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Determinants of Licensing Deals in Pharmaceutical Industry

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ABSTRACT: The drug discovery and development are very expensive, risky and time consuming. It requires several years and billions of dollars for developing a drug to the marketplace. Hence, smaller biotech companies seek to out-license or develop their drugs in collaboration with large pharmaceutical companies. On the other hand large pharmaceutical companies are constantly seeking new candidates to fill their product pipelines. From the perspective of a biotech company it is important to choose the licensing partner carefully as it takes several years of commitment and large investments to bring a new drug to the marketplace. However, recent analysis has shown that owing to the buoyant capital environment biotech companies have been able to raise capital and develop drugs to the marketplace. A sample of 101 pharmaceutical companies and 381 licensing deals that were announced in the period 2011-2015 were collected for quantitative analysis using Multilayer Perceptron technique and regression analysis. This study evaluated the five determinants including size of the company, pharmaceutical sales, number of employees, age of the company and pharmaceutical research and development expenditure that would have an effect on the licensing deal. The analysis of the data reveals that while seeking an out-licensing partner, a licensor preferred companies with R & D budget for expenditure and number of employees.

Keywords: product development, drug development, licensing, strategic partnership, collaboration.

I. INTRODUCTION

Licensing and collaborations are very important for the pharmaceutical and biotech institutes to discover, develop, manufacture and commercialize new medicines for treatment of human diseases [1]. With the advancement in science and technology, our understanding of human biology, drug targets and mechanisms of drug resistance have increased manifold. However, it takes several years and billions of dollars in investment to bring a new drug to the marketplace [2, 3]. The period for new product discovery, development and eventual approval for marketing is the longest in the case of pharmaceutical industry leading to loss of effective on-market patent life of a new molecule [4]. This coupled with the high risk of failure in clinical development makes it important for pharmaceutical companies to seek external innovation to fill their portfolio [5-8].

Biotech's that have achieved non-clinical or clinical proof-of-concept need the access to capital to conduct expensive phases of non-clinical and clinical drug development [9]. The licensing process can be very competitive as there would be several pharmaceutical companies interested in licensing first-in-class or best-in-class molecules at various stages of development [10]. However, it is important for biotech and pharmaceutical companies that are seeking licensing partners for their molecules to choose the partners carefully as it takes several years of commitment to bring a new drug to the market [11, 12].

Research has shown that products developed in an alliance with a large firm tend to have a higher probability of success since large firms have access to large capital and experience [13, 14]. Some studies have pointed to a non-linear relationship between Firm Size and licensing, indicating that smaller firms who do not have assets like production facilities and marketing channels, also are prone to licensing assets [15, 16].

In a study, related automobiles industry, it was observed that the Size of a Firm had an influence on the capacity of the firm to develop, adapt and absorb new technologies [17, 18].

Arnold *et al.,* (2002) analysed 105 licensing deals over 10 years and established that the type of a partner influenced the size of the licensing deal [19]. O'Connell *et al.,* (2014) analysed 800 licensing deals over 18 years and found that big pharma accounted for licenses on over half these drugs from external sources [20]. Companies that had greater focus on pharmaceutical sales like Merck & Co, were found to license more assets. The study also revealed that big pharma pays more as compared to a financially constrained smaller firm.

Pharmaceutical industry as the drug development, marketing and commercialization is extremely knowledge intensive. There would be several employees employed by the company specialized in drug development, manufacturing, registration and commercialization activities [21]. These activities are highly skill intensive in the case of a pharmaceutical industry [22]. Hence, the number of employees becomes an extremely important determinant and valuable assets for any company [23, 24]. Smaller firms who do not have access to a larger capital of human intellect can gain access to that capital by partnering with a large firm which has larger number of employees.

The Age of the firm gives it number of experiences over the years, and these experiences with past deals, collaborations, failures and successes help shape the firms competitiveness as a partner of choice [25]. Danzon *et al* (2005) described the importance of a firm's overall experience, and alliances with large and small firms [13]. The study suggested that smaller firms are benefitting through the experience of large firms who had spent several years perfecting the art of drug development. It is envisaged that the licensor's size and experience plays an important role in the licensing decision.

