Chapter-6

Strategic Impact of changing Indian IPR regime on Indian pharmaceutical business
This chapter depicts the interpretation of the primary data collected for analyzing the strategic impact of IPR regime on the Indian pharmaceutical business. This chapter concludes with important finding of the study which is used for testing the hypothesis.

The Indian Pharmaceutical industry is greatly affected by the implementation of TRIPs agreement which is the most talked about and debated agreement of WTO and may have lasting impact on the pharmaceutical business model and accessibility and affordability of drugs to the poor section of the society.

The entire Indian Pharmaceutical Industry is total of 20,000 manufacturing units as per the expert committee report by the government of India. However, according to the report the total number of manufacturing units engaged in the production of both bulk drugs and formulations within India is not more than 5877 out of which approximately 300 companies account for over 95% of the total domestic market, the rest are marginal players.

6.1 Sample Size and Sample Distribution

For the purpose of study the sample size is one hundred which are representing all the sizes of the firm i.e. Large Scale, Medium Scale and Small Scale. For the purpose of the study the Large scale is defined as any pharmaceutical company having annual turnover
of at least 500 crores, the Medium Scale is defined as any pharmaceutical company having annual turnover between 200 to 500 crores and the Small Scale is defined as any pharmaceutical company having annual turnover of less than 200 crores. The industry professional which were contacted are distributed in three types viz. Middle management, Senior management and Top management. For the purpose of the study the middle management is defined as any pharmaceutical industry profession have designation of Assistant General Manager to Sr. General Manager, the senior management is defined as any pharmaceutical industry profession having designation of Associate Director to Sr. Vice President and, the top management is defined as either promoter or large stake holder of the company.

Following is the graphical representation of the sample distribution amongst industry professional in turn of percentage of total sample size i.e. 100 industry professional.

**Graph 6.1 Sample distributions as per the scale of the company**

**Graph 6.2 Sample distributions as per the position in the management**

![Graph 6.1](image1.png)  
![Graph 6.2](image2.png)
6.2 Primary Data Analysis

Following is question wise detailed analysis of the data collected through primary means.

6.2.1 This question was directed to study perception about the level of awareness on the enforcement of intellectual property rights protection and its strategic importance in Indian Pharma Industry.

Graph 6.3 – Level of IP awareness

![Graph showing level of IP awareness]

- Awareness level is low
- Awareness level was low pre-2005 but it has increase recently post-2005
- Awareness level is very high both pre-2005 and post-2005

The above graphical representation of the results depicts that the overall awareness level has taken a shift post-2005 since everyone was anxious about the implication on pharma industry and according to the views of pharma professional lots of activities are being done not only by various institutions but also by government organizations which helped tremendously in improving the overall awareness level of the industry. However, still 40% of the professional surveyed feels that current awareness is not sufficient and it is still low which needs continuous educations amongst pharma professionals.
6.2.2 This question was directed to measure the importance given to intellectual property pre-2005 by Indian pharmaceutical industry.

Graph 6.4 - Importance to IP Pre-2005

Since the TRIPs minimum requirements has force India to introduce the mail box system the importance to intellectual property has began from 1995 itself. Therefore, the result depicts that 97% industry professional has given an affirmative answer. However, all have unanimously excepted that the importance was not that much pre-1995 and the importance has gain momentum specially in the period between 2000 to 2005 when India has beginning to get closer to implement the product patent regime. Further, in Pre-2005 era it was still not considered as an important strategic element and fitted in the pharma business model.
6.2.3 This question measures the importance of Intellectual Property (IP) protection as one of the strategic elements post-2005.

Graph – 6.5 Importance to IP Post-2005

Surprisingly, the result alarmingly reveals that 45% of the pharma industry professionals surveyed feel that still many companies are ignoring IP protection as an important strategic element. However, approximately 52% feel that IP has been an important strategic element post-2005.
6.2.4 This question measures level of importance given to the intellectual Property protection for an Indian pharmaceutical company in developing a business strategy for Indian pharmaceutical industry.

