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# IP and Development Concerns for India

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## ABSTRACT

*This paper is dealing with how much investment is invested in Research and development before TRIPs and after TRIPs, here we are focusing on the pharmaceutical industries, looking into the differences in outcomes and also analyse the impact of this investment with the help of Schumpeter's Theory. Analysing those with the help of data's given shows that there is no high difference in spending on Research and Development before and after the TRIPs.*

## I. INTRODUCTION

Intellectual property are the rights given to persons over the creation of their minds. That is this right give the creator an exclusive right over the use of his or her creation for a certain period of time. For the development of the country, technological transfer and Research and development are the two important factors, where technology transfer means the process of sharing IP with others and "Research and development" means in the simple terms gather the knowledge to create new products or discover new ways to improve their existing products and services.

"The main economic justification for granting patents is that they will encourage investment for research and development for innovation."<sup>2</sup> Since TRIPS came into effect in the mid-1990s, a portion of the Indian pharmaceutical business has seen a significant increase in research and development expenditures. It's not just that spending on research and development has increased. Additionally, the way Indian corporations do their research and development has changed. Since there was no such thing as a product patent prior to TRIPs, their main focus has traditionally been on developing new processes for producing pharmaceuticals. "In the early 1990s, its R&D expenditures amounted to only about 1.5 % of sales and even the larger companies such as Ranbaxy and Dr Reddys Laboratories spent only 2-3% of their sales on R&D in 1992-93. And after this mentioned period, or the early 2000s, there has been a substantial

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<sup>2</sup>Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, INDIAN INSTITUTE OF MANAGEMENT CALCUTTA (Sep 2017), <https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=f63f2ccb89eca8b80a40ba1918b7190f8adc8dc0>.

increase in research spending in a segment of the industry.”<sup>3</sup>

“Ranbaxy Laboratories Ltd, Dr. Reddy's Laboratories Ltd, Sun Pharmaceutical Ind. Ltd, Cipla Ltd, Cadila Healthcare Ltd. Lupin Ltd. Nicholas Piramal India Ltd, Torrent Pharmaceuticals Ltd, Wockhardt Ltd, Aurobindo Pharma Ltd. USV Ltd, Orchid Chemicals & Pharmaceuticals Ltd. Matrix Laboratories Ltd, Panacea Biotec Ltd, Glenmark Pharmaceuticals Ltd, Ind-Swift Laboratories Ltd, Strides Arcolab Ltd, Biocon Ltd, Ipca Laboratories Ltd. Dabur Pharma Ltd, Alembic Ltd, Shasun Chemicals & Drugs Ltd, Dishman Pharmaceuticals & Chemicals Ltd, Unichem Laboratories Ltd, J B Chemicals & Pharmaceuticals Ltd, Bharat Serums & Vaccines Ltd, Divi's Laboratories Ltd and Natco Pharma Ltd.”<sup>4</sup> These are major Indian Pharmaceutical companies we are looking into for analysing the tables regarding the research and development.

“Table 1: Research and Development by Indian Pharmaceutical Industry;”<sup>5</sup>

	Major spenders: No of cos	Major spenders: R&D exp as % of sales	Other cos: No of cos	Other cos: R&D exp as % of sales
1992-93	7	1.78	40	0.86
1994-95	14	2.42	64	1.15
1995-96	13	2.98	74	1.42
1996-97	16	2.80	73	1.23
1997-98	15	3.06	66	0.94
1998-99	15	3.10	71	0.86

<sup>3</sup> Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, INDIAN INSTITUTE OF MANAGEMENT CALCUTTA (Sep. 2017), <https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=f63f2ccb89eca8b80a40ba1918b7190f8adc8dc0>.

<sup>4</sup> Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, INDIAN INSTITUTE OF MANAGEMENT CALCUTTA (Sep. 2017), <https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=f63f2ccb89eca8b80a40ba1918b7190f8adc8dc0>.

<sup>5</sup> Sudip Chaudhuri, *Is Product Patent Protection Necessary in Developing Countries for Innovation? R&D by Indian Pharmaceutical Companies after TRIPS*, INDIAN INSTITUTE OF MANAGEMENT CALCUTTA (Sep. 2017), <https://citeseerx.ist.psu.edu/document?repid=rep1&type=pdf&doi=f63f2ccb89eca8b80a40ba1918b7190f8adc8dc0>.

