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A STUDY ON PROBLEMS AND PROSPECTS OF INTELLECTUAL PROPERTY RIGHTS IN INDIANPHARMACEUTICAL INDUSTRY

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ABSTRACT

Ideas, innovations, and creative expressions based on which the public is ready to confer the status of property have been classified as intellectual property rights (IPR). IPR give the inventors or developers of a property certain exclusive rights in order for them to profit commercially from their creative work or reputation. Intellectual property protection comes in many forms, including patents, copyright, trademarks, and so on. A patent is granted to an invention that meets the requirements of worldwide novelty, non-obviousness, and industrial applicability. IPR is required for better invention or creativity identification, planning, marketing, rendering, and therefore protection. Depending on its field of expertise, each industry should have its own IPR rules, management style, strategies, and so on. In the approaching period, the pharmaceutical industry's expanding IPR strategy will require a greater focus and approach. The pharmaceutical sector in India is expanding at a quicker pace. Indian pharma companies, on the other hand, are looking for worldwide commercial prospects like as export, contract research, and clinical trials. Intellectual Property Rights have become more important to many Indian businesses. The amount of money spent on research and development is likewise increasing. From their initial investment to strengthen their R&D to obtaining patent and other IP protection for their new breakthroughs, Indian pharmaceutical businesses confront numerous hurdles. Many legal formalities must be completed for drug discovery, paperwork, and clinical trials, among other things. The key issues confronting Indian pharmaceutical companies include the high cost of investment, the expiration of patented pharmaceuticals, the absence of clinical studies, the increased legal formalities, and the difficulties in getting IP protection.This research focused on both the issues that companies face as well as the opportunity that IPR provides for Indian pharmaceutical companies. The prevalent challenges related with IPR, particularly in relation to Indian pharmaceutical companies, provided a wider potential for this research. It is unavoidable that Indian pharmaceutical businesses will wish to safeguard their innovation through patents when they begin to invest more heavily in R&D and produce their own compounds that can be patented. As a result, the Indian government should promote and safeguard multinational company patents as well. Patents and other kinds of intellectual property (IP) rights are critical for industry and research and development. Businesses, particularly pharmaceutical companies, are unable to invest in R&D or produce new, creative treatments without robust protections.

Keywords: Intellectual Property Rights, Patent, Research &Development,ClinicalTrials,Copyrights,GenericDrugs.

I.INTRODUCTION

Ideas, innovations, and creative expressions based on which the public is ready to confer the status of property have been classified as intellectual property rights (IPR). IPR give the inventors or developers of a property certain exclusive rights in order for them to profit commercially from their creative work or reputation. Intellectual property protection comes in many forms, including patents, copyright, trademarks, and so on. A patent is granted to an invention that meets the requirements of worldwide novelty, non-obviousness, and industrial applicability. IPR is required for better invention or creativity identification, planning, marketing, rendering, and therefore protection. Depending on its field of expertise, each industry should have its own IPR rules, management style, strategies, and so on. In the approaching period, the pharmaceutical industry's expanding IPR strategy will require a greater focus and approach. Intellectual property (IP) refers to any creative work of the human mind, such as a work of art, literature, technology, or science. Intellectual property rights (IPR) are legal rights granted to an inventor or creator to safeguard his or her creation for a set length of time. These legal rights allow the inventor/creator or his assignee the exclusive right to fully employ his invention/creation for a set length of time. It is widely acknowledged that intellectual property (IP) plays a critical role in today's economy. It has also been proven decisively that the intellectual work associated with innovation should be prioritized so that public benefit can be realized. In terms of research and development, there has been a quantum leap (R&D). costs, as well as the related increase in investments, that are required to bring a breakthrough technology to market. The stakes for technology developers have risen dramatically, and protecting information from unauthorized use has become necessary, at least for the time being, to assure the recovery of R&D and other associated costs, as well as appropriate earnings for continued R&D investments. IPR is a powerful weapon for protecting the inventor/creator of an IP's investments, time, money, and effort, because it offers the inventor/creator an exclusive right to use his invention/creation for a certain length of time. As a result, IPR contributes to a country's economic development by encouraging healthy competition, industrial progress, and economic prosperity. The current review provides a quick summary of IPR, with a focus on medicines.