The Age of a Firm has been reported to have a positive influence on the capacity of the firm to develop, adapt and absorb new technologies [17].

In a survey carried out by the European Commission it was found that 16 pharmaceutical companies featured among the top 50 companies in the world by total R & D investment in the fiscal year 2014/15. "Novartis (5), Roche (7), Johnson & Johnson (8) and Pfizer (10) ranked in the top 10 of the leading R&D investing companies globally" [26]. Owing to various challenges and risks associated with drug discovery and development, despite higher R & D budgets, pharmaceutical companies had to resort to licensing activities to fill their drug pipelines [27]. Owing to buoyant capital market in recent years, several start-ups have raised capital from the market either by issuing shares or IPO's thus gaining access to budgets for conducing intensive drug development of their assets [28]. Thus, this provides an alternative to licensing to a large firm with higher R & D budgets. Several studies [29] have confirmed the positive relationship between R & D expenditure capacity and licensing.

However, in the current buoyant market environment there are recent changes being observed in the pharmaceutical industry with smaller companies alsobeing able to raise capital, license candidates, and develop drugs to the marketplace [11]. Hence, this study investigated the five determinants including size of the company, pharmaceutical sales, number of employees, age of the company and pharmaceutical research and development expenditure as key determinants that could have an effect on the licensing deal from the perspective of a biotech or pharmaceutical company when they are seeking licensing partners for their molecules. A sample of 101 pharmaceutical companies and 381 licensing deals that were announced in the period 2011-2015 were collected for quantitative analysis using Multilayer Perceptron technique and regression analysis.

II. OBJECTIVES

The study had the following objectives:

Objective 1: To find out the determinants that would have an effect on the licensing deal. This objective was analysed using Multilayer Perceptron technique.

Objective 2: To find the impact of determinants on licensing

III. METHODOLOGY

A sample of 101 pharmaceutical companies and 381 licensing deals that were announced in the period 2011-2015 were collected. Quantitative analysis techniques using Multilayer Perceptron technique and regression analysis were employed for data analysis.

A. Multilayer Perceptron (Neural network)

Multilayer Perceptron describes any general network which does not have recurrent connections [30]. Multilayer Perceptron consists of at least three layers and the input variables (independent) and the target variables (predicted) are connected between the layers. This model explains the importance and normalized importance for each of the predictor. The Multilayer Perceptron method has been used here to identify the important determinants.

B. Multiple Regression

Multiple Regression has been used to estimate the relationship between the dependent and independent variables for the study.

IV. ANALYSIS AND DISCUSSIONS

This research identified the licensing deals that have happened over the years (2011-2015). The study included pharmaceutical and biotech firms across the world. Licensing deals entered by 101 pharmaceutical and biotech companies in the period 2011 – 2015 were collected from companies' websites. This included 381 licensing deals.

A. Multilayer Perception (Neural Network) Analysis

This research used the Multilayer Perceptron technique to identify if all the determinants would have an equal effect on the probability of a licensing deal happening. The determinant variables used for testing in the Multilayer Perceptron method included the size of the firm, pharmaceutical sales, number of employees, age of the company and pharmaceutical R & D investments.

The determinant variables having normalized importance more than 40% were then considered for model building, and regression analysis was then used for testing the various hypothesis.

Multilayer Perceptron describes any general network which does not have recurrent connections. Multilayer Perceptron consists of at least three layers and the input variables (independent) and the target variables (predicted) are connected between the layers. This model explains the importance and normalized importance for each of the predictor. The results are discussed below.

Table 1: Multilayer Perceptron.