1999-2000	18	3.17	70	0.94
2000-01	21	3.88	68	1.16
2001-02	24	3.86	74	1.33
2002-03	25	4.72	72	1.18
2003-04	28	5.79	81	1.23
2004-05	28	7.83	73	1.40
2005-06	28	8.79	65	1.20

This above table shows the Research and Development by Indian Pharmaceutical Industry, this table analysed by Sudeep Chaudhuri, as they considered “the R&D expenditure for two sets of companies – (i) 28 major R&D spenders and (ii) the remaining 81 companies out of the 109 companies for which R&D data have been reported in the data base. For the later group, R&D expenditure as a percentage of sales continues to fluctuate around 1%. In 2005-06, the proportion was only 1.2%. But for the group of 28 major spenders, R&D expenditure has increased steadily from 1.78% of sales in 1992-93 to 3.86% in 2001-02, and then sharply to 7.83% in 2004-05 and 8.79% in 2005-06.”<sup>6</sup>

But here we can question the statement that they stated, the Research and Development is steadily increase from “1992-93 to 2005 - 06”, earlier that is, 1992-93 period 7 major companies R&D expenditure as percentage of sale was 1.78, and on 2005-06 it was 8.79%, here it is important to kept in mind was on 2005 – 2006, 28 major companies combined and spent 8.79%. That is the number of spenders is increased but not the amount of expenditure that they spend on Research and Development. Thus, can argue there was no increase in spending on Research and development.

“Table 2: Research and Development Expenditure of Major Indian Pharmaceutical Companies”<sup>7</sup>

<sup>6</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

<sup>7</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

	R&D exp 2004-05 Rs million	R&D exp as % of sales 2004-05	R&D exp 2005-06 Rs million	R&D expenditure as % of sales 2005-06	R&D exp 2005-06 \$ million
Ranbaxy Laboratories Ltd.	3996.6	9.35	6393.3	17.21	144.40
Dr. Reddy's Laboratories Ltd.	2977.9	17.12	2539.5	10.85	57.36
Sun Pharmaceutical Ind. Ltd.	1159.8	11.09	1614.9	11.93	36.48
Cipla Ltd.	983.8	4.10	1554	5.01	35.10
Cadila Healthcare Ltd.	1032	8.96	1187	8.87	26.81
Lupin Ltd.	836.1	6.86	1080.2	6.29	24.40
Nicholas Piramal India Ltd.	1084.4	8.29	911.5	6.04	20.59
Torrent Pharmaceuticals Ltd.	673.2	12.46	873.6	11.74	19.73
Wockhardt Ltd.	692.8	7.86	810.8	8.73	18.31

Aurobindo Pharma Ltd.	543.1	4.67	770.1	5.22	17.39
USV Ltd.	269.3	5.24	624.6	10.74	14.11
Orchid Chemicals & Pharmaceuticals Ltd.	522.1	7.57	613.6	6.95	13.86
Matrix Laboratories Ltd.	272	4.09	599	7.48	13.53
Panacea Biotech Ltd.	199.5	5.82	490.2	8.87	11.07
Glenmark Pharmaceuticals Ltd.	486.8	9.04	466.9	7.52	10.55
Strides Arcolab Ltd.	168.8	6.90	401.9	12.13	9.08
Ind-Swift Laboratories Ltd.	286.5	12.51	458.6	14.18	10.36
Biocon Ltd.	240.9	3.49	400.8	5.48	9.05
Ipca Laboratories Ltd.	335.9	4.58	378.8	4.62	8.56
Dabur Pharma	215	9.12	268.9	9.94	6.07

Ltd.					
Alembic Ltd.	311.2	5.44	266.7	4.00	6.02
Shasun Chemicals & Drugs Ltd.	308.2	9.27	263.6	7.14	5.95
Dishman Pharmaceuticals & Chemicals Ltd.	39.7	2.49	245.1	11.18	5.54
Unichem Laboratories Ltd.	153.9	3.64	123.2	2.58	2.78
J B Chemicals & Pharmaceuticals Ltd.	66.1	1.75	121.8	2.53	2.75
Bharat Serums & Vaccines Ltd.	93.6	10.23	114	11.67	2.57
Divi's Laboratories Ltd.	94.6	2.58	100.6	2.55	2.27
Natco Pharma Ltd.	52.2	3.04	74.3	4.30	1.68

