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Does R&D Intensity and Innovative Activities drive Indian Pharmaceutical Exports?

A Banerji[1]* and F K Suri[2]

[1]Department of Management Studies, Maulana Azad National Institute of Technology, Bhopal, Madhya Pradesh 462003, India

[2]Regional Centre for Biotechnology, Faridabad, Haryana, 122016, India

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R&D intensity is critical to the growth of hi-tech sectors like pharmaceuticals and information technology and is aimed at boosting innovation. In turn, innovation brings new products that could earn revenues to further boost R&D intensity[1]. Indian pharmaceutical industry earns nearly sixty percent of its revenues from exports and is a leader in global generics market with largest share of ANDA and DMF filings. Significant increase in patenting activity is also observed post India's accession to TRIPS agreement in 1995 and subsequent introduction of Product Patent Regime in 2005[2]. This study aims at establishing a causal relationship amongst R&D intensity, patents, regulatory filings and export intensity. Also, the impact of these variables on export intensity of Indian Pharmaceutical sector has been studied by fitting them into an econometric model.

Keywords: Technology Management, R&D intensity, Export intensity, Innovation and export intensity, patents, Indian Pharmaceutical Industry

Introduction

The study uses real financial data for Indian pharmaceutical industry for period 2000-01 to 2013-14 as shown in table 1. The study period starts from 2000-01 as the R&D intensity of Indian pharmaceutical industry; patent data as well as regulatory filings were negligible prior to 2000-01. As the study takes into the regulatory filings, therefore the data up to 2013-14 has been taken into account as USFDA was reporting ANDA and DMF filings till 2013-14 and thereafter the reporting pattern changed to ANDA and DMF approvals. For this reason, the study period was selected as 2000-01 to 2013-14.The data for exports and R&D expenditure have been drawn from Center for Monitoring of Indian Economy (CMIE), Prowess Database. Data for ANDA and DMF filings (referred as regulatory filings) have been taken from annual reports of Department of Pharmaceuticals, Government of India& United States Food and Drug Administration (USFDA). Patent data has been extracted from World Intellectual Property Organization (WIPO) Statistics Database[3]. Eviews 8 was used for statistical and econometric analysis. All data points were made stationary by converting to natural log and then taking first difference. This study attempts at determining a causal relationship between variables namely; R&D intensity (RDI), pharmaceutical export intensity (PEI), regulatory filings (RF), and total patents granted (TP). Econometric analysis was performed using Granger causality to test two way causal relationships amongst the variables. This was followed by fitting the variables into Autoregressive distributed lag (ARDL) model.

Results and Discussion

It was found that R&D intensity Granger causes export intensity. A two way causal relationship was found between regulatory filings and R&D intensity. Similarly, a two way causal relationship was observed amongst variables; total patents and regulatory filings. Also, total patents granted as well as regulatory filings were found to be Granger causing pharmaceutical export intensity as shown in table 2. The results of Granger causality tests can be explained with the fact that R&D expenditure is aimed at developing new products for domestic as well as overseas markets. Firms invest in R&D to boost their presences in regulated markets like US and Europe and that the

*Author for Correspondence
E-mail: amitbanerji123@gmail.com

Table 1 — Data Set: Pharmaceutical Exports, R&D Expenditure, Regulatory Filings and Patents Granted in Indian Pharmaceutical Industry during 2000-01 to 2013-14.

1	Regulatory Filings (ANDAs & DMFs)	Total Patents	Pharma Export Intensity (Exports/Total revenue)	Pharma R&D Intensity (R&D spend/Total Revenue)
2000-01	229	56	0.400023	0.019931
2001-02	255	99	0.477345	0.024177
2002-03	345	147	0.391371	0.027066
2003-04	413	246	0.38167	0.035952
2004-05	573	379	0.401192	0.046411
2005-06	624	382	0.404112	0.05069
2006-07	649	550	0.403725	0.047615
2007-08	762	513	0.398848	0.046945
2008-09	769	520	0.466846	0.048782
2009-10	836	497	0.435808	0.044427
2010-11	849	545	0.439821	0.03999
2011-12	897	496	0.528043	0.047597
2012-13	1005	635	0.653466	0.053569
2013-14	938	635	0.593169	0.048624

Source; United States-Federal Drug Administration (USFDA), CMIE, Prowess Database, Annual reports of Department of Pharmaceuticals-Government of India, WIPO IP Statistics Data Center

