

Evaluating pharmaceutical outsourcing



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PHARMACEUTICAL BUSINESS OVERVIEW

The pharmaceutical companies in their nascent times were always categorized by high profits and as an attractive sector for investors with outperforming stocks. The companies generated high revenues from the sale of innovative drugs against which it acquired patents and thus had to face monopolistic competition. United States and Western Europe were the hubs of leading pharmaceutical companies providing majority of their revenues and profits. The pharmaceutical industry grew at an average of approx 11% year on year due to the following factors.

- Increased demand due to increasing population of aged people
- Development of innovative and patent protected drugs
- Rise of biotechnology

CHANGING PHASE OF PHARMACEUTICAL INDUSTRY

But however in the most recent years, the image of pharmaceutical sector has undergone tremendous change. They have become laggards from being financial leaders. The sector which gave contribution of approx 20% in 1980-2000, posted consolidated negative earnings in the most recent years. This turnaround in the pharmaceutical sectors has been mainly because of these reasons.

- The long profitable heritage has led to low level of check on internal efficiencies with respect to efficient use of capital.
- Most of the blockbuster drugs protected by patents which generated high revenue became vulnerable to expiring patents. Globally patents expiring in 2007 exposed \$67.8 billion dollar to generic erosion

- The most important factor for low margins has been the declining productivity in its core operations i. e. sales marketing and research and development

The pharmaceutical companies have responded to these challenges by mostly increasing their sales marketing expenditure, extensive research and development in order to bring new products in the market, and consolidating through mergers and acquisition in order to benefit from synergies in research and development and sales marketing. But however all these measures are considered to be short term solutions and do not provide long term solution to the challenges faced by the industry.

CHALLENGES FACED BY PHARMACEUTICAL COMPANIES

1)SALES MARKETING

2)RESEARCH AND DEVELOPMENT

LESS EFFECTIVE SALES MARKETING

The declining productivity in sales marketing has important implication for R&D outsourcing as low productivity in sales marketing indirectly puts burden on the R&D to pump out new and innovative drugs to increase the revenues. The sales marketing expenditure measures approx 15% of revenue. The most of this expenditure is dedicated to physician detailing, who are considered to give highest return on investment in sales marketing as potential prescriptions become actual revenues. But however the return from these methods is decreasing because air tight competition has led to increased number of sales force targeting the same top high prescribing physicians, thus reduced time allocation to sales rep by the physicians. Hence increased expenditure on sales marketing has not yielded complementary results.

DECLINING PRODUCTIVITY IN RESEARCH AND DEVELOPMENT

Patent expiry on most of the blockbuster drugs has forced the pharmaceutical R&D to pump new innovative drugs to the market. As it can be seen in table 1, the R&D expenditure has risen more than 20 times from year 1980 to 2006 but the number of drugs that have hit the market has been almost the same.

The reasons for declining productivity have been mainly

- The average time from drug discovery phase to approval has increased over the years. The Tufts Center for the Study of Drug Development estimates that the average time for a drug to progress from preclinical trials through to approval has risen from 11.6 years in the 1970s through to 14.9 years in 2001. The increased time to roll out a new drug has direct implications on the revenues as each day lost counts lost sales.
- The increase complexity of regulatory submissions and clinical trials has led to an increased expenditure on research and development process.
- The increased cost of labour involved in clinical trials has also effected the soaring expenditure on R&D
- Some of the steps taken by pharmaceutical companies to combat the declining productivity in R&D have been
- Adjusting the R&D organisational structure and internal incentives
- Investing in latest technologies such as high throughput screening, proteomics, biotechnology to boost R&D productivity
- Mergers and acquisitions to benefit from scale of operations

- Outsourcing

But however all these measures except outsourcing have been found to be short term and have not provided long term solution to R&D challenges. This is because of the major upheaval in the R&D process of pharmaceutical sector. Traditionally, where in-house R&D yielded all new drugs, has now completely changed to knowledge based drug discovery where any sourceful person or an organisation could develop new drugs with requisite technology thus leaving big pharmaceutical companies at risk of losing competition.

OUTSOURCING R&D AS A SOLUTION

Thus pharmaceutical companies have resorted to outsourcing the R&D to CRO's i. e. contract research organisations, which are specialist organisations, carrying out various phases of R&D process. The drivers for outsourcing R&D to CRO's are

- The increased complexity of regulatory submissions and clinical trials. These services are specialisation of CRO's as they have ongoing patent physician relationships and therefore can be performed more effectively.
- The pharmaceutical companies get rapid access to additional R&D technologies which would have taken lot of time if they were built in house. With increasing market of CRO's the pharmaceutical companies can access wide variety of technologies at short disposable time.
- By outsourcing R&D, the pharmaceutical companies can reduce the fixed cost required in establishing in house R&D and thus these costs become their variable cost which can be incurred when and required.