The above table shows the Research and Development Expenditure of Major Indian Pharmaceutical Companies, were they analysed this as, "Ranbaxy is the largest R&D spender in the Indian pharmaceutical industry and in 1994-95, when TRIPS came into effect, it spent Rs 365.8 million on R&D (4.61% of its sales). Initially the increase was moderate with R&D

expenditure reaching 5.5% of sales in 2002-03. But thereafter it shot 4 up to 9.35% in 2004-05 and 17.21% in 2005-06 with an expenditure of Rs 6339.3 million. For Dr Reddys the second largest R&D spender, expenditure increased steadily and sharply from Rs 39.8 million (2.01% of sales) in 1994-95 to Rs 2977.9 (17.12 %) in 2004-05. The following year, the company's R&D expenditure declined to Rs 2539.5 million, but it still constituted 10.85% of its sales.”<sup>8</sup>

So, here the question is: Is this the increase?

What they stated was, Dr Reddys research and development expenditure increased steadily and sharply from Rs 39.8 million (2.01% of sales) in 1994-95 to Rs 2977.9 (17.12 %) in 2004-05. The following year, the company's R&D expenditure declined to Rs 2539.5 million, but it still constituted 10.85% of its sales. They stated that even though there is a decrease from 17.12% to 10.85%, still it constituted 10.85%. Thus, this can be considered as an increase in the expenditure of research and development.

Among the other major spenders, “between 1994-95 and 2005-06, R&D expenditure has increased for Sun from 4.05% to 11.93%, for Torrent from 2.68% to 11.74%, and for USV from 0.73% to 10.74% of sales”. There are 9 companies with the R&D proportion exceeding 10% of sales in 2005-06. The larger Indian pharmaceutical companies are among the largest investors in R&D among all industries combined in India. “Each of the top five R&D spenders in corporate India are pharmaceutical companies they are Ranbaxy, Dr Reddys Laboratories, Sun and Cipla. The only non-pharmaceutical company is the second ranked Tata Motors which spends about 2.3% of its sales on R&D. Ten of the top 20 Indian R&D spenders in India are pharmaceutical companies.”

“The objectives of R&D conducted by Indian companies can be broadly classified as, Development of new chemical entities (NCEs), Modifications of existing chemical entities to develop new formulations, compositions, combinations, which is also known as incrementally modified drugs and Development of generics that is, development of processes for manufacturing active pharmaceutical ingredients and development of formulations to satisfy quality and regulatory requirements for marketing patent-expired drugs.”<sup>9</sup> NCE R&D is not yet a significant part of R&D activities of Indian companies, it constitutes less than a quarter of the total R&D expenditure by the major companies. It should be noted that most of the large R&D

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<sup>8</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

<sup>9</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.



spenders are not involved in NCE R&D. “For example, Cipla is not yet involved in NCE R&D, but it is the fourth largest spender and its R&D expenditure has increased by more than 50% in 2005-06, above table 2 shown this clearly.”<sup>10</sup>

When look into Schumpeter’s theory and those data, Schumpeter stated that the monopoly should be given to large firms not to small firms, then only further innovation happens. Here in table 1, we cannot see any large firms and the given large firms, shown on table 2 spend on Research and Development is not so high when compared to the small firms and can also question the number of inventions from this R and D, is this is the innovation mentioned by Schumpeter? Here, they also shown the Research and Development expenditure as sales, Thus the question here comes is whether the disclosed data are correct or not?

“Table 3: Export intensity of major Indian Pharmaceutical Companies,2005-06”<sup>11</sup>

Company	Exports Rs million	Exports as % of sales	Exports as % of total exports of India
Ranbaxy Laboratories Ltd.	22243.4	59.89	10.31
Cipla Ltd.	15136.4	48.77	7.01
Dr. Reddy's Laboratories Ltd.	11966.6	51.11	5.55
Aurobindo Pharma Ltd.	8163.3	55.32	3.78
Lupin Ltd.	7611.0	44.32	3.53
Orchid Chemicals & Pharmaceuticals Ltd.	6210.1	70.32	2.88
Matrix Laboratories Ltd.	3902.7	49.50	1.81
Ipca Laboratories Ltd.	3857.7	47.02	1.79

