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Patents, R&D Expenditure, Regulatory Filings and Exports in Indian Pharmaceutical Industry

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The impact of R&D expenditure, regulatory filings and patents granted on exports from Indian Pharmaceutical Industry has been studied. Pair wise Granger causality test between total patents granted and pharmaceutical exports suggests that total patents granted Granger causes pharmaceutical exports. Also, it was found that the R&D expenditure Granger causes regulatory filings like ANDAs and DMFs with a lag of one year. The relationship amongst variables namely pharmaceutical exports (as dependent variable) and regulatory filings and total patents granted (as independent variables) was analyzed using Autoregressive Distributed Lag (ARDL) Model. The ARDL model is suggestive of strong positive relationship amongst regulatory filings and pharmaceutical exports at one year lag. Also, there exists positive relationship between total patents granted and pharmaceutical exports. However, the impact of regulatory filings on exports is stronger as compared to that of total patents granted. It was found that in Indian Pharmaceutical Industry, regulatory filings have a major role in exports and the impact of patents granted is relatively small owing to the fact that Indian pharmaceutical firms have so far commercialized very few patented pharmaceutical products in global market.

Keywords: Pharmaceutical exports, patents, regulatory filings, R&D expenditure, Indian pharmaceutical industry

Patenting Activity of Indian Pharmaceutical Industry

Patenting innovations is an important parameter of measuring the output of R&D activity of the Indian Pharmaceutical Industry. India has become WTO/TRIPS compliant post-GATT era. Inventions are patented in respective countries through conventional route or simultaneously in multiple countries through Patent Co-operation Treaty (PCT). Nowadays, several patents are granted wherein developed formulations are protected by claiming every indication/use of the drug product.[1]

For period 1997-2010, Fig. 1 indicates patent application filings relating to drugs ranging from 9 to 22 percent based on year by year basis. The patent application filings were high during the transition period 1995-2005 wherein, India made a mailbox facility in accepting product patents as well. Several patent applications belong to chemical and bio-technology class and may also belong to pharmaceuticals.[2] Table 1 shows 19.75% of all patent applications during 1997-2010 belongs to chemicals class followed by 12.39% for drugs and 4.72% for bio-technology which sums up to 36.8% of patents applications during 1997-2010.

The World Intellectual Property Organization (WIPO) statistics for pharmaceutical patents granted globally during the year 2000 to 2014 (Table 2) also shows the number of patents granted to Indian pharmaceutical firms during the same period. It can be noted that the share of Indian pharmaceutical firms remained consistently near 1% mark indicating a negligible presence in the global innovative space.[3]

WIPO statistics for PCT publications for pharmaceuticals for the period 2000 to 2014 is shown in Table 3. It is interesting to note that India's share in global PCT publications is significantly higher as compared to its share in global patents granted.

R&D Activity of Indian Pharmaceutical Industry

There has been a significant increase in R&D spend by the Indian companies post accession to Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1995. Despite more money being spent on pharmaceutical R&D in India during TRIPS regime, it is significantly less in comparison to

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the R&D expenditure of global MNCs.[4] The R&D spends of Indian Pharmaceutical companies further increased post 2005 upon introduction of Product Patent Regime. Due to large investments, companies have built strong product pipelines for the US market, but negligible development has taken place on the New Chemical Entity (NCE) front.[5]

R&D expenditures by 25 leading Indian pharmaceutical companies have gone up significantly by 28.8% in 2014-15 as compared to the previous year. R&D to sales ratio of Indian pharmaceutical industry has been ever increasing with approximately 7% of sales being utilized for R&D[9]. Most of the investments went into developing cost effective generic products for US and European markets in key therapeutic segments with little focus on new drug discoveries.[6]

