EMERGENCE OF OUTSOURCING WITH NEW BUSINESS MODELS FOR INDIAN PHARMACEUTICAL INDUSTRY

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Abstract

After modifications to the Indian patent system in 2005 made it possible to patent pharmaceutical items, the focus shifted to the development of novel medications. So, even though many Indian companies are investing heavily in pharmaceutical R&D, India is not yet an innovator's market. Strong FDI, mergers, and partnerships are occurring in India's pharmaceutical industry. The generics industry at home is eager to get into the lucrative international market. The number of ANDAs submitted to the FDA in the United States is likewise rising each year. There has been a shift in the industry's focus from the manufacturing of generic drugs to drug research and development. Following the 2019 release of the New Drugs and Clinical Trial Rules, the clinical testing sector has expanded fast, with many companies choosing India as a trial venue for their global Medicines. The commercial components of the sector are the primary focus of this research, which also suggests some changes to the existing business model and future directions.

Keywords: Emergence, Outsourcing, Business Models, Pharmaceutical Industry

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1. Introduction

Companies often keep up with trade partners in order to outsource manufacturing. Contract manufacturing agreements are the most common kind of outsourcing in various sectors. The problem is that these deals are seldom finalized and are usually supported by empty words. Having all production handled by a CM enables a company to put more resources into product development, advertising, and design, all while reaping the financial benefits of the CM's experience and skills.A customer enters into a contract manufacturing arrangement with a contractor when the client wants to outsource the production of a product in return for a fee.

12 Industries as diverse as electronics, pharmaceuticals, automobiles, and food and beverage all employ contract manufacturing agreements (Tully 1994). In 2015, the electronics sector alone was forecast to generate $515 billion in contract manufacturing revenue worldwide, while the pharmaceutical business was projected to generate $40.7 billion. Annual growth rates of 8.6% and 6.4% are predicted for the relevant sectors, suggesting even further expansion (Rajaram 2015, Pandya and Shah 2013). These two fields are also distinguished by their unique features. Because moving between CMs may be expensive, clients that have new, complicated products, such as those found in electronics, tend to choose single-source contract manufacturing agreements. Conversely, when goods commodify, as in pharmaceutical manufacturing facilities, customers get access to a plethora of interchangeable CMs.

Contract manufacturing is when one company contracts out some of its manufacturing to another in order to take advantage of the former's production economies of scale and economies of scale. Conventional product designers, engineers, and consumers may all find what they need at Contract Manufacturing, a reputable contract manufacturer. The pharmaceutical industry has shifted its focus from an integrated strategy to a supplier system in response to rising financial pressure and the need to reduce costs and improve efficiency. Overall, contract manufacturing has grown into a significant part of the pharmaceutical industry. Contract manufacturing began as a serendipitous trend but has now evolved into a strategic business model; today, outsourcing is most common in manufacturing and is rapidly expanding into other areas of the pharmaceutical industry. The process of "the one stop shop" service provision is gaining traction as CMOs provide a wide range of services, from initial planning and discovery to final packaging. Since the beginning of the last few years, the business world has seen observable trends that are indicative of a growing consensus. The evolution of key assembly is one of the most anticipated developments in the outsourcing industry. The comparison between the vendor and the customer was a part of the cycle model of agreement building. However, contract manufacturers today are abandoning the traditional approach and instead investing in initiating key unions with CMO partners to reduce production costs and increase production lines. Markets for agreement manufacturing, which may be further subdivided into API manufacturing and FDA manufacturing, have expanded rapidly over the last few years due to factors like, for example, cost-effectiveness, process-capability, and time-efficiency gains. There is a plethora of both established and up-and-coming CMOs in today's commercial hub, and their range of services, from maintenance to full-scale operations, is expanding rapidly. Despite challenges such as high levels of competition and declining government support, contract manufacturing has been a boon to the pharmaceutical industry. There is no doubt that the pharmaceutical contract manufacturing industry has bright future growth potential; CMOs who can provide specific differentiating characteristics targeting different customer groups will have the most success in this cutthroat market.

