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Challenges faced by the Indian pharmaceutical companies in protecting various forms of intellectual property rights

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Abstract---Intellectual Property (IP) is a pharmaceutical or Biotech Company's most valuable resource, and its protection is a key to that company's future success. Recent challenges over patents for HIV drugs has reminded the industry that progress is still needed in balancing the opposing forces of innovation through protection of IP rights, versus the provision of affordable drugs for the developing world. Pharmaceuticals companies must face the daily challenge of creating value through the exploitation of IP rights, but avoiding considerable reputational harm. This situation was well illustrated in South Africa during the late 1990s when the balance between IP protection and the urgent needs of patients were not aligned. Since then, companies have become more aware of the potential damage that can be caused by too strict an interpretation of IP rights. Working in collaboration with national governments, trans-national organizations such as the WHO, and non-governmental organizations such as the Bill and Melinda Gates Foundation, pharmaceuticals companies have begun to find ways through the minefield of IP protection in less developed countries, and most now have donation schemes for drugs to treat diseases such as leprosy and HIV.

Keywords---intellectual property rights, patent, research development, clinical trials, copyrights, generic drugs.

Introduction

In relatively strong emerging markets such as China and India though, additional issues prevail. Multinational pharmaceuticals companies require and expect IP rights to be strictly enforced in countries where there are countless local manufacturers with the ability to produce cheap counterfeit copies of patented drugs, which often find their way back to western markets. At the same time, the implementation and enforcement of IP laws in India and China is improving. Combined with the ability to leverage lower cost expertise, on the whole, these countries are still very much an opportunity rather than a threat. Nevertheless, companies need to be aware of and able to manage the considerable risks of doing business there. Closer to home, drug patents are coming under increased attack from generics companies who believe they have identified a weakness in the IP protecting a product. For instance, in 2004 a major ulcer treatment drug was the subject of a patent challenge in the US by a generic manufacturer just three years after its launch. With the generics industry consolidating and becoming more aggressive, pharmaceutical companies are facing more rigorous and frequent challenges to their intellectual property monopolies and growing pressure internally to bring the realization of value in R&D forward, without compromising standards or regulatory compliance.

Main Big Challenges

There are many big challenges are faced by the Indian Pharmaceutical Companies in protecting various forms of Intellectual Property Rights. The researcher has decided to gather such information by categorizing into four categories. They are-

- Worthy attributes and unnecessary claims
- Worthy outrage for the new IPR regime and trips
- Analysis of the notions and beliefs
- Critical analysis of the flexibilities.

An effort was made by the researcher to gather various information related to above mentioned aspects. The following Table 1.1 reveals the information about worthy attributes and unnecessary claims related to Intellectual Property Rights in Indian Pharmaceutical Industry.

Table 1.1
Worthy attributes and unnecessary claims

Sl. No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Strengthening R&D	24 (38.71)	19 (30.65)	12 (19.35)	4 (6.45)	3 (4.84)
2	International investor's confidence	17 (27.42)	16 (25.81)	18 (29.3)	7 (11.29)	4 (6.45)
3	Availability of AIDS drug.	9 (14.82)	14 (22.58)	12 (19.35)	18 (29.3)	9 (14.82)
4	Manufacturer's deserve	11	15	17	16	3

	patent rights	(17.74)	(24.19)	(27.42)	(25.81)	(4.84)
5	Copy-cat drugs disable to recoup the development cost	19 (30.65)	17 (27.42)	13 (20.97)	8 (12.90)	5 (8.6)
6	Protection period helps generate research funds	21 (33.87)	18 (29.3)	15 (24.19)	6 (9.65)	2 (3.23)
7	Strategic alliance with small biotech companies	16 (25.81)	13 (20.97)	18 (29.3)	11 (17.74)	4 (6.45)
8	Donations to the poor and the needy	6 (9.68)	14 (22.58)	20 (32.26)	13 (20.97)	9 (14.82)
9	Public-private relationship helps the poor country	22 (35.48)	20 32.26)	12 (19.35)	5 (8.6)	3 (4.84)
10	Lowering the price by a big drug industry	24 (38.71)	18 (29.3)	9 (14.82)	6 (9.68)	5 (8.6)
11	Stringent inspection process of coy-cat drugs.	6 (9.68)	11 (17.74)	18 (29.3)	16 (25.81)	11 (17.74)
12	Copy-cat drugs reduce incentives to research	3 (4.84)	6 (9.68)	14 (22.58)	18 (29.3)	21 (33.87)
13	Employment to skilled, technical workers	13 (20.97)	9 (14.82)	24 (38.71)	10 (16.13)	6 (9.68)
14	Improving export capability	9 (14.82)	12 (19.35)	16 (25.81)	19 (30.65)	6 (9.68)
15	Price control proves more expensive in the long run	20 (32.26)	23 (37.10)	11 (17.74)	5 (8.6)	3 (4.84)
16	Does not create monopoly but rigorous competition	18 (29.3)	16 (25.81)	19 (30.65)	5 (8.6)	4 (6.45)