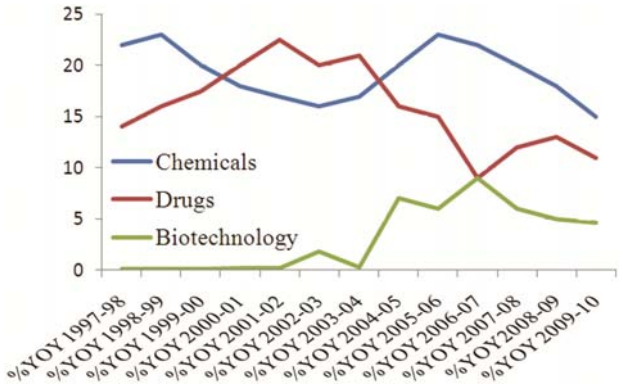

Fig 1 — Percentage year on year (YOY) basis of patent applications of drugs, chemicals and bio-technology[2]at IPO

Table 1 — Patent applications filed at Indian Patent Office (IPO) during 1997-2010[2]

Year	Chemical	Drug	Bio-technology	Total
Applications filed	44730	28064	10697	226501
Overall percent based on applications in all fields	19.75%	12.39%	4.72%	36.8%

Regulatory Filings from Indian Pharmaceutical Industry

Regulatory authorities not only specify the quality, safety and efficacy of a drug product but also prescribe the norms for its development, manufacturing, distribution and promotion. More than 100 countries have established regulatory requirements for approval of a drug product. Global pharmaceutical market is divided into two groups: Regulated and Emerging Markets. Regulated markets comprise of countries having defined regulatory requirements set by regulatory authorities. North America (including US and Canada) and European Union are the biggest and the most potential markets and are categorized as regulated markets. Emerging markets are those countries that are still in the process of putting forward a defined set of regulations for drugs. These include Rest of the World (ROW) and Brazil, Russia, India, China and South Africa are the largest and high potential emerging markets.[7]

Regulatory filing or the dossier required to be filed for bulk drug is called DMF. DMF is to be filed before the USFDA for authorizing the use of a bulk drug in a formulation that is intended to be sold in the US market. In US, regulatory filing with USFDA to obtain marketing authorization for a formulation (new product) is called New Drug Application (NDA) and for a generic product is called ANDA. In Europe, regulatory filing with European Medicines Agency (EMA) for a formulation is called Marketing Authorization.[7]

United States had approximately 40% of the global pharmaceutical market with a size of US$ 377 billion in 2014 (IMS Health 2015). With a significant generic substitution, US is also the largest generic market. With patent expiries, worth $ 100 billion during 2013 to 2018; generic business in the US indicates significant opportunities for Indian pharmaceutical firms who have expertise in generic drug development for regulated markets. Besides patent expirations, healthcare reforms initiated by the US Government, aimed at reducing

Table 2 — Pharmaceutical patent statistics (WIPO-World Intellectual Property Organization)[3]

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Global	15434	17354	19369	22979	23806	21820	29160	25173	26197	26814	29609	33735	37449	39400	39933
Indian	27	52	74	134	219	180	327	278	296	269	295	241	340	379	336
Indian % of global	0.17	0.30	0.38	0.58	0.92	0.82	1.12	1.10	1.13	1.0	1.0	0.71	0.91	0.96	0.84

Table 3 — PCT publications by technology (Pharmaceuticals)[3]

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
PCTs Global	3808	4356	4864	5586	5845	7476	8677	8795	8960	8400	7837	7715	7814	7739	8590
PCTs from India	29	47	73	112	160	202	223	235	224	228	250	255	295	256	285
Indian % of Global	0.8%	1.1%	1.5%	2.0%	2.7%	2.7%	2.6%	2.7%	2.5%	2.7%	3.2%	3.3%	3.8%	3.3%	3.3%

healthcare spending and covering a larger proportion of population under public healthcare are also likely to boost growth in the generics market[1]. Generic opportunity in the US market has led to a wave of ANDA and DMF filings by the Indian companies. Most of the leading Indian companies have significantly expanded their ANDA filings during 2005 to 2015. US is also one of the most matured of all the markets.[3,8] The price erosion post patent expiration is also amongst the highest in the US, reflecting the extent of competitive pressures.[9]

Drugs, pharmaceuticals and fine chemicals have been fifth largest exported principal commodity of the country, accounting for 4.8% of India's Total Exports. In line with last two decades India's Pharmaceutical Industry, has achieved a positive trade balance and is approximately USD 9.0 to 10.0 billion. As per the statistics released by Director General of Commercial Intelligence & Statistics (DGCIS), Kolkata, India's Exports of Drugs and Pharmaceuticals during 2014-15 was USD 15.33 billion with a growth of 2.64%. India's export in INR terms recorded a growth of 4.35% and reached INR 94,275 crore during 2014-15.