Network Information			
Input Layer	Covariates	1	Pharmasales
		2	TOTALSALES
		3	pharmaR_D
		4	Age_Company
		5	Size_Company
	Number of Units[a]		5
	Rescaling Method for Covariates		Standardized
Hidden Layer(s)	Number of Hidden Layers		1
	Number of Units in Hidden Layer 1[a]		4
	Activation Function		Hyperbolic tangent
Output Layer	Dependent Variables	1	No_of_deals
	Number of Units		1
	Rescaling Method for Scale Dependents		Standardized
	Activation Function		Identity
	Error Function		Sum of Squares
a. Excluding the bias unit			

Table 1 depicts that the number of units excluding the bias unit is 5. The rescaling method for covariates is standardized. The number of hidden layers is 1, and the activation method is hyperbolic tangent. There is a single dependent variable : “Licensing deals”.

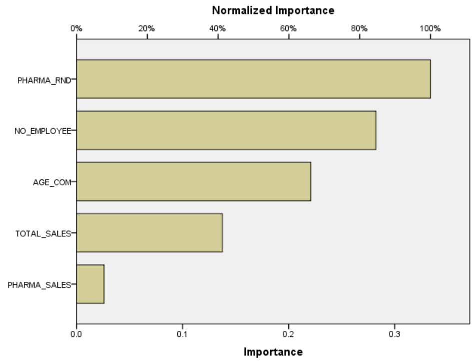

Fig. 1. Normalized Importance.

The importance of the variables in the model is displayed as normalized in Fig. 1. It is observed that Pharma R & D, number of employees, age of the company, and total sales (representing size of company) have good effect on prediction of licensing deals.

Table 2: Independent Variable Importance.

	Importance	Normalized Importance
PHARMA_SALES	0.026	7.8%
TOTAL_SALES	0.137	41.2%
PHARMA_RND	0.334	100.0%
AGE_COM	0.221	66.1%
NO_EMPLOYEE	0.282	84.6%

The variables having normalized importance more than 40% are considered for the model building. Total Sales, Pharma R & D, Age of the Company and Number of Employees were identified to have a normalized importance more than 40 % and were selected for further analysis. Regression model was then developed to study the impact of the important variables on licensing deals using the variables whose normalized importance is higher than 40%.

B. Regression Analysis and Hypothesis

The study employs Regression Analysis to test the hypothesis. The Dependent Variable chosen is the Licensing Deals, while the Independent variables chosen for this study includes Pharma R & D, No. of employees, Age of the company and Total Sales.

Table 3: Regression output.

Regression Statistics	
Multiple R	0.8009775
R Square	0.641565
Adjusted R Square	0.6266302
Standard Error	4.4558857
Observations	101

ANOVA					
	df	SS	MS	F	Significance F
Regression	4	3411.69	852.9226	42.95775	**1.30035E-20**
Residual	96	1906.072	19.85492		
Total	100	5317.762			

	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%
Intercept	-0.94997	0.767055	-1.23846	0.218565	-2.472559915	0.572625
Size of the company	-0.00014	0.000101	-1.36595	0.175146	-0.000337346	6.23E-05
Pharma R&D	0.002596	0.000445	5.831281	7.38E-08	0.001712571	0.00348
Age of company	0.0149	0.008154	1.827373	0.07075	-0.001285135	0.031085
No. of employees	7.87E-05	3.69E-05	2.132751	0.035496	5.45417E-06	0.000152

Hypothesis for ANOVA table:

Ho : The model is not a good fit

H1 : The model is a good fit

The Anova table (output) shows whether the regression model explains a statistically significant proportion of variance.

P value = F Significance = 1.30035E-20 ≅ 0.000 (very small value)

P value = 0.000 α = 0.05

Hence, the null hypothesis Ho is rejected. Thus, the study concludes that the regression model statistically significantly predicts the dependent variable or this model is a better predictor of the outcome variable. Thus, this model is a good fit for the data.

The Regression output shows R-square value of 0.641565. R-squared value is a statistical measure of how close the data are to the fitted regression line. It is also known as the coefficient of determination, or the coefficient of multiple determination for multiple regression.