Graph 6.6 – Level of Importance to IP as strategic element

![Bar Graph]

The results reveals that intellectual protection is an extremely important element in business strategy for pharma industry as 48% of industry professional surveyed has considered very important and 43% of the industry professional perceived as most important in developing a business strategy for Indian pharmaceutical industry.

6.2.5 The objective of putting this question is to evaluate the rating of intellectual property management IPM in formulating the business strategy with respect to all the import strategic component for an Indian Pharmaceutical company.
i.e. marketing, finance, production, research and development, human resource management. The rating scale was 1 to 6 of which 1 is considered as most important and 6 is considered as the least important. Following is the analysis

Graph 6.7 – Rating of the Strategic elements

This results highlights that 68% of the companies has already started recognizing intellectual property as an important strategic element which is depicted in their promotion strategy to the doctors. On the other side there are still a healthy number of companies 32% not giving the due importance to intellectual property.

6.2.6 The objective this question is to evaluate whether industry professional strongly feels that in the current scenario every pharmaceutical company should increase their Intellectual assets by creating more and more invention.
Remarkably, a unanimous answer from all the industry professional surveyed which is affirmatively endorses the importance of intellectual wealth creation by developing your intellectual portfolio which leads to more and more invention. This leads to the fact that each and every industry professional surveyed accepts that investment in research and development is inevitable in the current scenario which helps in building intellectual assets.

6.2.7 This objective this question is to reconfirm that above fact on whether industry professional strongly feels that in the current scenario every pharmaceutical company should increase their Intellectual assets by focussing on the research and development.

Another unanimous answer from all the industry professional surveyed which is affirmatively endorses the importance of intellectual wealth creation by developing your intellectual portfolio by focusing on the research and development. This answer reconfirms the objective clarity on industry’s focus on research and development.

The answers of both the questions depicts that Indian Pharmaceutical industry is anticipating the implication and the resulting shift in focus from marketing to research and development. Therefore the current era demands the focus on research and development which lead to creation of substantially portfolio of IP which help firm not only survive but grow in post-2005 scenario.
6.2.8 This question is subdivided into fourteen questions. These questions are directed towards accessing the overall perspective of Industry professionals on implications for the changing environment of the Pharma Industry, post-2005. The industry professional were asked to tick one of the options out of which expressively depict their discernment towards each statement provided in each sub-question.

6.2.9 *Intellectual property Management is one of the important components for an Indian Pharmaceutical industry*

The results state that 83% of the professional surveyed strongly agrees with this and 13% are not very strong however, in agreement with this. They perceived that all the pharmaceutical companies should increase the focus on intellectual property management because that would be the
driving factor and would make the Indian Pharmaceutical industry globally competitive in post-2005 scenario.

6.2.10 Under current scenario, the image of a pharma company is directly proportion to the intellectual property owned by the company.

As the above graph depicts, the majority of professionals perceived that the image of a pharma company is directly proportion to the intellectual property owned by the company.

6.2.11 Indian Pharma company should increase the investment in research and development to increase the Intellectual Property
Here also, the above graph depicts that the Indian Pharma companies should increase the investment in research and development to increase the Intellectual Property. They particularly felt that the increase in investment would bring about the increase in intellectual property portfolio.

6.2.12 *An Indian pharmaceutical company should go for partnership in order to build the strong Intellectual property portfolio*
Merger and acquisition can be one of the strategies to exchange the expertise which in turn help in not only increasing the market share but also expanding the competitive horizon that help sustaining in the changing environment. The result shows that professionals have also expected the fact that partnership can be a strategy which would help building a strong intellectual portfolio.

6.2.13 The business strategy has observed a drastic change from Pre-2005 scenario to post-2005 scenario

Indian pharmaceutical industry has witnessed a sea change during last decade particularly pre-1995, post-1995 and post-2005 when the patent law is subject to amendment in order to comply with TRIPS requirement. Indeed, 99% of industry professional surveyed are in agreement out of which 74% are in strong agreement that the business model is subject to change per the change in patent regime mainly after the introduction of product patent regime.
Under current scenario the strategy of an Indian pharma company should be Intellectual property Management driven.