Indian pharmaceutical exports grew at a CAGR of 13.70% from 2009-10 to 2013-14. Fig. 2 indicates a steady increase in pharmaceutical exports from 2009 to 2014. Growth in pharmaceutical exports can be attributed to patent expiries of a number of branded products marketed by MNCs in developed markets like US and Europe. Indian generics are benefitting from the ongoing wave of patent expiries and it would continue till 2020 as branded products worth approximately $ 100 billion being off patent between 2012 and 2017. Almost all leading Indian companies are expanding their Abbreviated New Drug Application (ANDA) pipelines in line with the patent expiries.[10]

USA has been the highest grossing export destination for Indian pharmaceutical products with a share of 26.73 %, amounting to $ 4022 million and a growth of 7.9%.[11] India offers almost every product which has gone off patent and with a large vendor base. India's filings of Drug Master File (DMF) with United States Food and Drug Administration (USFDA) as of December 2013, was 3411, the highest filed by any country in the world.[12]

Fig 2 — Indian pharmaceutical exports

Source; Director General of Commercial Intelligence & Statistics (DGCIS), Kolkata, 2014 and CMIE Prowess Database, 2013.

Literature Review and Theoretical Framework

There have been many studies on trends of R&D activity, patenting activity and exports of Indian Pharmaceutical Industry post India's compliance to TRIPS in 1995 and introduction of product patent regime since 1st January 2005.[11,13-19] Studies have shown that many firms in the pharmaceutical industry invest heavily in R&D as a prerequisite to remaining or becoming competitive.[19] Most of these studies are descriptive in nature and indicated an increase in R&D expenditure, patents and exports. Few of these studies showed a causal relationship between patents granted and exports. These papers supported innovation led exports growth hypothesis despite the fact that Indian firms have been mainly exporting generic versions of patented products to developed markets and that the share of patented products in their export profile is negligible. It is therefore important to include regulatory filings as one of the key factors driving exports.

Chaudhuri (2007) found that R&D expenditure had dramatically increased for a segment of the Indian pharmaceutical industry after TRIPS came into effect. It is not only that the amount of R&D expenditure increased, but there was a drastic shift in the structure of R&D activities of the Indian companies. Earlier Indian firms were primarily engaged with the development of new processes for manufacturing drugs, now they are also involved in R&D for new chemical entities (NCE).[17]Indian companies have been increasing their rate of DMF filings every quarter. Indian generic players are also increasing their participation in the advanced markets, particularly the US. ANDA filings with USFDA are also increasing in Post- TRIPS period.[18] Indian pharmaceutical firms earned more than 60% of their revenue from exports of generic version of patented drugs to regulated markets like US and Europe for period 2005-06 to 2013-14.[6]

This research aims at studying whether regulatory filings (ANDAs and DMFs) or total patents granted are the key drivers of exports. This research aims at

analyzing a two-way causal relationship amongst R&D expenditure and exports, R&D expenditure and regulatory filings (DMFs and ANDAs), Pharmaceutical exports and patents granted; and regulatory filings and exports.

Data, Methodology and Analysis

The data set used in this empirical investigation is consists of a sample of Indian Pharmaceutical firms covered by the Center for Monitoring of Indian Economy (CMIE), Prowess Database. The data for variables namely; pharmaceutical exports and R&D expenditure are from CMIE-Prowess Database for period 2000-01 to 2013-14. Data for total patents granted is obtained from WIPO IP Statistics Data Center. Data on regulatory filings (DMFs and ANDAs) are obtained from USFDA (Table 4). Reviews 8 are used for statistical and econometric analysis. All data points were made stationary by converting to natural log and then taking first difference (DLNRDE, DLNPE, DLNRF, DLNTP).