Hypothesis for coefficients:

1. Pharma R & D

Ho: Pharma R&D does not explain variation in dependent variable

H1: Pharma R&D explains variation in dependent variable

The Regression analysis shows P-value of 7.38E-08 equals 0.000, which is less than alfa = 0.05. In this case, the null hypothesis is rejected and alternative hypothesis is accepted. Thus, biotech firms and pharmaceutical companies would choose Firms with more R & D budgets as their licensing partners.

Out of the four independent variables, “Pharma R&D” and “No. of employees” are found to be statistically significant as the p-values of these two variables are 0.000 and 0.035 respectively which are lesser than α = 0.05.

The coefficient of “Pharma R&D” is 0.002, which is positive thus indicates more Pharma R&D expenditure may lead to more licensing.

2. Number of Employees of a Firm

H0: Number of Employees of a firm does not explain variation in dependent variable.

H1: Number of Employees of a firm does explain variation in dependent variable.

This study reveals a P-value of 0.035496, which is less than alfa = 0.05 for the Number of Employees. The "No. of employees" has a coefficient of 0.0007, which is positive but very low, indicating that more No. of employees may lead to more licensing. In this case the null hypothesis is rejected and the alternative hypothesis is accepted. Thus, the Number of Employees of a Firm is found to be a significant determinant in the process of choosing a licensing partner.

3. Size of the firm

H0: Size of the firm does not explain variation in dependent variable.

H1: Size of the firm does explain variation in dependent variable.

The results show a negative correlation co-efficient value of -0.00014, signifying that there is no relationship between the size of the firm and number of licensing deals. Further, the Regression analysis shows a P-value of 0.175, showing that the Size of the Firm has no direct correlation with the selection of the firm as the partner for the licensing deal.

4. Age of the firm

Hypothesis

H0: Age of the firm does not explain variation in dependent variable.

H1: Age of the firm does explain variation in dependent variable.

This study shows a P-value of 0.07075 for the 'Age of the Firm' variable which is insignificant.

Thus, the 'age of the company' was found to be insignificant variable, thereby implying that they do not contribute to explaining the dependent variable 'Licensing'.

V. DISCUSSIONS

The size of the firm, pharmaceutical sales of the firm, R & D expenditure of the firm, age / experience of the firm and the number of employees of the firm all are important determinants that should be considered by an academic institute, a biotech firm or a pharmaceutical company in choosing the right partner for the asset to be licensed [1, 6, 14, 27]. Since R & D is a long process and time consuming, it is important that the right capabilities and experience exists with the partner organization. At the same time, drug development is very resource intensive, requiring several millions of dollars in investment over several years, and hence choosing a right partner for drug development and commercialization is very important for companies.

This study used Multilayer Perceptron technique to identify if all the determinants would have an equal effect on the probability of a licensing deal happening. The determinant variables having normalized importance more than 40% were then considered for model building. Total Sales, Pharma R & D, Age of the Company and Number of Employees were identified to have a normalized importance of more than 40% and were selected for further analysis, and Pharma sales was dropped.

A. Results of the quantitative analysis using Multilayer Perceptron (Neural network) and Regression Analysis

Regression model was then developed to study the impact of the important variables on licensing deals using the variables whose normalized importance is higher than 40%. The Dependent Variable chosen was the Licensing Deals, while the Independent variables chosen for this study included Pharma R & D, No. of employees, Age of the company and Total Sales. The alternative hypothesis for the model stated that "The model is a good fit". However, the ANNOVA table output revealed a p-value of 1.30035E-20 ≅ 0.000 (very small value), and hence the null hypothesis was rejected and the study concluded that the regression model statistically significantly predicts the dependent variable or this model is a better predictor of the outcome variable. Thus this model was a good fit for the data. The Regression output showed a R-square value of 0.641565. R-squared value is a statistical measure of how close the data are to the fitted regression line. It is also known as the coefficient of determination, or the coefficient of multiple determination for multiple regression. The regression output R-square value of 0.641565, showed that 64% of the variations are explained by the determinants chosen for this study. Further, the study tested the hypothesis that "Pharma R & D does not explain variation in dependent variable". The Regression analysis shows P-value of 7.38E-08 equals 0.000, which is less than alfa = 0.05. In this case, the null hypothesis is rejected and alternative hypothesis is accepted. Thus, biotech firms and pharmaceutical companies would choose Firms with more R & D budgets as their licensing partners. The hypothesis that "Number of Employees of a firm does not explain variations in dependent variable" was also tested. This study reveals a P-value of 0.035496, which is less than alfa = 0.05 for the Number of Employees. The "No. of employees" has a coefficient of 0.0007, which is positive but very low, indicating that more No. of employees may lead to more licensing. However, the 'size of the company' and 'age of the company' were found to be insignificant variables, thereby implying that they do not contribute to explaining the dependent variable 'Licensing'. The results show a negative correlation co-efficient value of -0.00014, signifying that there is no relationship between the size of the firm and number of licensing deals. Further, the Regression analysis shows a P-value of 0.175, showing that the Size of the Firm has no direct correlation with the selection of the firm as the partner for the licensing deal. This study shows a P-value of 0.07075 for the 'Age of the Firm' variable which is insignificant.