II.REVIEWOFLITERATURE

Czarnitzkietal.(2005)adoptedHedonic regression is a method for calculating the Market Value of a company's knowledge assets. They presented a summary of previous results from applying the approach to data on market value, capital, R&D, and patents for US and European enterprises, as well as a more extensive discussion of some recent outcomes for US and European firms. They found that R&D, patents, and citation-weighted patents are all highly significant in market value regressions, albeit patent-based measures are slightly less significant when R&D measures are present. According to the findings, an additional dollar of R&D spending adds slightly less than

a $1 to market value in most nations; an alternative interpretation is that R&D assets decay at a rate somewhat more than 15% per year.

DengandLev(2004)foundthere is a strong link between the value of in-process R&D and the cash flows of acquiring corporations three years after the purchase, supporting the FASB's recommendation to treat in-process R&D as an asset. They came to the conclusion that in-process R&D contributes to future cash flows and is thus an asset, and that R&D has a life of at least three years.

Katherine and Klock (2003) investigated whetherUsing data from 1982 to 2001, measures of intangible capital based on advertising and R&D can explain variation in Tobin's Q ratio for the pharmaceutical and chemical industries. The study discovered that intangible capital metrics are statistically significant factors. ofTobin'sQ.

LevandRadhakrishanan(2002)determinedthe contribution to revenue growth of the four key resources: physical assets, labour, brands, and R&D, was calculated using statistical analysis for a sample of 300 public corporations. Some businesses are more productive than others, according to the findings. They outperform comparable organizations in terms of revenue growth for the same level of resources.

Gow(2002)hadidentifiedR&D, advertising, capital spending, information technology, technology acquisitions, and human resource practices are the six key drivers of intangible driven profitability.

Greenhalgh and Longland (2002) assessed whetherthe overall quantity of Intellectual Assets, or the total amount of R&D, is vital for a company's performance. The results of the empirical study show that companies that file trademarks and patents, as well as do R&D, are more productive.

Aboody andLev (2001) provide present compelling and compelling grounds for researching intangible capital in the chemical sector The fact that the industry is enormous, pervasive, and extremely innovative is one of these causes. A priori, the study anticipates this business to be one in which intangible assets, such as invention, have high value.

GuandLev(2001)conductedastudytoidentify and quantify the drivers of intangible capital, and thus business value, and discovered that human resource practices are substantially connected with intangible earnings and capital.

III.STATEMENTOFTHEPROBLEM

India has a small number of pharmaceutical companies. Due to the availability of low-cost labour in India, the Indian pharma sector is primarily operated and controlled by large multinational businesses with operations in India. Even international pharma businesses operating in India virtually entirely employ Indians from the lowest levels to the highest levels of management. Firms are highly hierarchical, mirroring the societal structure. Like many other enterprises in India, homegrown pharmaceuticals are frequently a mix of state and private

entrepreneurship. Despite the fact that many of these businesses are publicly traded, leadership is passed down from father to son, and the original family owns the bulk of the stock. The pharmaceutical sector in India is expanding at a quicker pace. Indian pharma companies, on the other hand, are looking for worldwide commercial prospects like as export, contract research, and clinical trials. Intellectual Property Rights have become more important to many Indian businesses. The amount of money spent on research and development is likewise increasing.From their initial investment to strengthen their R&D to obtaining patent and other IP protection for their new breakthroughs, Indian pharmaceutical businesses confront numerous hurdles. Many legal formalities must be completed for drug discovery, paperwork, and clinical trials, among other things. Indian pharmaceutical companies confront considerable challenges such as high investment costs, patented medicine expiration, a lack of clinical studies, increased legal formalities, and difficulties securing IP protection. In terms of wider acceptability, revenue generation, and market capitalization, intellectual property rights have a direct impact on pharmaceutical businesses' performance. Due to the aforementioned issues, Indian pharmaceutical businesses are having difficulty obtaining Intellectual Property Protection for their products. This research focused on both the issues that companies face as well as the opportunity that IPR provides for Indian pharmaceutical companies. The prevalent challenges related with IPR, particularly in relation to Indian pharmaceutical companies, provided a wider potential for this research.

OBJECTIVESOFTHESTUDY

The following objectives are formulated inorder to make an in-depth analysis in to thestudyarea.

1) ToanalyzethegrowthofIndianPharmaceuticalIndustry inIndia.

2) To evaluate the importance and growth ofIPProtectioninIndianPharmaceuticalMarket.

3) Toidentifythechallenges,issuesandproblemsfacedbytheIndianPharmaCompanies in IPR.