Source: Primary data

The above analysis in Table 1.1 outlays that out of sixteen factors identified and listed in the above, Public-private relationship helps the poor country (Mean score 4.05), Strengthening R&D (Mean score 3.92), Lowering the price by a big drug industry (Mean score 3.80) and Copy-cat drugs disable to recoup the development cost (Mean score 3.44) stand first, second, third and fourth positions respectively. In addition, an effort was also made by the researcher to make further invading in to IPR regime and Trips. Fourteen factors related to worthy outrage for the new IPR regime and Trips are given for the opinion to respondent units and the gathered data is grouped and also listed in the following Table 2.1.

Table 1.2
Worthy outrage for the new IPR regime and TRIPS

Sl.No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Non-transfer of technology or making FDI.	23 (33.87)	19 (30.65)	10 (16.13)	7 (11.29)	3 (4.84)
2	Limitation to reverse engineering.	21 (33.87)	20 (32.26)	14 (22.58)	5 (8.6)	2 (3.23)
3	High Prices of life-saving drugs.	19 (30.65)	21 (33.87)	13 (20.97)	5 (8.6)	4 (6.45)

4	20-year protection will eliminate competition.	16 (25.81)	19 (13.65)	12 (19.35)	10 (16.30)	5 (8.60)
5	Monopoly to pharmaceutical companies.	9 (14.82)	18 (29.3)	14 (22.58)	17 (27.42)	4 (6.45)
6	Product as well as processes patent.	6 (9.68)	19 (13.65)	14 (22.58)	13 (20.97)	10 (16.13)
7	Future of traditional medicines.	24 (38.71)	19 (30.65)	14 (22.58)	13 (20.97)	10 (16.13)
8	Indian firms will remain junior partners.	22 (35.48)	19 (30.65)	16 (25.81)	3 (4.84)	2 (3.23)
9	Risky and expensive process of drug discovery.	18 (29.3)	10 (16.13)	22 (35.48)	7 (11.29)	5 (8.6)
10	Cheaper, generic version of drugs for poor.	9 (14.82)	7 (11.29)	18 (29.3)	17 (27.42)	11 (17.74)
11	Concern over policy of non-disclosure.	24 (38.71)	17 (27.42)	11 (17.74)	6 (9.68)	4 (6.45)
12	Returns for huge amounts invested by the manufacturer	16 (25.81)	18 (29.3)	12 (19.35)	10 (16.13)	8 (12.90)
13	Investing millions in R$D	21 (33.87)	16 (25.81)	17 (27.42)	5 (8.6)	8 (12.90)
14	Limitation on generic medicines	19 (30.65)	18 (29.3)	14 (22.58)	9 (14.82)	2 (3.23)

Source: Primary data

It was inferred from the above Table 1.2 that Out of fourteen factors associated with worthy outrage for the new IPR regime and trips, Limitation to reverse engineering (Mean score 3.85), Non-transfer of technology or making FDI (Mean score 3.84), Investing millions in R&D (Mean score 3.84), Concern over policy of non-disclosure (Mean score 3.82), 20-year protection will eliminate competition(Mean score 3.71), Limitation on generic medicines (Mean score 3.69) stand on the top and share first, second, Third, fourth, fifth and sixth rank respectively.

Table 1.3
Analysis of the notions and beliefs

Sl.No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Capture 20-25% of world's generic market	24 (38.71)	16 (25.81)	8 (12.9)	9 (14.82)	5 (8.06)
2	Restriction on the use of ideas to promote development	19 (30.65)	20 (32.26)	13 (20.97)	6 (9.68)	4 (6.45)
3	Access to all of vitally needed medicines	15 (24.19)	17 (27.42)	12 (19.35)	10 (16.13)	8 (12.90)