- The declining productivity of in-house R&D has also led to companies outsourcing R&D, where they get better efficiency from the CRO's.
- As CRO's are globally spread, therefore pharmaceutical companies can better network themselves around the world and better informed about different markets.

R&D PROCESS AND UTSOURCED WORK

As seen in the figure the pharmaceutical R&D process consists of 3 stages i. e drug discovery in stage 1, preclinical trials in stage 2, clinical trials in stage 3 and finally drug approval and mass production. The CRO's perform wide range of functions like clinical trials, data management, clinical monitoring for phase 2-4. These CRO's can be one stop solution for pharmaceutical companies and can also provide fragmented services.

RELATION WITH THEORIES

1) INSTITUTIONAL THEORY

2) RESOURCE BASED VIEW THEORY

3) TRANSACTION COST THEORY

INSTITUTIONAL THEORY

Institutional theorists believe that organizational decision-making is influenced by normative pressures that arise from both external sources (i. e. government, industry alliance) and internal sources. These normative pressures and assumptions determine what constitutes appropriate or acceptable behaviour for the organization (Oliver, 1997).

According to institutional theory the firm's decision to outsource is affected by social and competitive factors. These factors drive the firm to outsource. The firms taking institutionary perspective may either do well or fail in

different markets. The pharmaceutical sector undergoes institutional perspective as it faces pressure from competitors and legal requirements of the particular country regarding regulatory submissions and clinical trials.

As a pharmaceutical company outsources R&D, it gets benefits in terms of low cost, wider access to technology etc. which gives them a competitive advantage. As more and more companies start outsourcing, it forces the other pharmaceutical companies to use outsourcing to sustain themselves. This form of competitive pressure affects the decision of an individual company and thus leading to an industry practice. Under institutional perspective the firm may also wait and look at performances of other players.

Also legal requirements like strict regulatory submissions and clinical trial projects in a particular company exerts a pressure on the pharmaceutical company to outsource its regulatory submissions to organisations who can efficiently deal with legal requirements. Considering from the point of view of institutional theory, this is a social factor which has driven the firm to outsource.

Though taking decision under institutional perspective to outsource can help the firm to take control over the market but its implications may be considered. For example:- The pharmaceutical company may not be well conceived in the home country because it outsources its clinical trials in poor countries where it may be using malpractices.

In contrary the decision of pharmaceutical company to outsource in a particular market may be affected due to institutional factors affecting the

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market where it is outsourcing. Social factor like country laws may affect company's decision, where it believes there is risk of loss of intellectual property due to prevalent law related to protecting intellectual property. For example:- The pharmaceutical outsourcing market has not grown much despite the fact of significant cost reductions in countries like India and China due to loss of intellectual property.

RESOURCE BASED VIEW

The resource based view explains that how firms manage their strategic resources in order to gain competitive advantage. These resources can be physical resources, human resources and organizational resources (Barney, 1991). In essence, RBV puts forward that competitive advantage is not a function of just opportunities in the external environment but also a function of which resources the firm can identify, develop, deploy, and protect (Barney, 1991; Penrose, 1959; Wernerfeldt, 1989). In the context of increasing global competitive pressure, companies are advised to concentrate on their core competencies and utilize outsourcing to capitalize on the expertise of others (Domberger, 1998; Porter, 1990; Prahalad and Hamel, 1990).

According to Barney (1991), a resource with the potential to create competitive advantage must meet a number of criteria, including value, rarity, imitability and organization. For example a resource is unable to generate competitive advantage if it is easily imitated by the competitors. In relation to pharmaceutical R&D outsourcing as a resource, it meets the above criteria's to generate competitive advantage. This is due to the fact that CRO's provide specialised services after the drug discovery process,

which is retained inhouse by the pharmaceutical companies. The risk of imitability gets zeroed, as the result and the process of the outsourcing completely depends on the drug discovery phase conducted inhouse which is different for all the companies.

An important made by Penrose was that firms can create value by just not possessing the resources but also by effective and innovative management of resources. This clearly outlines that a firm can create value even by outsourcing where it does not possess any resources, giving it a competitive advantage.

In pharmaceutical companies, the core operations are R&D and sales marketing. Within R&D the drug discovery is the area of core competence. As resource based view suggests that companies should focus on core competencies and let non core operations to be done by specialised agencies, the pharmaceutical companies tend to outsource their pre clinical and clinical trials to CRO. This is because the CRO's can better serve this cause as compared to operations done inhouse. By focussing on core competencies and leveraging the expertise of others in non core areas, the pharmaceutical companies can achieve competitive advantage by improving the efficiency of the overall R&D process, enhanced productivity and sharing risk of drug failures. Thus, organisation of strategic resources to gain competitive advantage becomes the key driver for the firms to outsource and in the case of pharmaceutical companies this organisation initially relates to concentrate on drug discovery and outsource non competence areas like pre clinical and clinical trials.