DMF and ANDA approvals in US have been taken as a proxy for regulatory filings as the USFDA is regarded the most stringent regulatory authorities in world and product development strategy for leading pharmaceutical companies are mainly driven by patent expiry of the product in US.[7] Also, US accounts for 30% of pharmaceutical exports from India. Top 10 Indian Pharmaceutical companies account for more than 70% of their formulation exports to US. Also, India's share of ANDA approvals compared to other countries is gradually increasing and reached 42.7% of all ANDAs approved by USFDA in 2013. Moreover, India accounts for 40% of generic drugs in US with the highest number (550) of USFDA approved manufacturing plants that also caters to other markets like Europe, South Africa, Latin America and Asia.[20]

This research attempts at determining a causal relationship amongst variables namely R&D expenditure (DLNRDE), pharmaceutical exports (DLNPE), regulatory filings (DLNRF) and total patents granted (DLNTP) in Indian pharmaceutical industry. Also, the variables namely pharmaceutical exports (DLNPE), total patents granted (DLNTP) and regulatory filings (DLNRF) are embedded into a structural model.

Granger causality is a statistical concept of causality that is based on prediction. According to Granger causality, if a signal X_1 "Granger-causes" a signal X_2, then past values of X_1 should contain information that helps to predict X_2 above and beyond the information contained in X_2 alone.[21] Pairwise Granger causality test over the variables namely R&D expenditure and ANDA approvals with one year lag shows Granger causation from R&D expenditure to ANDA approvals with more than 99% confidence as shown in Table 5. A similar relationship exists between R&D expenditure and DMF approvals wherein R&D expenditure Granger causes DMF approvals with one year lag. These findings are in line with the recent trend amongst leading Indian pharmaceutical firms to invest in R&D to boost their presences in regulated markets like US and Europe

Table 4 — Data set: Pharmaceutical exports, R&D expenditure, regulatory filings and patents granted in Indian Pharmaceutical Industry during 2000-01 to 2013-14

Year	Pharmaceutical exports (INR crores)	R&D expenditure (INR crore)	No. of ANDAs	No. of DMFs	Regulatory filings (ANDAs & DMFs)	Pharmaceutical PCT publications	Pharmaceutical patents (Indian origin)	Total patents
2000-01	10557	526	9	220	229	29	27	56
2001-02	13643	691	9	246	255	47	52	99
2002-03	12826	887	15	330	345	73	74	147
2003-04	15213	1433	22	391	413	112	134	246
2004-05	17228	1993	23	550	573	160	219	379
2005-06	21230	2663	48	576	624	202	180	382
2006-07	25666	3027	63	586	649	223	327	550
2007-08	29354	3455	117	645	762	235	278	513
2008-09	39821	4161	137	632	769	224	296	520
2009-10	42456	4328	126	710	836	228	269	497
2010-11	48810	4438	130	719	849	250	295	545
2011-12	65000	5859	154	743	897	255	241	496
2012-13	79400	6509	201	804	1005	295	340	635
2013-14	81234.14	6659	158	780	938	256	379	635

Source; CMIE, Prowess Database, US Food & Drug Administration, WIPO IP Statistics Data Center
Note: 1 Crore equals INR 10 Million.

Table 5 — Granger causation (With 1 lag is stronger as compared to 2 yrs lag)