4	Clampdown on violators will cause social unrest	9 (14.82)	13 (20.97)	16 (25.81)	15 (24.19)	9 (14.82)
5	Social and economic problems arisen	20 (32.26)	18 (29.03)	14 (22.28)	7 (11.29)	3 (4.84)
6	World class facilities by Indian Patent Act 1970	9 (14.82)	2 (3.23)	14 (22.58)	21 (33.87)	16 (25.81)
7	TRIPS takes away manufacturing facilities	6 (9.68)	12 (19.25)	13 (20.97)	17 (27.42)	14 (22.58)
8	Negotiating process of the Agreement was unbalanced	21 (33.87)	19 (30.65)	6 (9.68)	13 (20.97)	3 (4.84)
9	TRIPS flexibilities problematic	19 (30.65)	16 (25.81)	14 (22.58)	9 (14.82)	4 (6.45)
10	Lack of legal clarity of the TRIPS Agreement	5 (8.06)	7 (11.29)	22 (35.48)	18 (29.03)	10 (16.13)
11	Interpretation of TRIPS to the best interest of a country	24 (38.71)	17 (27.42)	13 (20.97)	6 (9.68)	2 (3.23)

Source: Primary data

The analysis related to notions and beliefs made in the above mentioned Table 4.26 express that Capture 20-25%of world's generic market, Negotiating process of the Agreement was unbalanced and Restriction on the use of ideas to promote development are top ranked factors in analysis of notions and beliefs. An effort was also made by the researcher to make an invading in to Critical Analysis of the flexibilities. The following Table exhibits the Critical analysis of the flexibilities in Indian Pharma industry.

Table 1.4
Critical analysis of the flexibilities

Sl.No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Doha assurance for hassle free compulsory licensing	21 (33.87)	14 (22.58)	16 (25.81)	7 (11.29)	4 (6.45)
2	India port for "medicines to all"	19 (30.65)	12 (19.35)	15 (24.19)	10 (16.13)	6 (9.68)
3	Efforts to ensure minimum Corporate Social Responsibility	6 (9.68)	13 (20.97)	18 (29.3)	17 (27.42)	8 (12.90)
4	Introduction of transitional periods	18 (29.3)	17 (27.42)	11 (17.74)	9 (14.82)	7 (11.24)
5	Validity of Legal laws and their amendments	6 (9.68)	12 (19.35)	16 (25.81)	19 (30.65)	9 (14.82)
6	Validity of parallel imports	20 (32.26)	16 (25.81)	14 (22.58)	7 (11.29)	5 (8.6)

Source: Primary data

The above Table highlights the critical analysis of the flexibilities and it was found that Validity of parallel imports (Mean score 3.63), Doha assurance for hassle free compulsory licensing (Mean score 3.61), Introduction of transitional periods(Mean score 3.39) are most dominant factors followed by India port for "medicines to all", Efforts to ensure minimum Corporate Social Responsibility and Validity of Legal laws and their amendments.

Table 4.25
Worthy outrage for the new IPR regime and TRIPS

Sl. No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Non-transfer of technology or making FDI.	23 (33.87)	19 (30.65)	10 (16.13)	7 (11.29)	3 (4.84)
2	Limitation to reverse engineering.	21 (33.87)	20 (32.26)	14 (22.58)	5 (8.6)	2 (3.23)
3	High Prices of life-saving drugs.	19 (30.65)	21 (33.87)	13 (20.97)	5 (8.6)	4 (6.45)
4	20-year protection will eliminate competition.	16 (25.81)	19 (13.65)	12 (19.35)	10 (16.30)	5 (8.60)
5	Monopoly to pharmaceutical companies.	9 (14.82)	18 (29.3)	14 (22.58)	17 (27.42)	4 (6.45)
6	Product as well as processes patent.	6 (9.68)	19 (13.65)	14 (22.58)	13 (20.97)	10 (16.13)
7	Future of traditional medicines.	24 (38.71)	19 (30.65)	14 (22.58)	13 (20.97)	10 (16.13)
8	Indian firms will remain junior partners.	22 (35.48)	19 (30.65)	16 (25.81)	3 (4.84)	2 (3.23)
9	Risky and expensive process of drug discovery.	18 (29.3)	10 (16.13)	22 (35.48)	7 (11.29)	5 (8.6)
10	Cheaper, generic version of drugs for poor.	9 (14.82)	7 (11.29)	18 (29.3)	17 (27.42)	11 (17.74)
11	Concern over policy of non-disclosure.	24 (38.71)	17 (27.42)	11 (17.74)	6 (9.68)	4 (6.45)
12	Returns for huge amounts invested by the manufacturer	16 (25.81)	18 (29.3)	12 (19.35)	10 (16.13)	8 (12.90)
13	Investing millions in R$D	21 (33.87)	16 (25.81)	17 (27.42)	5 (8.6)	8 (12.90)
14	Limitation on generic medicines	19 (30.65)	18 (29.3)	14 (22.58)	9 (14.82)	2 (3.23)

Source: Primary data

It was inferred from the above Table 4.26 that Out of fourteen factors associated with worthy outrage for the new IPR regime and trips, Limitation to reverse

engineering (Mean score 3.85), Non-transfer of technology or making FDI (Mean score 3.84), Investing millions in R&D (Mean score 3.84), Concern over policy of non-disclosure (Mean score 3.82), 20-year protection will eliminate competition(Mean score 3.71), Limitation on generic medicines (Mean score 3.69) stand on the top and share first, second, Third, fourth, fifth and sixth rank respectively.