The industry professionals surveyed are in agreement with the view that under current scenario the strategy of an Indian pharma company should be Intellectual property Management driven. The result depicts that 30% strongly agree with the perception while 64% are in agreement with this whereas 6% could not comment on this and remained neutral.
Interestingly, the result reveals that majority of industry professionals felt that the product patent regime can have negative impact on competitive environment. The number depicts that 98% feel out of which 76% strongly feels that the product patent can create monopolistic environment. Therefore, the policy measures taken by the government in order to restrict this effect would be extremely important according to professionals surveyed.
6.2.16 *Drug prices will increase after the product patent in place (Post-2005)*

Every one has shown complete agreement towards the perception that government’s role is extremely critical in negotiating with WTO for TRIPs compliance as well as minimizing the adverse impact on drug prices. Therefore, 97% are in agreement with the perception that drug prices would increase in the product patent regime. However, they have also suggested that if adequate measures are being taken by the government and industry then this impact could be minimize at least for essential medicines.
6.2.17 *In the post-2005 scenario, government's role is important to protect the domestic industry*

This is question is a follow up question of the earlier question which essentially suggests how to minimize the adverse impact of product patent regime on likely drug price increase. Majority of the industry professionals have shown complete agreement towards to the perception that government’s role is extremely critical in negotiating with WTO for TRIPs compliance as well as minimizing the adverse impact on drug prices. Policy measures taken by the government are critically examined by Industry in the days to come since it would affect directly to the fate of the industry in global environment.
Interestingly, the views of industry professionals are divided for this particular query. Out of the industry professional surveyed, 63% are in agreement including 48% which are in strong perception that the product patent regime would adversely affect the small scale industry in particular because of the non or less availability of huge funds which are required for R & D investment and building up in intellectual property portfolio.
6.2.19 It would be easier for the company to be able to enter in the developed markets which has proper Intellectual property protection

The above graph depicts a common answer from all the industry professionals surveyed which is affirmatively endorses the perception that it would be easier for the company to be able to enter in the developed markets which has proper Intellectual property protection. All the professionals (100%) surveyed has acknowledged the strategic importance of intellectual property in entering into the developed markets like US and Europe.
Indian pharma companies can compete more effectively by giving strategic importance to Intellectual property management.

This answer also augments the perception of industry professionals on strategic importance of intellectual property management. As revealed by the above graph, industry professionals are in agreement, especially 29% of them are in strong agreement with the hypothesis that Indian pharma companies can compete more effectively by giving strategic importance to Intellectual property management.
The intellectual property protection is a must to enter in the developed markets like US and Europe.

In order to be globally competitive, Indian companies must fetch some market share from extremely voluminous developed market. Therefore it is important to evaluate the role of intellectual property while entering in the developed market. The answer gives a clear indication that it is inevitable not only to have a substantial intellectual portfolio but also respect other intellectual property as the intellectual property protection is a must to enter in the developed markets like US and Europe as perceived by the industry professional, surveyed.
6.2.22 The government can play an important role in complying the TRIPs requirement without compromising the public health concerns.

As it became compulsory for the Indian Government to modulate the Indian Patent Law in such a way that it would become TRIPs compliant the industry is strongly accepting government to play an active role in minimizing the adverse impact. The result depicts that industry professionals are of the opinion that the government can play an important role in complying the TRIPs requirement without compromising the public health concerns. As the graph reveals 30% are in strong agreement whereas as 67% are not in strong but certainly in agreement with this hypothesis.
6.2.23 The objective of this question was to evaluate the perceived value of new patent regime introduced by the government with respect to protecting the interest of domestic industry. The industry professional are being ask to rank the new patent regime 2005 in a scale of 5 (0 is the most ineffective and 5 is the most effective) in terms of protecting the domestic industry.

There are several measure which are incorporated in the amended version of the Indian Patent Act to protect the interest of domestic industry. Although some the industry professionals feels that the new regime is marginally effective as 29% of industry profession rank the effectiveness of the new product patent regime upto three, majority of the industry professionals(71%), ranks the current version of Indian patent act more than three. This shows that in industry professional perception, government is indeed successful in protecting the interest of domestic industry.
6.2.24 The objective of this question was to evaluate the perceived value of new patent regime introduced by the government with respect to protecting the interest of multinational companies (MNCs) operating in India. The industry professional are being ask to rank the new patent regime 2005 (0 is the most ineffective and 5 is the most effective) in a scale of 5 in terms of protecting the interest of MNCs in India.