From the stand point of RBV, the strategic resources undergo a change as the outsourcing relationship matures. Initially cost reduction was considered a strategic resource but as the pharmaceutical outsourcing is maturing, non cost benefits such as market information, innovative technology are being considered as strategic resources. As the outsourcing relationship matures in the pharmaceutical sector, strategic alliances will help companies to overcome challenges like loss of intellectual property, risk sharing etc.

TRANSACTION COST THEORY

The term “ transaction cost” was first used by Ronald Coase who used it for developing theoretical framework in order to understand which economics tasks would be carried out by firm and which economic tasks will be performed on market. But however the concept gained its importance through Oliver Williamson. According to him the factors incorporated in transaction cost were frequency, asset specificity, uncertainty, limited rationality and opportunistic behaviour.

According to TCE, whether a firm produces an input for its production depends on the degree of uncertainty related to the input, the specificity of the input or its underlying asset(s), the frequency of interactions with the supplier, and the opportunistic tendencies of the supplier (Coase, 1937; Williamson, 1975, 1985).

Asset specificity is low for pharmaceutical companies, which outsource their R&D and the long term cost savings become the drivers for outsourcing. The significant advantage to companies outsourcing is that they can save fixed cost in developing in house R&D by outsourcing to CRO's. The potential fixed

cost become variable costs for the outsourcing company. In pharmaceutical business, these fixed costs relate to heavy investment in new technologies, human capital (qualified doctors, analysts etc.) and plant and building. Depending upon the size and scope of the facility, initial expenses to build such an infrastructure can range from \$10m to more than \$500m with annual maintenance costs of an additional \$2m to \$100m. Also the maintenance cost to support these has to be incurred. Therefore companies enjoy long term savings. But however there is high asset specificity on the part of CRO's. This is compensated by high amount charged by CRO's and serving multiple companies. But long term savings exceed these short term expenditures for pharmaceutical companies.

On the contrary, there may be opportunistic behaviour on the part of supplier because there can be leakage of valuable information which can affect the core competence of the pharmaceutical company. This is taken care by pharmaceutical company by outsourcing fragments of R&D process which are non core and retaining the core operation which is drug discovery. Also information asymmetry between the big pharmaceutical companies and specialised CRO's dampens the opportunistic behaviour on the part of the supplier.

Also TCE is controversial from the point of view, that pharmaceutical R&D outsourcing to CRO's involves high level of uncertainty increasing the transaction cost. The high level of uncertainty arises from the increased dependence of the project on the supplier and low level of control of pharmaceutical companies. The performance of CRO can be very crucial in the success of the project. But it is argued that as the strategic alliance of <https://assignbuster.com/evaluating-pharmaceutical-outsourcing/>

pharmaceutical companies and CRO's increase and with high frequency of transactions, developed governance mechanisms will replace general governance mechanisms which will eventually eliminate the risks of uncertainty and opportunistic behaviour.

THEORIES APPLIED COLLECTIVELY

When all the three theories applied together in the evolving pharmaceutical R&D outsourcing, the companies will simultaneously consider corporate image, external environmental threats and opportunities, best governance structure, cost efficiency and supplier relations. However these are for matured relationships and will take place after some maturity in the alliance between pharmaceutical companies and CRO's.

CONCLUSION

The upheaval in the R&D process of pharmaceutical industries has led to high level of outsourcing to Contract Research Organisations. The R&D outsourcing is expected to grow to \$36 billion by 2010 from \$9.3 billion in 2001. This growth will be fuelled by the high drug targeting through advanced technologies like throughput screening, genomics which will lead to increased number of clinical trials. Currently, CRO's which are competing on the grounds of providing specialised services, will have to consolidate in future in order to remain competitive. Though the relation between CRO's and pharmaceutical companies is still at its early age, but it promises to be continued for long with high level of alliances between both the parties.

However there has been surge in pharmaceutical outsourcing but it still has not gained momentum as it has found in other industries. This is mainly due to the following reasons

- There is clash of culture, as outsourcing remains mainly confined to the developing countries whereas pharmaceutical companies have their foothold in developed countries.
- There is high level of risk, as there may be opportunistic behaviour on the part of supplier. Though this can be curtailed by fragmented outsourcing, but still the risk of loss of intellectual property remains high.
- Also by outsourcing components of the core operation, the entire project is under of getting affected by the poor performance of CRO's. The dependence of the pharmaceutical companies on CRO's becomes extremely high.

Although these factors have restricted the growth of outsourcing market in pharmaceutical R&D, but still there is scope for high growth as the relationship matures and the alliance between CRO and pharmaceutical companies becomes more and more strategic.