Table 2 — Results of Econometric Analysis

Pairwise Granger Causality Tests

Sample: 1 14

Lags: 1

Null Hypothesis:	Obs	F-Statistic	Prob.
DPEI does not Granger Cause DRDI	12	0.60300	0.4574
DRDI does not Granger Cause DPEI		3.75138	0.0847
DRF does not Granger Cause DRDI	12	20.0445	0.0015
DRDI does not Granger Cause DRF		78.3758	1.E-05
DTP does not Granger Cause DRDI	12	64.8069	2.E-05
DRDI does not Granger Cause DTP		469.740	4.E-09
DRF does not Granger Cause DPEI	12	3.89655	0.0798
DPEI does not Granger Cause DRF		0.93581	0.3586
DTP does not Granger Cause DPEI	12	3.90333	0.0796
DPEI does not Granger Cause DTP		0.81170	0.3911
DTP does not Granger Cause DRF	12	17.6064	0.0023
DRF does not Granger Cause DTP		12.5278	0.0063

ARDL Model

Dependent Variable: PEI

Method: Least Squares

Sample (adjusted): 2 14

Included observations: 13 after adjustments

Variable	Coefficient	Std. Error	t-Statistic	Prob.
RDI	7.830368	2.846284	2.751085	0.0403
LNTP	-0.129055	0.097836	-1.319097	0.2443
LNRF	0.249905	0.215931	1.157340	0.2994
C	-1.387805	0.445791	-3.113127	0.0265
PEI(-1)	0.368086	0.191750	1.919616	0.1130
RDI(-1)	-1.265347	3.769674	-0.335665	0.7508
LNTP(-1)	-0.297353	0.096082	-3.094786	0.0270
LNRF(-1)	0.356776	0.120209	2.967952	0.0312

R-squared	0.936636	Mean dependent var	0.459647
Adjusted R-squared	0.847926	S.D. dependent var	0.084393
S.E. of regression	0.032910	Akaike info criterion	-3.714808
Sum squared resid	0.005415	Schwarz criterion	-3.367147
Log likelihood	32.14625	Hannan-Quinn criter.	-3.786268
F-statistic	10.55845	Durbin-Watson stat	1.579074
Prob (F-statistic)	0.009784		

Source: Result of analysis using Eviews 8

ANDA and DMF approvals are one of the major R&D productivity indicators in India[4, 5]. ARDL model (Table 2) suggested that the current year R&D intensity had a positive and significant impact on pharmaceutical export intensity. Also, the lagged year regulatory filings had a positive and significant impact on export intensity of Indian pharmaceutical industry. Results of the ARDL model suggested that lagged year total patents granted to Indian

pharmaceutical industry had a significant but negative impact on export intensity. This seems to be merely a statistical artifact as patents filed through PCT route are aimed at securing innovations in overseas markets and shall have a positive impact on export intensity. This result does not corroborate with the finding of previous studies wherein patenting activity is positively affecting pharmaceutical exports [6]. Total patents granted may not have a positive impact on exports over one year lag as patents are mainly a protection for an innovative product or process. It is then followed by further development and testing of the new product which may take 3-4 years time till it is approved by regulatory authorities for launch [7].

Conclusion

It was found from the current study that Indian pharmaceutical exports were mainly driven by regulatory filings (ANDAs and DMFs) and not by total patents granted. It was observed that R&D efforts as well as R&D expenditure made by Indian pharmaceutical industry were focused at developing generics (due to patent expiries) for developed markets especially US and Europe. It is evident that fewer resources were committed towards innovative research resulting in fewer patents. This finding was validated from the fact that nearly sixty percent of the revenue of Indian pharmaceutical firms are from exports and India is has the largest share in generics market in the US[8].

References

1 Briones PenalverA J, Antonio C Santos J, Bernal Conesa J A, & Santos M C, Innovation Management and Strategy, *J Sci Ind Res*, **77** (2018), 437-441.

2 Thomas R, Narayanan K, Kathuriya V, Tyagi S, Mahajan V, & Nauriyal D.K, Innovations in Indian Drug and Pharmaceutical Industry: Have they impacted exports*? J Intellec Prop Rights*, **19** (2014), 243-252.

3 WIPO IP Statistics Data Center, https://www3.wipo.int/ipstats/index.htm?tab=patent,(accessed on 02.04.2018).

4 13thAnnual Report 2016-17, Pharmaceutical Exports Promotion Council of India (Pharmexcil), https://pharmexcil.com/docs/Pxl13thAnnualReport2017.pdf., (accessed on 04.04.2018).

5 Suri F K, Banerji A, Patents, R&D Expenditure, Regulatory Filings and Exports in Indian Pharmaceutical Industry, *J Intellec Prop Rights*, **22**(1)(2017), 136-145.

6 Tyagi S, Nauriyal D K, Gulati R, Firm level R&D intensity: evidence from Indian drugs and pharmaceutical industry, *Rev Man Sci*,**12**(1) (2017), 167-202.

7 Dhar B & Gopalkumar K M, Effects of Product Patents on Indian Pharmaceutical Industry, (2011), http://wtocentre.iift.ac.in/Papers/3.pdf (accessed on 07.02.2018).

8 Vaidya M, Garg S, Singh C, & Mahajan M M, Changing Dimensions of Drug Patents of Indian Pharmaceutical Industry, *J Intellec Prop Rights*,**23** (2018), 111-118.