4) ToevaluatetheopportunitiesandprospectsavailableforIPProtectioninIndianPharmaceuticalIndustry.

5) Tosuggestsuitablemeasuresfortheidentifiedproblems.

6) Toidentifythekeyfactorsinfluencingtheattritionand HRpracticesintheorganizedretailingsector.

SCOPEOFTHESTUDY

This study has greater scope due to the increasinglevel of importance given by Indian PharmaceuticalcompaniesingettingtheirIPProtectionandnumerousproblemsfacedbythemineverystageandthecostinvolved.

IV.RESEARCHMETHODOLOGY

ThetotalnumbersofIndianPharmaceuticalCompaniesthosewhoarehavingResearchandDevelopmen

t facilities and also having IntellectualPropertyRightsforthepastfiveyearsconsecutivelyaretakeforthisstudy.Therewere69such pharmaceutical Indian companies in India. CensusSurveywasemployedtosurveyall69pharmaceutical companies. But the researcher wasabletogatherinformationfrom62Indianpharmaceuticalcompanies.Itwastakenasfinalsizeforthis studyand studywascarriedout

LIMITATONS OFTHESTUDY

Eventhoughanationallevelscopeisavailablethisstudyisrestrictedonlytotheproblemsandprospects ofIntellectualPropertyRightswithspecialreferencetoIndianpharmaceuticalcompanies.Therearemany other areas are left out due to paucity of time. Thestudy period is restricted to 22 years of existence ofthecompany.

HYPOTHESISFORTHESTUDY

The following are the proposed hypothesis framedbytheresearcherfor thisstudy.

1. Thereisnosignificantrelationshipbetweenlevelof investment made in Research & Development(R&D) and Number of Patent earned by IndianPharmaceuticalcompanies.
2. There is no significant relationship betweennumber of therapeutic segments owned by thepharma companies and number of IP Assets ownedbythem.
3. There is no significant association betweennumber of employees appointed in R& DDepartmentandIP Assets obtained.
4. There is no significant relationship between theexportrevenuegeneratedandthelevelofIP Assetsownedby therespondents

V.ANALYSISANDINTERPRETATION

Ownershipstatusesvaryfromorganizationtoorganizationbasedonthevolumeofinvestmentmadeandnatureofpeopleinvolved.Indian Pharmaceuticalindustryisalsonotanexceptionaltothis.So,theresearcherhasmadeanattempttoidentifythenatureofOwnershipavailabletheresearcharea.Theresearcherhasidentifiedtheprevalence of ownership in the form of private Ltd.,publicLtd.,Partnershipfirmsandsole ProprietorshipinIndianPharmaceuticalindustry.The

Sl. No	Ownership Particulars	No. of Respondent	Percentage
1.	Private Ltd,	11	17.74
2.	Public Ltd,	42	67.74
3.	Partnership,	07	11.29
4.	Sole Proprietorship	02	3.23
	Total	**62**	**100**

gathered information is listed in the followingTable

Table1Ownershipdetails

The above Table shows the fact that majority ofIndianPharmaceuticalcompaniestakenforthisstudyfallundercompanyformsofownership.Majority of (67.74%) the Pharma companies belongtopublicLtd.,Alittlebelowtwentypercent(17.74%) belong to private Ltd., A little above tenpercent (11.29%) belong to partnership firms and averylittle(3.23%)amountbelongtosoleProprietorship

Table2Yearsofexistence

Sl. No	Year of Experience	Number of Respondents	Percentage
1	0- 5Years	02	3.23%
2	6 to 10 years	08	12.90%
3	11to 15 years	16	25.80%
4	16 to 20years	14	22.58%
5	Above 21years	22	35.48%
	Total	**62**	**100.00**

From the above Table, it was found that majority ofthe Pharmaceutical companies (58.06%) are havingtheexperienceofabovefifteenyears.Whereas16.13percentoftheUnitsarehavinglessthantenyearsofexperience.35.48percentoftherespondentunitsarehavingtheexperienceofmorethantwentyyear sand
3.23percentoftheunitsarehavingexactlyfiveyearsofexperience.Innutshell,almostallrespondentunits arehavinggood experience.