2. Literature Review

Mahajan, V., Nauriyal, D.K. & Singh, S.P. (2020), Because of the increasing presence of global pharmaceutical corporations in the Indian market since the execution of the product patent system in 2005, this article seeks to analyze the competitiveness of the Indian drug and pharmaceutical business in the domestic market. The research included 141 Indian pharmaceutical companies from 2000-2001 to 2012-2013, spanning the pre- and post-product patent regimes, and used a data envelopment analysis technique to assess relative efficiency and productivity increases. The results of this research show that the Product Patent Act has a detrimental effect on efficiency ratings. Research shows that technological progress contributed to productivity development, while advances in technical efficiency illustrate how input resources might be used more effectively to boost output. R&D spending was included in our sensitivity analysis to verify the reliability of our input variables. The research indicated that the new patent system had a little effect on the efficiency of R&D-performing companies, but a big effect on the efficiency of large firms, R&D-intensive firms, and group-owned enterprises. Pharmaceutical companies with high R&D budgets, private-foreign ownership, and a focus on medication formulations were shown to

perform well in the research. In addition, ownership, capital importation intensity, and size all exhibit positive, statistically significant relationships with efficiency scores, whereas age, the time dummy, and size square all have negative, statistically significant relationships. Based on these findings, it's clear that Indian businesses need to make major efficiency gains by using cutting-edge management techniques, optimizing their use of existing assets, and increasing their expenditures on research and development.

Y. Mitsumori (2020),Today, India's pharmaceutical market is the third largest in the world. India reintroduced product patents in 2005 after revising its patent legislation in response to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which came into effect in 1995. Large foreign capital pharmaceutical corporations gradually re-entered the Indian market after TRIPS implementation in 1995 and the return of product patents in India in 2005. They resumed research and development (R&D) and production of formulations and active pharmaceutical ingredients (APIs) (APIs). When the Indian Patent Office (IPO) began reviewing product patent applications in 2005, such firms investing in India from outside began submitting them for consideration under the country's newly updated patent legislation. Although IPO and IQVIA statistics suggest a downward trend in pharmaceutical patent applications over the previous several years.

Yaser Mohammed Al-Worafi (2020),Authorities in charge of licensing, registering, and granting pharmaceutical corporations' authorization to commercialize new or already licensed pharmaceuticals to treat various illnesses and ailments have been doing so for over a century. Increases in population size and age, the prevalence of chronic illnesses, infectious diseases, lifestyle choices, and the discovery of new diseases all contribute to the fact that more people than ever before are using pharmaceuticals. This chapter covers the background of pharmaceutical regulations, as well as the registration, marketing, and post-marketing safety issues associated with pharmaceuticals, as well as the unique difficulties these processes present in developing nations. Finally, it offers suggestions for how these issues can be addressed to better ensure the safety of pharmaceuticals in these regions.

Kapoor D, Vyas R B and Dadarwal D (2018),Medicine is a strategic product, thus its delivery is a key priority in every healthcare system. Pharmaceutical producers, wholesalers, distributors, consumers, information service providers, and regulatory agencies are just few of the many players involved in the increasingly complicated process of managing pharmaceutical supply chains in today's health-conscious society. The literature on pharmaceutical supply networks is scant. The pharmaceutical industry faces several threats as a key link in the medication supply chain. These threats hinder the efficiency of the pharmaceutical industry by preventing the right drugs from reaching the right people at the right time.

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3. Strategy Selection Model Results

Table 1 displays the outcomes of the multinomial logit regression. I provide the regression results in three columns, one each for international subsidiaries, in-country outsourcing, and international contracting. The foundational category is comprised of in-house suppliers. The coefficients for outsourcing to overseas subsidiaries suggest that larger and older enterprises are more likely to do so than smaller and younger ones. As was suggested in the prior section, worse performance also raises the chance of offshore to overseas affiliates. As a consequence of the considerations at the project level, it seems that international affiliates are more likely to handle bigger Medicines than the home office. For international subsidiaries, other characteristics such as phase, place of origin, and parent type had little impact on performance.