<sup>10</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

<sup>11</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

Sun Pharmaceutical Inds. Ltd.	3652.1	26.97	1.69
Biocon Ltd.	3577.2	49.10	1.66
Divi's Laboratories Ltd.	3348.0	84.91	1.55
Wockhardt Ltd.	3201.7	34.49	1.48
Strides Arcolab Ltd.	2624.1	79.22	1.22
Shasun Chemicals & Drugs Ltd.	2452.8	66.41	1.14
J B Chemicals & Pharmaceuticals Ltd.	2447.1	50.87	1.13
Nicholas Piramal India Ltd.	2201.5	14.59	1.02
Cadila Healthcare Ltd.	2073.0	15.48	0.96
Ind-Swift Laboratories Ltd.	1507.1	46.60	0.70
Unimark Remedies Ltd.	1468.2	44.39	0.68
Dishman Pharmaceuticals & Chemicals Ltd.	1431.6	65.31	0.66
Glenmark Pharmaceuticals Ltd.	1408.1	22.68	0.65
Torrent Pharmaceuticals Ltd.	1344.2	18.06	0.62
Alembic Ltd.	1192.5	17.91	0.55
Dabur Pharma Ltd.	1158.5	42.84	0.54
Ajanta Pharma Ltd.	1116.3	52.56	0.52
Claris Lifesciences Ltd.	1039.0	36.47	0.48
Neuland Laboratories Ltd.	1037.5	60.80	0.48
Total	117371.7	44.93	54.39

The growth in exports is one of the most outstanding features of the pharmaceutical industry in India. Exports were negligible in the product patent regime before the 1970s. Exports started picking up in the 1970s after the amendment of the Patents Act. Initially the growth was modest. It accelerated in the 1980s. Exports have grown particularly rapid since the mid-1990s. Exports

have increased at an annual compound rate of 21.4% from \$698.7 million in 1995-96 to \$ 4874 million in 2005-06. The export market is larger than the domestic market for a number of Indian pharmaceutical companies. For example, for Ranbaxy, 60% of sales, for Dr Reddys Laboratories, 51%, for Orchid, 70%, for Divi's, 85%, and for Shasun, 66%.

“Table 4: R&D Output of Major Indian Pharmaceutical Companies as on 2006-07”<sup>12</sup>

Name of companies	No of DMFs	No of ANDAs	No of patents issued in USA
Aurobindo Pharma Ltd	105	70	9
Dr Reddys Laboratories Ltd	103	84	73
Cipla Ltd	88	4	3
Matrix Laboratories Ltd	80		
Ranbaxy Laboratories Ltd	77	204	79
Cadila Healthcare Ltd	73	50	3
Lupin Ltd	55	49	17
Sun Pharmaceutical Ind. Ltd	53	78	8
Orchid Chemicals &Pharmaceuticals Ltd	44	36	21
Hetero Drugs Ltd	35		5
Wockhardt Ltd	35	51	13
Divi's Laboratories Ltd	29		1
Glenmark Pharmaceuticals Ltd	26	29	5
Neuland Laboratories Ltd	25		

<sup>12</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

Ipsa Laboratories Ltd	24	1	1
USV Ltd	19		8
Jubilant Organosys Ltd	19	18	3
Shasun Chemicals and Drugs Ltd	17		1
Cadila Pharmaceuticals Ltd	17		2
Biocon India Ltd	16		6
Alembic Ltd	16		5
Wanbury Ltd	15		
Natco Pharma Ltd	13	2	1
Sekhsaria Chemicals Ltd	11		1
Ind Swift Laboratories Ltd	10		1
Unichem Laboratories Ltd	8	2	
Nicholas Piramal India Ltd	6		3
Unique Chemicals	6	10	2
Torrent Pharmaceuticals Ltd	5	9	2
Dabur India Ltd	5	4	37
Panacea Biotech			13

Table 4: R and D expenditure by MNCs in India

Sales	R&D exp	R&D exp	
Million	million	as percentage	
1992-93	14386.9	192.3	1.3
1993-94	22694.9	205.8	0.9
1994-95	24982.5	214.3	0.9

1995-96	26312.1	264	1.0
1996-97	27324.1	308	1.1
1997-98	29955.5	311.7	1.0
1998-99	32623.6	296.2	0.9
1999-2000	36011.9	303	0.8
2000-01	33081.5	302.2	0.9
2001-02	37040.6	291.5	0.8
2002-03	43221.7	349.7	0.8
2003-04	44295.1	343.9	0.8
2004-05	48525.8	374.7	0.8
2005-06	52021.7	375.1	0.7
2006-07	55450.9	408.6	0.7
2007-08	57847.8	439.6	0.8
2008-09	61869.6	563.5	0.9
2009-10	65687.7	570.2	0.9
2010-11	81170.2	325.5	0.4
2011-12	89134.7	246.7	0.3

