will provide the broad directions and the answers will often be a mixture of internal as well as external solutions.

To learn more about the way in which IMS can help you to develop winning franchise strategies, please contact Nigel Seear nseear@uk.imshealth.com

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