Pairwise Granger Causality Tests

Sample: 1 14
Lags: 1

Null Hypothesis:	Obs	F-Statistic	Prob.
DLNDMF does not Granger Cause DLNANDA	12	2.14392	0.1772
DLNANDA does not Granger Cause DLNDMF		0.08120	0.7821
DLNPCT does not Granger Cause DLNANDA	12	2.43374	0.1532
DLNANDA does not Granger Cause DLNPCT		0.95191	0.3547
DLNPE does not Granger Cause DLNANDA	12	0.28869	0.6041
DLNANDA does not Granger Cause DLNPE		0.78127	0.3997
DLNRDE does not Granger Cause DLNANDA	12	6.32936	0.0330
DLNANDA does not Granger Cause DLNRDE		1.41830	0.2641
DLNPCT does not Granger Cause DLNDMF	12	10.5238	0.0101
DLNDMF does not Granger Cause DLNPCT		0.02207	0.8852
DLNPE does not Granger Cause DLNDMF	12	1.00839	0.3415
DLNDMF does not Granger Cause DLNPE		0.54995	0.4772
DLNRDE does not Granger Cause DLNDMF	12	8.31533	0.0181
DLNDMF does not Granger Cause DLNRDE		0.47668	0.5073
DLNPE does not Granger Cause DLNPCT	12	0.00212	0.9643
DLNPCT does not Granger Cause DLNPE		2.69459	0.1351
DLNRDE does not Granger Cause DLNPCT	12	1.14471	0.3125
DLNPCT does not Granger Cause DLNRDE		19.6759	0.0016
DLNRDE does not Granger Cause DLNPE	12	1.12952	0.3156
DLNPE does not Granger Cause DLNRDE		0.04127	0.8435

Table 6 — Pairwise Granger Causality Tests

Sample: 1 14
Lags: 1

Null Hypothesis:	Obs	F-Statistic	Prob.
DLNTP does not Granger Cause DLNPE	12	5.17051	0.0491
DLNPE does not Granger Cause DLNTP		0.26795	0.6172

and that the ANDA and DMF approvals are one of the major R&D productivity indicators in India.[22] Also, total patents granted to Indian pharmaceutical firms were found to be Granger causing pharmaceutical exports with one year lag as shown in Table 6. This is in line with well-established trade-innovation macroeconomic framework that offers mainstream theoretical models to account for a relationship between R&D/innovation and exporting with the causation running from the former to the latter. [23] This theoretical model is supported by the fact that a majority of pharmaceutical exports from India is to North America and especially for products going off patent in specific years.[11] Moreover, due to intense competition and rapid price erosion in the generic drug market of North America, Indian companies have to build a pipeline of ANDAs to retain sales. Also, due to price erosion, it becomes imperative for Indian firms to remain competitive in terms of pricing to retain their market share for respective products. This requires continuous R&D effort for process innovation to reduce costs. Furthermore, increasing exports to a certain geographical destination leads to further export orders requiring capacity expansion and process modification.[24]

Autoregressive distributed lag (ARDL) are standard least squares regressions which include lags of both dependent variable and explanatory variables as regressors (Greene 2008). ARDL models have been in use for decades but they gained popularity in recent years as a method of examining long-run and co-integrating relationships between variables. [25] ARDL model was used to analyze the long run relationship between variables namely; regulatory filings, pharmaceutical exports and total patents granted. ARDL model is used to test the presence of long run relationships between economic time series. ARDL model was introduced by Pesaran *et al.* (2001) in order to incorporate I (0) and I (1) variables in the same estimation. In this case, variables are non stationary I(1), VECM (Johanson Approach) has been adopted.[20] In ARDL I(1) model, lagged dependent variables have an impact after one year. Null

hypothesis is; residuals are multivariate normal (Fig. 3). With a significance of 0.92, fails to reject the null hypothesis. ARDL model suggest that the pharmaceutical exports is impacted by regulatory filings as well as total patents granted. However, the regulatory fillings have a greater impact on pharmaceutical exports as compared to that of total patents granted (Table 7). The ARDL co-integrating model seems to be the best fit equation as under:

The current and lagged year regulatory filings and total patents (current and lagged year) are highly significant. Though, the coefficient of total patents is higher, however; regulatory filings (current and lagged year) are far more significant.