Table3VolumeofExports

Sl. No	Export (in Rs)	Number of Respondents	Percentage
1	Less then Rs.25 Crores	01	1.61%
2	Rs.26 to 50 Crores	03	4.84%
3	Rs.51 to 75 Crores	02	3.23%
4	Rs.76 to 100 Crores	05	8.06%
5	Rs.101 to 150 Crores	08	12.90%
6	Rs.151 to 200 Crores	17	27.42%
7	Rs.200 &above	26	41.94%
	Total	**62**	**100.00**

Theaboveanalysisreflectsthefactaboutthevolumeofexportsmadebyindianpharmaceuticalcompanies. A little above forty percent (41.94%) ofthe respondent units are making the export of morethan200crores.27.42percentofunitsarehavingtheexport sale of 151 to 200 crores. Whereas 17.74percent of the respondents are making the export ofless than 100 crores.

Sl. No	Availability of R & D	Number of Respondents	Percentage
1	Yes	62	100.00
2	NO	0	-
	Total	**62**	**100.00**

Table4ResearchFacility

The above Table reveals the fact that all units takenfor this study are well equipped with R&D facility.EvenasingleunitwasexcludedwithR&Dfacilities.It shows the nature of interest and important shownby theIndianPharmaceuticalcompaniestowardsR&Dfacilities.

Table5ManufacturingFacility

Sl. No	Availability of Own manufacturing	Number of Respondents	Percentage
1	Yes	62	100
2	NO	0	0
	Total	**62**	**100.00**

TheaboveTableanalysisshowsthatallPharmaceutical companies taken for this study arehavingtheirownwell-equippedmanufacturingfacilities.ItshowsthatIndianPharmaceutical companiesarehavingtheirownsetuptomanufacturedifferenttypesoftherapeuticsegments.

Table6ClinicalTrial

Sl. No	Availability	No. of Respondent	%
1.	Yes	37	59.68%
2.	No	25	40.32%
	Total	**62**	**100.00**

Six out oftencompaniestaken forthis studyisequippedwithfacilitiestocarryouttheclinicaltrialsby own. Four out of ten units are not having thefacilityofdoingclinicaltrialswithintheircompany.So, it is observed that majority (59.68%) of IndianParmacompaniesarehavingtheirprovisionstoconduct clinical trials and remaining (40.32%) arenothaving such provisions

Table7CompetitiveAdvantage

Sl. No	Source	No. of Respondents	%
1	People	09	14.52
2	Products	11	17.71
3	Brand	09	14.52
4	Image	05	8.06
5	Speed to Market	04	6.45
6	Service	04	6.45
7	Geographic Reach	02	3.23
8	Sector Specialization	02	3.23
9	Price	04	6.45
10	Technical Knowledge	02	3.23
11	Distribution Channels	03	4.84
12	Business Processes	02	3.23
13	Knowledge	05	8.06
	Total	**62**	**100.00**

Source: Primary data

The above Table 4.17 reveals the fact that out ofthirteensourcesidentifiedforcompetitiveadvantage,products(17.74%)standfirstinprovidinggreat competitiveadvantageforpharmaceuticalcompanies. Wide spectrum and availability of newdrugs which are clinically proved have createdagoodsymptomofgrowth.Thetechnofriendlypeople having good hands on experience in research(14.52%)andthepowerfulbrandsownedbycompanies(14.52%)standsecondincreatingcomp etitiveadvantageforIndianPharmaceuticalcompanies.Theimageofthecompanyisalsoequallyimport ant.Image(8.06%)standthirdinorder followed by speed to the market (6.45%) andservices support (6.45%). Pharmaceutical companiescorestrengthintheirdistributionchannels. Distributionchannels(4.84%)standsfifthinorderincreatingcompetitiveadvantageforcompanies-

followed by geographical reach (3.23%) , Sectorsspecialization(3.23%)andbusinessprocesses(3.23%)

HypothesisTesting

1) Ho:ThereisnosignificantrelationshipbetweenlevelofinvestmentmadeinResearch&Development(R&D)andNumberofPatentearnedbyIndianPharmaceuticalcompanies

Table8LevelofInvestmentandPatent

Calculated Value χ^2	Table value	Remarks
73.90	26.296	Null Hypothesis is rejected

Thecalculatedvalueis73.90.Thenullhypothesisisrejected because the calculated value is more thanTablevalue.So,theresearcherfoundtherelationshipbetweenthelevelofinvestmentmadeinResearch&Developmentandnumberofpatentobtainedby Indian pharmaceutical companies. It is essentials tomakemoreandmorereliableinvestmentinResearch& Development department to ensure good numberofpatentearned.