Table 1: Multinomial Logit Model Estimates

Strategy	**Foreign Affiliates**	**Domestic**	**Offshore**
		Outsourcing	**Outsourcing**
Intercept	**3.21*** **	**-0.105**	**4.69*** **

Size	**0.003****	**-0.0072*****	**-0.005****
Age	**0.015*****	-0.019	-0.011
Performance	**-0.309*****	-0.023	**-0.371*****
Phase	-0.359	**0.045*****	**0.245*****
TA	-0.03	0.056	-0.002
Size of Trial	**0.372*****	-0.063	**0.084****
Parent Type	0.234	-0.602	-0.932
Country of Origin	-0.031	-0.012	-0.034
Log Likelihood	0.622*	0.131	0.128

For domestic outsourcing, I discover a statistically significant inverse association between company size and the likelihood of using an external provider, suggesting that smaller businesses are more likely to choose domestic outsourcing over in-house sourcing. In addition, I discover that the clinical trial phase is substantial and beneficial, suggesting that the more standardized latter stages are the ones that are often outsourced to domestic service providers. No additional variables were found to be important, even if their indications pointed in the right direction.

In my last column, I said that offshore outsourcing is more common among smaller and low-performing businesses. Like with domestic outsourcing, companies often outsource Medicines development and testing to other countries. A positive and marginally significant finding from the size of the clinical trial suggests that bigger studies are often outsourced to countries with less stringent regulations. Negative results were found for all other variables and controls.

4. Performance Outcome Model Results

Table 2 displays the results of the second stage model in which price was the dependent variable. Model 3 involves my estimating the performance model for each sourcing technique independently while taking into consideration the possibility of self-selection. Only for domestic outsourcing does have a substantial negative value, suggesting that domestic outsourcing is a deliberate choice made by businesses. It seems that elements that can't be seen have a role in determining whether or not core functions are outsourced inside the country. The results of the OLS model are consistent with the prediction that domestic outsourcing has superior performance than in-house, and domestic outsourcing was the sole strategy option that was not statistically significant. There is a beneficial and statistically significant effect of size, phase, therapeutic area, and medicine size controls. Consistent with OLS estimates, these results are found.

Table 2: Performance Outcome Model (Cost)

DV - Cost		**Model 3**		
	In-house	**Foreign**	**Domestic**	**Offshore**
		Affiliate	**Outsourcing**	**Outsourcing**
Intercept	**9.312*****	**9.745*****	**2.255****	**8.739*****
Size	**0.0052*****	**0.014*****	**-0.013**	-0.002
Age	-0.003	0.044	0.012	0.013
Performance	-0.086	0.075	0.392	-0.032
Phase	**0.224*****	**0.0149***	**0.511*****	**0.136*****

TA	**0.162*** **	**0.0632*** **	**0.066***	0.017
Size of Trial	**0.853*** **	**1.212*** **	1.3296	**0.8417*** **
Parent Type	0.162	0.074	-0.989	-0.038

I can estimate how well various tactics will perform on average by using a model of self-selection. For instance, I am able to foresee how businesses might have fared had they outsourced or offshored rather of conducting trials in-house. When I take the vector of firm characteristics for each subsample and multiply it by the coefficient estimates from the subsample regressions (Leiblein et al., 2002; Shaver, 1998), I am able to forecast how the strategies will perform differently. The expected results of the four approaches are shown in Table 3. For internal sources, results are shown in the second column. Spending was an average of $71,976,000 for companies that did their primary work in-house. If the same set of companies had undertaken the same trials in their overseas affiliate, I estimate that they would have spent $158,355,000. This is based on the self-selection performance models. Outsourcing inside the country would have cost $55,783,000, while outsourcing internationally would have cost $130,985,000.

Foreign affiliates, domestic, and international outsourcing costs are shown in the following three columns. In general, the trend indicates that domestic outsourcing provides the highest performance, with the lowest cost of doing Medicines. Then comes domestic sourcing, then outsourcing to other countries, and finally, overseas subsidiaries.