Table 4: Mean value of various determinants.

Determinants	Average
Size of the company	8517 Mn USD
Pharma R&D expenditure	1218 Mn USD
Pharma Sales	6543 Mn USD
Age of the company	79 years
Number of employees	19,651

The analysis of the research samples showed that on an average the size of the company had a sales of 8517 Mn USD. The pharmaceutical division contributed USD 6543 Mn in total sales on an average. These companies spend 1218 Mn USD on R & D on an average.

It was found that the average age of the company was 79 years, and the average number of employees were 19,651. These details are provided in the table 4. The multilayer perceptron study showed that Size of the company, Pharma R&D expenditure, Age of the company and the Number of employees of the company had a normalized importance of more than forty percent on the licensing. Further, regression analysis showed that the Size of the company and Age of the company were insignificant, whereas, Pharma R & D expenditure and the number of employees were significant variables. The analysis of the current economic situation shows that biotech companies are able to access capital and human resources via several means, including the buoyant capital environment, IPO's, venture capitalists, etc. On the other hand, several of the research and development activities can be contracted out to the Content Research Organisations (CROs) who specialize in manufacturing or clinical development or registration or marketing. Several of such deals have been reported recently. Hence, inference can be drawn that the age of the company or the size of the company may not matter in the current economic environment. At the same time it's important that adequate amount of R&D expenditure is available to the entity for developing the candidate further. Hence, Pharma R&D and number of employees engaged either directly or indirectly with the asset via CRO's do play an important role.

VI. FINDINGS

The study makes seminal observations and adds to the existing knowledge in the field of pharmaceutical licensing and life-cycle management of licensed candidates. These determinants selected in this research study included size of the company, pharmaceutical sales, number of employees, age of the company and pharmaceutical R&D expenditure.

A. Findings based on Multilayer Perceptron (Neural network) analysis

– Of these five determinants chosen in this study (Section 4.1), four were having more relevance on the dependent variable viz 'number of licensing deals" based on Multilayer Perceptron analysis. The variables having normalized importance more than 40% were considered for the model building.

– Total Sales, Pharma R&D, Age of the Company and Number of Employees were identified to have a normalized importance more than 40 % and were selected for further analysis and Pharma sales was dropped.

B. Findings based on Regression analysis:

– Further, Multiple Regression method was used to identify the relationship between the dependent variables and the four independent variables, namely size of the firm (measured as total sales), number of employees, age of the company and pharmaceutical R&D expenditure, and following are the key findings of the study.

– Out of the four independent variables, "Pharma R & D" and "No. of employees" are found to be statistically significant as the p-values of these two variables are 0.000 and 0.035 respectively which are lesser than $\alpha = 0.05$.

– The companies with more 'pharmaceutical R&D budgets' were open to more in-licensing deals. Firms having more R&D Budgets are involved in more licensing deals. More budgets available for research and development provided flexibility to companies to develop multiple candidates. Firms having larger R & D budgets also have regular monitoring and governance bodies that act as stage gates in the process of drug development.