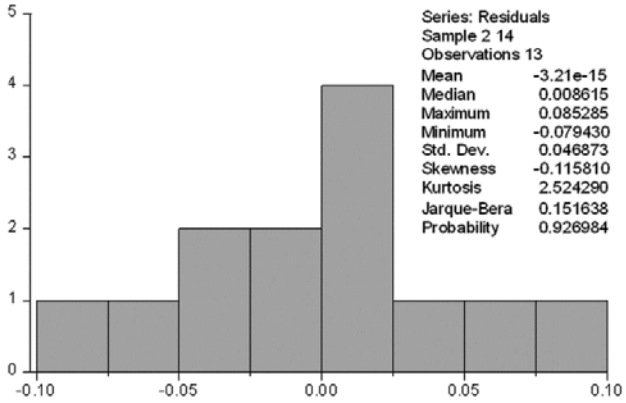

Fig.3 — Residual Normality Test

With R^2 greater than 0.99 having F-stat value 275.5010 with significance 0%, estimation equation seems to be the best fit. DW stat of 2.458193 is suggestive of no auto-correlation. A 1% rise in total patents granted (current year) gives rise to Rs. 0.12 crore of pharmaceutical exports; other things remaining constant. On the other hand, a 1% rise in previous year's total patents granted gives rise to pharmaceutical exports by Rs. 0.42 crores.

A 1% rise in last year's regulatory filings gives rise to an increase of Rs. 0.22 crores in pharmaceutical exports; other things remaining constant. The autonomous exports is approximately Rs. 10.77 crores i.e. based on reasons other than regulatory filings and total patents granted. Continuously compounded pharmaceutical exports generate Rs. 0.18193 crores of exports. This growth is on account of momentum generated by export performance. Table 8 shows strong correlation between pharmaceutical exports and total patents granted.

Table 9 shows Single equation Engle Granger Co-integrating equation. The test indicates the presence of one co-integrating equation with pharmaceutical exports being co-integrating with total patents granted with first difference stationary. This

Table 7 — ARDL Co-integration Model

Dependent Variable: LNPE
Method: Least Squares
Sample (adjusted): 2 14
Included observations: 13 after adjustments

Variable	Coefficient	Std. Error	t-Statistic	Prob.
C	10.76775	0.355321	30.30428	0.0000
DLNPE	0.181932	0.171177	1.062829	0.3231
LNTP	-0.125591	0.138464	-0.907030	0.3945
RF	0.001947	0.000405	4.808342	0.0019
LNTP(-1)	-0.417263	0.115466	-3.613728	0.0086
RF(-1)	0.002166	0.000323	6.700350	0.0003

R-squared	0.994944	Mean dependent var.	10.34471
Adjusted R-squared	0.991333	S.D. dependent var.	0.659203
S.E. of regression	0.061371	Akaike info criterion	-2.439724
Sum squared reside	0.026365	Schwarz criterion	-2.178978
Log likelihood	21.85820	Hannan-Quinn criter.	-2.493319
F-statistic	275.5010	Durbin-Watson stat.	2.458139
Prob (F-statistic)	0.000000		

Estimation Equation
LNPE = C(1) + C(2)*DLNPE + C(3)*LNTP + C(4)*RF + C(5)*LNTP(-1) + C(6)*RF(-1)

Substituted Coefficients
LNPE = 10.7677469528 + 0.181931949071*DLNPE - 0.125591415152*LNTP + 0.00194749538335*RF - 0.417262817506*LNTP(-1) + 0.00216568751285*RF(-1)

implies that total patents granted pulls back the exports to the path of growth (Error Correction Mechanism).

Residual Tests: ARDL Model

Test for Serial Correlation

Null hypothesis is absence of serial correlation. The F-stat value of 0.62 of significance 0.57 fails to reject the null hypothesis. No serial correlation between the residuals (autocorrelation).

Hetero-skedasticity

Null hypothesis in homo-skedasticity is present. The Bruesch Pagan test fails to reject null hypothesis. Therefore, hetero-skedasticity is absent. Therefore, there is no long run pattern within the residuals.

Model Stability

Testing the long run stability of model, CUSUM test was applied at 5% significance. It was observed that model was found to be stable as per Figure 4 i.e. in not only have predictive power but the model is stable in the long run. CUSUM test is based on cumulative sum of recursive residuals based on the first set of n observations. It is plotted recursively and is plotted on the break points. If the plot of CUSUM remains within 5% significance level, then estimated coefficients are said to be stable.