2) Ho:ThereisnosignificantrelationshipbetweennumberoftherapeuticsegmentsownedbythepharmacompaniesandnumberofIPAssetsownedby them.

Table9TherapeuticdrugsandIP

Calculated Value χ^2	Table value	Remarks
82.96	15.507	Null Hypothesis is rejected

Thecalculatedvalueis82.96.Thenullhypothesisisrejected because the calculated value is more thanTablevalue.So,theresearcheridentifiedtherelationshipbetweennumberoftherapeuticsegmentsownedbythepharmacompaniesandnumber of IP Assets owned by them. It is observedfrom the above that wider therapeutic segments areassisting Indian Pharma companies to own more IPAssets. In nutshell, better the therapeutic segment,bettertheIPAssets.

3) Ho: There is no significant relationship betweenthe number of employees in researchand the levelofIPAssets owned bytheorganisation

Table10NumberofresearchemployeesandIPassets

Calculated Value χ^2	Table value	Remarks
112.4	24.996	Null Hypothesis is rejected

Thecalculatedvalueis112.4.Thenullhypothesisisrejected because the calculated value is more thanTablevalue.So,theresearcheridentifiedtherelationshipbetweennumberofemployeesappointedi

nR&DDepartmentandIPAssetsobtained.

VI.SUMMARYANDCONCLUSION

MajorityofIndianPharmaceuticalcompaniestakenforthisstudyfallundercompanyformsofownership .Majorityof(67.74%)the Pharma companiesbelongtopublicLtd.,Alittlebelowtwentypercent(17.74%)belongtoprivateLtd.,Alittleabovetenpercent(11.29%) belong to partnership firms and a very little(3.23%)amountbelongtosole.MajorityofthePharmaceuticalcompanies(58.06%)arehavingtheexperienceofabovefifteenyears.Whereas16.13percent of the Units are having less than ten years ofexperience. 35.48 percent of the respondent units arehavingtheexperienceofmorethantwentyyears.Innutshell, almost all respondent units are having goodexperience.

All units taken for this study are well equipped withR&D facility. Even a single unit was excluded withR&D facilities. It shows the nature of interest andimportantshownbytheIndianPharmaceuticalcompanies towardsR&Dfacilities.

Many of the pharma Units (64.51%) are having lessthan 30 employees their R&D wing. 8.06 percent ofthe Units are supported with 30 to 40 employees.Whereas 14.52 percent of the units are having 40 to50 employees in their R&D division. 12.90 percentof the respondent units are having more than 50employees in theirR&Ddivision.

All Pharmaceutical companies taken for this studyare having their own well-equipped manufacturingfacilities.ItshowsthatIndianPharmaceuticalcompaniesarehavingtheirownsetuptomanufacturedifferenttypesoftherapeuticsegments. Six out oftencompanies taken forthis studyisequippedwithfacilitiestocarryouttheclinicaltrialsby own. Four out of ten units are not having thefacilityofdoingclinicaltrialswithintheircompany.So, it is observed that majority (59.68%) of IndianParmacompaniesarehavingtheirprovisionstoconduct clinical trials and remaining (40.32%) arenothaving such provision

Allpharmaunitstakenforthisstudyarehavingbothpatentsandtrademarks.12.9unitsarenothavinganyregistereddesigns.19.3unitsarehavingtheircopyrights. Trade secrets are very limited i.e., 9.68percent.Itshowsthefactthatmanypharmaunitsarewell aware and holding multiple IP Assets undertheirportfolio.

It is evident that managing IP and IPR is a multifaceted process that necessitates a variety of activities and methods that must be consistent with national laws as well as international treaties and norms. It is no longer solely motivated by national interests. Market needs, market response, the cost of turning IP into a commercial endeavour, and so on all have a significant impact on IP and its associated rights. To put it another way, trade and commerce factors are crucial in IPR management. Varied types of IPR necessitate different treatment, handling, planning, and strategies, as well as the involvement of people with a variety of domain skills, including science, engineering, medical, law, finance, marketing, and economics. Depending on its field of expertise, each sector should have its own IP rules, management style, strategies, and so on. The pharmaceutical industry's intellectual property strategy is currently developing. Antitrust law must step in to ensure that invalid rights are not being unlawfully asserted to build and sustain

illegitimate, albeit limited, monopolies within the pharmaceutical business, given the greater likelihood that some IPR are invalid. In this context, there are still numerous issues to be handled.

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