–The research confirmed that 'number of employees' was found to be a statistically significant variable having an effect on the licensing deal.

– This research found that the 'size of a firm' (measured as total sales) has no clear correlation with licensing.

– Another important variable that could contribute to the licensing deal decision was the age of the company. However, this research found that age of the company was insignificant variable having an effect on the licensing deal.

– Several candidates are prioritized for development, while several others are dropped for various reasons including lack of safety, efficacy, differentiation, regulatory requirements or commercial considerations. Thus, these larger firms are constantly seeking first-in-class or best-in-class assets to fill their pipelines. Also these companies with larger R & D budgets are preferred partners for smaller biotech's as they have the financial power required to develop candidates through expensive late phase clinical development, fulfill regulatory requirements, do marketing and undertake commercialization.

– With significant changes happening in the pharmaceutical and biotech industry, with mergers, acquisitions, several large companies are either getting merged or acquired, leading to formation of new companies by their experienced executives. Further buoyant capital environment in developed markets like USA, Europe, Japan or China has given access to large budgets available to companies for expenditure. Thus, this research shows that biotech companies looking to license their assets seek companies with larger R&D budgets and employees, compared to determinants like size of the company or age of the company.

– Thus the analysis of the data reveals that while seeking an out-licensing partner, a licensor preferred companies with R&D budget for expenditure and number of employees.

This study sheds light on the importance of licensing between pharmaceutical and biotech institutes. The deal making and partner selection process is a very complex process. There are several determinants that should be carefully evaluated when deciding a prospective licensing partner for a molecule. This research studies the determinants including the licensee's size of the company, the sales contributed by the pharmaceutical sales, the number of employees, the age of the company and the pharmaceutical research and development expenditure that could be considered while selecting a potential licensee for a product. The statistical analysis first using the Multilayer Perceptron technique showed that the determinants including the size of the company, the number of employees, the age of the company and the pharmaceutical research and development expenditure played a crucial role on the licensing deal.

Based on regression analysis the study concluded that Pharmaceutical Research and Development expenditure and the number of employees of a firm plays a significant role. On the other hand the Size of the firm and the Age of the firm was not found to be significant based on the regression analysis but the presence of these variables above the average value in the case studies reveal that they do have impact on licensing. Lately, there have been reports of big pharma doing a role reversal from being a licensee of innovative assets to now being open to licensing out its assets.

VII. LIMITATIONS OF THE STUDY

The study has the following limitations. The study is limited to the data sample included in this analysis. The study involved a research sample of only 381 licensing deals involving 101 pharmaceutical and biotech companies during the limited time period of 2011-2015. This study is focussed on the quantitative method and each licensing case study may differ from the other. Although it adds to the knowledge base, there are several cases of product development by other biotech companies which needs to be studied to analyse their product development and life-cycle management strategies.

VIII. CONCLUSION

The economics of the pharmaceutical and biotech industry is driven by their ability to discover and develop new drugs for the marketplace. New first-in-class and best-in-class drugs can provide significant competitive edge to the pharmaceutical companies and also benefitting the patients. There has to be a continuous flow of innovation of new drugs satisfying unmet medical needs for the pharmaceutical and biotech institutes. Hence, it is important for pharmaceutical and biotech companies to collaborate with each other.

Prior research suggested that large pharmaceutical companies would usually in-license assets. However, this research shows that the licensor in the current economically buoyant environment where the talent pool is mobile has the option of selecting a potential licensee who can commit to necessary expenditure and has the required expertise. Thus, the licensor may not be heavily influenced by the size of the firm or the age of the firm, but in current times will look for the R & D expenditure and the number of employees that the firm is willing to commit to the product. Further, there have been many innovative licensing and financing models in the pharmaceutical industry where non-clinical, clinical, manufacturing, as well as marketing activities are contracted out to other entities. Thus the licensors, be it a large pharmaceutical company or the biotech may look for commitment in terms of R&D funding and sufficient number of individuals committed to the program either directly from the company or through contractual relationships via Contract Research Organizations (CRO).

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