“In the early 1990s before TRIPS came into effect, these MNCs spent on R&D only about 1 per cent of sales. Since then, rather than going up, R&D expenditure as a percentage of sales has actually declined to about 0.3 per cent in 2012-13. In absolute terms too R&D expenditure has started falling recently. Compared to ₹570.2 million in 2009-10, these MNCs spent ₹246.7 million in 2011-12 and ₹337.1 million in 2012-13”<sup>13</sup>

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<sup>13</sup> Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

Table 5: Company wise R &amp;D by MNCs in India

₹	1994-95		2000-01		2005-06		2012-13	
	<i>per</i>		<i>₹ per</i>		<i>₹ per</i>		<i>₹ per</i>	
	<i>million</i>	<i>cent</i>	<i>million</i>	<i>cent</i>	<i>million</i>	<i>cent</i>	<i>million</i>	<i>cent</i>
Abbott India	9.9	0.4	22.8	0.6	15.1	0.3	17.8	0.1
AstraZeneca Pharma	15.3	2.8	46.1	4.2	21.7	0.9	NA	NA
India								
Glaxosmithkline	48.6	0.5	41.4	0.4	43.9	0.3	24.6	0.1
Pharmaceuticals								
Merck.	4	0.3	6.4	0.2	16.1	0.4	64.2	0.9
Novartis India	14.6	0.3	16.4	0.4	16.2	0.3	2.2	0.02
Pfizer	22	0.9	142.3	3.8	223.6	3.1	175.8	1.6
Sanofi India.	91.9	3.1	15.2	0.4	33.4	0.4	41.7	0.3
Wyeth.	8	0.6	11.6	0.4	5.1	0.2	10.8	0.2
Total for 8 MNCs	214.3	0.9	302.2	0.9	375.1	0.7	337.1	0.4

The R&D expenditure for Pfizer increased steadily from about ₹20 million in the early 1990s. But after reaching a peak of ₹292.7 million in 2009-10 (3.7% of sales), it has started declining. In 2012-13 it spent only ₹175.8 million (1.6%). For the largest MNC in India GSK, R&D expenditure remained steady around ₹40-50 million before declining in recent years. In 2012-13 it spent only ₹24.6 million (0.1%). “In the mid-1990s, two MNCs spent more than 1 per cent of their sales in R&D, AstraZeneca (2.8%) and Sanofi-India (3.1%). For AstraZeneca, it improved to 4.2 per cent in 2000-01 but it has gone down both in absolute and relative terms since then. Sanofi-India was the largest R&D spender in the mid-1990s. It further increased its expenditure to more than ₹100 million in the late 1990s. But it now spends only ₹41.7 million (0.3%).”<sup>14</sup>

<sup>14</sup>Sudip Chaudhuri, *INTELLECTUAL PROPERTY RIGHTS AND INNOVATION: MNCs in Pharmaceutical Industry in India after TRIPS*, INSTITUTE FOR STUDIES IN INDUSTRIAL DEVELOPMENT (Nov. 2014), <https://www.researchgate.net/publication/282503175>.

## **II. CONCLUSION**

Here from the shown data, it is clear that there is no difference in spending on research and development after the TRIPs. That is there is no high difference in spending on Research and Development before and after the TRIPs. The outcome of R&D rather than on the incentives for R&D, it found that even after TRIPs, India's proficiency continues to be in process development. While R&D activities have diversified, Indian pharmaceutical firms have yet to prove their competence in innovating new products. No NCE has yet been developed. The Indian companies have really demonstrated is the ability to develop generics for the regulated and other markets, an ability which they acquired and improved during the pre-TRIPs period. When examining the data in light of Schumpeter's theory, there seems to be a disconnect between the theory and the observed trends in the pharmaceutical sector. This is particularly because the sector's primary focus on profitability rather than fostering innovation. Additionally, considering the nature of the pharmaceutical industry, which is fundamentally rooted in healthcare, the emphasis on profit-making appears to overshadow any alignment with Schumpeter's theory of innovation-driven monopolies.

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