Table 3: Predicted Performance Values from Performance Model (Cost)

	In-house	**Foreign Affiliate**	**Domestic Outsource**	**Offshore Outsource**
In-house Model	**71,976,000**	85,305 ,000	114,704,000	142,707,000
Foreign Affiliates Model	158,355,000	**108,770,000**	185,853,000	166,874,000
Domestic OutsourcingModel	55,783,000	61,203,000	**67,258,000**	55,195,000
Offshore Outsourcing Model	130,985,000	102,002,000	183,678,000	**156,110,000**

Estimates for the second dependent variable are shown in Table 4. Upon breaking down the data into four distinct sub-strategy groups (Model 4), I discover that self-selection occurs solely for domestic outsourcing. Firms self-select solely for domestic outsourcing based on unobservable criteria, as shown by the marginally significant and negative value of when success is assessed by length of the project. Positive and substantial controls for medicine phase and trial size show that late-stage and bigger studies require more time to finish.

Table 4: Performance Outcome Model (Duration)

DV - Duration	**In-house**	**ForeignAffiliate**	**Model 4DomesticOutsourcing**	**OffshoreOutsourcing**
Intercept	**1.539*** **	**1.622*** **	**2.384**	**1.905*** **
Size	-0.124	-0.0029	-0.0027	-0.0026
Age	-0.012	-0.0019	0.0013	-0.0457
Performance	0.018	0.103	-0.023	0.049

Phase	**0.238*** **	**0.2465** **	**0.2468** **	**0.349** **
TA	-0.557	-0.094	-0.197	-0.182
Size of Trial	**0.284*** **	**0.078*** **	**0.249***	**0.113*** **
Parent Type	0.894	0.377	0.712	0.477
Trend	**0.032***	**0.543**	**0.022**	**0.05***

Time estimates are provided in Table 5, I once again discover that local outsourcing takes the least amount of time, followed by in-house, offshore outsourcing, and international affiliates. Except for the subsample of companies that genuinely have Medicines operations in their overseas subsidiaries (Column 3). Trials conducted at overseas affiliates tend to be completed more quickly than those conducted at an offshore vendor, given my experience with this subset.

Table 5: Predicted Performance Values from Performance Model

	In-house	**Foreign Affiliate**	**Domestic Outsource**	**Offshore Outsource**
In-house Model	**10.15**	10.89	6.64	8.63
Foreign Affiliates Model	15.24	**17.25**	18.89	14.23
Domestic Outsourcing Model	8.71	9.89	**6.23**	6.76
Offshore Outsourcing Model	14	17.36	12.43	**12.42**

All three competing hypotheses are supported by the outcomes of the two sets of models. As stated in my alternative hypothesis 10b, I contend that domestic outsourcing improves performance in comparison to in-house operations. We found considerable evidence to support this theory due to the cheaper costs and shorter length of domestic outsourcing compared to in-house trials. For hypothesis 11b, I find full support for my prediction that, owing to greater cost and longer duration, the performance of overseas affiliates is poorer than that of in-house while undertaking core operations. Finally, in hypothesis 12b I assert that it is more expensive and takes more time to execute key operations that are offshore outsourced. The estimated performances agree with my idea. No evidence was found in favor of null hypothesis 12a, which claimed that exporting jobs to developing countries would improve productivity.

5. Conclusion

There has been a paradigm change in the way pharmaceutical firms are organized, from a vertically integrated corporation to one that uses a variety of outsourcing agreements, partnerships, and other contractual and relational structures to build up networks of collaboration. Investment in India will be a key part of this interconnected future. Businesses who are able to effectively manage and combine a variety of contractual arrangements and partnership strategies will find the greatest success operating in India.

No matter what kind of company you decide to pursue, you'll still have to deal with a few practical concerns. While considerable progress is being made in addressing infrastructure gaps, they persist. As much progress as has been made in protecting intellectual property, there are still certain holes that need to be closed. While India's regulatory climate has improved greatly in recent years, the sector still confronts several open questions. Government policies on drug price control, access to OTC pharmaceuticals, tax policy, intellectual property protection, and infrastructure expenditure have not been finalized.

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