The ARDL co integration test assumes that only one long run relationship exists between the dependent variable and exogenous variable[23,27]. The Table 9 shows F-test with critical values of Pesaran (2001) as maximum critical values of Narayan (2005)

Table 8 — Correlations between pharmaceutical exports and total patents granted

		LNPE	LNTP
LNPE	Pearson Correlation	1	.816(**)
	Sig. (2-tailed)		.000
	N	14	14
LNTP	Pearson Correlation	.816(**)	1
	Sig. (2-tailed)	.000	
	N	14	14

** *Correlation is significant at the 0.01 level (2-tailed).*

Table 9 — Single Equation Engle Granger Co-integrating Equation

Series: DLNPE DLNTP
Sample (adjusted): 2 14
Included observations: 13 after adjustments
Null hypothesis: Series are not cointegrated
Cointegrating equation deterministics: C
Automatic lags specification based on Schwarz criterion (maxlag=1)

Dependent	tau-statistic	Prob.*	z-statistic	Prob.*
DLNPE	-5.147237	0.0076	-17.34382	0.0036
DLNTP	-1.452143	0.7828	-3.013156	0.8675

*MacKinnon (1996) p-values.
Warning: p-values may not be accurate for fewer than 20 observations.

Intermediate Results

	DLNPE	DLNTP
Rho - 1	-1.445319	-0.429783
Rho S.E.	0.280795	0.295965
Residual variance	0.008730	0.032847
Long-run residual variance	0.008730	0.013343
Number of lags	0	1
Number of observations	12	11
Number of stochastic trends**	2	2

**Number of stochastic trends in asymptotic distribution

Breusch-Godfrey Serial Correlation LM Test:

F-statistic	0.620263	Prob. F(2,5)	0.5746
Obs*R-squared	2.584211	Prob. Chi-Square(2)	0.2747

Heteroskedasticity Test: Breusch-Pagan-Godfrey

F-statistic	0.475599	Prob. F(5,7)	0.7848
Obs*R-squared	3.296435	Prob. Chi-Square(5)	0.6544
Scaled explained SS	0.728436	Prob. Chi-Square(5)	0.9814

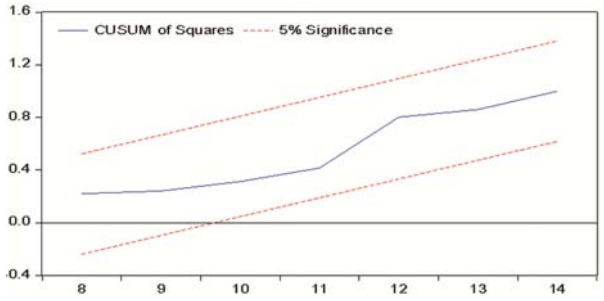

Fig 4 — Model Stability Test (CUSUM of squares of residuals)

Table 10 — Coefficient Diagnostics [26, 27]

Wald Test:
Equation: Untitled

Test Statistic	Value	df	Probability
F-statistic	25.59857	(2, 7)	0.0006
Chi-square	51.19714	2	0.0000

for small sample; the F-test is sensitive to number of lags imposed on each first difference variable. Table 10 gives the F-value at 5% significance. It is observed that the calculated value is greater than the critical value indicating co integration between variables. The null hypothesis is rejected i.e. no cointegration exists between variables [26, 27].