Table 4.26
Analysis of the notions and beliefs

Sl.No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Capture 20-25% of world's generic market	24 (38.71)	16 (25.81)	8 (12.9)	9 (14.82)	5 (8.06)
2	Restriction on the use of ideas to promote development	19 (30.65)	20 (32.26)	13 (20.97)	6 (9.68)	4 (6.45)
3	Access to all of vitally needed medicines	15 (24.19)	17 (27.42)	12 (19.35)	10 (16.13)	8 (12.90)
4	Clampdown on violators will cause social unrest	9 (14.82)	13 (20.97)	16 (25.81)	15 (24.19)	9 (14.82)
5	Social and economic problems arisen	20 (32.26)	18 (29.03)	14 (22.28)	7 (11.29)	3 (4.84)
6	World class facilities by Indian Patent Act 1970	9 (14.82)	2 (3.23)	14 (22.58)	21 (33.87)	16 (25.81)
7	TRIPS takes away manufacturing facilities	6 (9.68)	12 (19.25)	13 (20.97)	17 (27.42)	14 (22.58)
8	Negotiating process of the Agreement was unbalanced	21 (33.87)	19 (30.65)	6 (9.68)	13 (20.97)	3 (4.84)
9	TRIPS flexibilities problematic	19 (30.65)	16 (25.81)	14 (22.58)	9 (14.82)	4 (6.45)
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11	Interpretation of TRIPS to the best interest of a country	24 (38.71)	17 (27.42)	13 (20.97)	6 (9.68)	2 (3.23)

Source: Primary data

The analysis related to notions and beliefs made in the above mentioned Table 4.26 express that Capture 20-25%of world's generic market, Negotiating process of the Agreement was unbalanced and Restriction on the use of ideas to promote development are top ranked factors in analysis of notions and beliefs. An effort was also made by the researcher to make an invading in to Critical Analysis of the flexibilities. The following Table exhibits the Critical analysis of the flexibilities in Indian Pharma industry.

Table 4.27
Critical analysis of the flexibilities

Sl.No	Attributes	(5)	(4)	(3)	(2)	(1)
1	Doha assurance for hassle free compulsory licensing	21 (33.87)	14 (22.58)	16 (25.81)	7 (11.29)	4 (6.45)
2	India port for "medicines to all"	19 (30.65)	12 (19.35)	15 (24.19)	10 (16.13)	6 (9.68)
3	Efforts to ensure minimum Corporate Social Responsibility	6 (9.68)	13 (20.97)	18 (29.3)	17 (27.42)	8 (12.90)
4	Introduction of transitional periods	18 (29.3)	17 (27.42)	11 (17.74)	9 (14.82)	7 (11.24)
5	Validity of Legal laws and their amendments	6 (9.68)	12 (19.35)	16 (25.81)	19 (30.65)	9 (14.82)
6	Validity of parallel imports	20 (32.26)	16 (25.81)	14 (22.58)	7 (11.29)	5 (8.6)

Source: Primary data

The above Table highlights the critical analysis of the flexibilities and it was found that Validity of parallel imports (Mean score 3.63), Doha assurance for hassle free compulsory licensing (Mean score 3.61), Introduction of transitional periods(Mean score 3.39) are most dominant factors followed by India port for "medicines to all", Efforts to ensure minimum Corporate Social Responsibility and Validity of Legal laws and their amendments.

Conclusion

The new rule regarding the "product patent" had made a huge impact on growth of the pharmaceutical sector in India. Though the Patent System is important for Industrial Growth but it should be such that it should encourage the growth of the small scale industries. The number of patent filing lacks in Pharmaceutical and biotechnological industry as compared to other industries. As shown by the survey done by Entirely it is co-related that there should be enough funding so that small scale industries along with major player can involve in research work and so more patents can be filed. . There should be special amendment in the patent law which can encourage small scale sector to participate in research. In developing countries like India, government along with association with the regulatory body should allow easy access to patents documents, which can be easily downloaded and their legal status can be accessed. Patents are the sign of development in research for a developing country. Hence every research work should be paid importance to convert it into reality which would serve the humanity.

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