Results and Discussion

An empirical analysis was carried out to study the impact of patents granted and regulatory filings on exports from Indian pharmaceutical industry. It was found that the R&D expenditure Granger causes regulatory filings like ANDAs and DMFs with a lag of one year. This finding is in conformance to the increasing trend of R&D expenditure since 1 January 2005 (Post WTO/GATT Era) which is mainly aimed at developing generics for the US: most lucrative market of the world and contributing nearly 30% of Indian pharmaceutical exports. Also, pair wise Granger causality test between total patents granted and pharmaceutical exports suggests that total patents granted Granger causes pharmaceutical exports. This can be explained by the fact that the study period (2000-01 to 2013-14) covers post TRIPS period as well as post accession to Product Patent Regime (Post 1 January 2005) wherein Indian Pharmaceutical Industry adapted to TRIPS and Product Patent Regime by increasing their patenting activity in India and abroad and at the same time leveraged the benefit of ongoing patent expiries for patented products in US and Europe.[14] However, Granger causation between regulatory filings and pharmaceutical exports was not found which is highly unlikely as regulatory filings (ANDAs and DMFs) are filed primarily for the purpose of exporting pharmaceutical products in US.[7] The relationship amongst variables namely pharmaceutical exports (as dependent variable) and regulatory filings and total patents granted (as independent variables) was analyzed using Autoregressive Distributed Lag (ARDL) Model. The ARDL model is suggestive of strong positive relationship amongst regulatory filings and pharmaceutical exports at one year lag. Also, there exists positive relationship between total patents granted and pharmaceutical exports. Lagged regulatory filings and lagged total patents were found to be positively and significantly affecting Indian Pharmaceutical exports. However, the impact of regulatory filings on exports is stronger as compared to that of total patents granted. This is in line with India having largest number of USFDA approved manufacturing plants outside US and Indian Pharmaceutical firms contributing 40% of generic medicines in the US in 2014 (NASDAQ 2016). Regulatory filings (ANDAs and DMFs) are form of marketing authorizations for the US market and lead to export of pharmaceutical products to US. Therefore, the impact of regulatory filings on exports can be very well explained through the industry dynamics. ARDL co-integrating model suggest that a 1% rise in last year's regulatory filings gives rise to an increase of Rs. 0.22 crores in pharmaceutical exports; other things remaining constant. The autonomous export is approximately Rs. 10.77 crores i.e. based on reasons other than regulatory filings and total patents granted. Continuously compounded pharmaceutical exports generate Rs. 0.18193 crores of exports. This growth is on account of momentum generated by export performance. On the other hand, patents granted is a set of exclusive rights granted for an innovation. A patent may or may not translate into trade. ARDL model used in current research suggests that a 1% rise in total patents granted (current year) gives rise to Rs. 0.12 crore of pharmaceutical exports; other things remaining constant. On the other hand, a 1% rise in previous year's total patents granted gives rise to pharmaceutical exports by Rs. 0.42 crores.

It is a subject for further research to understand the contribution of patented formulations and active pharmaceutical ingredients in total pharmaceutical exports. This would help in understanding whether patents granted are translating into trade. It is a subject of further research to quantitatively segregate

the contribution of regulatory filings (for generics) and patents in Indian pharmaceutical exports. Current research suggests that both regulatory filings and patents are determinants of exports but the extent of their individual contribution using separate data for exports of patented products provides scope for further research on this subject matter.

Conclusion and Recommendations to the Industry

It can be concluded from the current study that Indian pharmaceutical exports are driven collectively by regulatory filings (ANDAs and DMFs) as well as total patents granted. It implies that in post TRIPS era (post 1995) and after the start of product patent regime (post 1st Jan 2005); Indian pharmaceutical firms increased their R&D expenditure in order to enhance patenting activity and at the same time leveraged the opportunity of supplying generics to lucrative regulated markets like US and Europe. During the study period 2000-01 to 2013-14; there has been a surge in patenting activity as well as in filing ANDAs and DMFs. In 2013, Indian firms contributed 36% of all ANDA approvals which led to approximately 40% share of Indian firms in the US generic market. Although, pair wise Granger causality test between total patents granted and pharmaceutical exports suggests that total patents granted Granger causes pharmaceutical exports but, India's share in global pharmaceutical patents is approximately 1% since many years and is suggestive of negligible presence of Indian pharmaceutical firms in patented products market. This implies that the share of exports of patents products in Indian pharmaceutical exports is very small. However, the share of Indian firms in global PCT publications in pharmaceutical domain is 3.3% which is comparatively higher as compared to the share of global patents granted. This suggests that Indian firms are targeting overseas markets more intensively for patented products besides being amongst major generics supplier to the global markets. Indian pharmaceutical firms have little experience in developing new chemical entities (NCE) and therefore it is strongly recommended to the industry to target acquisition of small and med sized companies in foreign markets having expertise and experience in developing and commercializing new chemical entities and biological products. This strategy could help Indian firms to gain access to technology and knowledge required to innovate and commercialize patented branded products in global markets.[24]

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