![Graph showing industry professional rankings]

It is equally important for the government to be fair towards the MNCs because they determine the foreign direct investment which is critical for Indian economy. However, as far as MNCs are concerned they are not happy with the current amended version specially with some of the clause such as section 3(d), section 11(7) which goes beyond the TRIPs requirement as per some of the MNCs professionals surveyed. The other perception drawn out of this question was that industry professionals feels that government should not be over protective for the domestic industry. The results clearly depicts that as majority of industry professionals feels that the new regime is marginally effective as 94% of industry profession rank the effectiveness of the new
product patent regime upto three, whereas only 6% ranks the current version of Indian patent act more than three.

6.2.25 The objective of this question was to evaluate as to which is the most effective way in which government could promote a satisfactory technology level and product innovation.

For Indian Pharma industry to become globally competitive in the product patent era, it is imperative to be technologically advance and innovative culture. In creating and propagating this culture is one of the most important role of government. Therefore, this question was posed to industry professional to evaluate the most effective way in which government could perform the role wherein it could not only a satisfactory technology level and product innovation. Following table depicts the results of this survey:

**Table-6.1 Evaluating the most effective way in which government could promote a satisfactory technology level and product innovation.**

<table>
<thead>
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<th></th>
<th>One</th>
<th>Two</th>
<th>Three</th>
<th>Four</th>
<th>Five</th>
<th>Six</th>
<th>Seven</th>
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<tbody>
<tr>
<td>Provide R&amp;D incentives</td>
<td>31</td>
<td>60</td>
<td>7</td>
<td>7</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Strong IPR regime</td>
<td>64</td>
<td>33</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Educating more R&amp;D people</td>
<td>3</td>
<td>7</td>
<td>86</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Joint research</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>10</td>
<td>82</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Introduction of new technology from abroad</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>82</td>
<td>2</td>
<td>11</td>
<td>5</td>
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<tr>
<td>Transferring technology through govt. sponsored research institutions</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>5</td>
<td>0</td>
<td>85</td>
<td>8</td>
</tr>
<tr>
<td>Helping firms to establish their own brand names</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>15</td>
<td>.3</td>
<td>81</td>
</tr>
</tbody>
</table>

The above result depicts that the utmost importance is give to to promote a satisfactory technology level and product innovation and those are providing R&D
incentive and implementing a strong IPR regime. Majority of industry professionals felts that both ways are extremely effective in driving the entire industry towards R&D investment and filing more an more patent applications and creating a strong intellectual portfolio which results in a competitive edge in global scenario, specially in product patent regime. Majority of industry professional have told that government should provide more and more benefits for R&D incentive such as tax benefit, recognition in the form of award, government funding facility etc. They have also said that strong intellectual property regime would also force the companies to stop copying other molecule and create and innovate their own molecules and their synthesis processes.

6.2.26 The objective of this question was to evaluate whether government bodies will play an important role in determining the fate of the Indian Pharmaceutical Industry or not.

Graph 6.8 Importance of role of Government

![Graph showing importance of role of Government]

Every one has shown complete agreement towards to the perception that government's role is extremely critical in negotiating with WTO for TRIPs
particularly in deciding the fate of the Indian pharma industry. The result as depicted in the graph states 99% are strongly in agreement whereas as 1% are not in agreement with this.

6.2.27 This question was more directed towards evaluating the likely change in the business model so that an Indian Pharmaceutical company should prepare itself in order to face the challenges of post-2005 scenario. Until early 2005 any management strategy was mainly centered around marketing fundamentals and very less or no importance was given to marketing management.

Graph 6.9 – Change in Strategic importance

Interestingly, all the industry professionals have affirmatively recognize the strategic shift in importance to the intellectual property management (IPM) as strategic element. Each and every professional have expected the fact that in post-2005 scenario when product patent regime in place you can not market a product if it is protected by a product patent even if it has a excellent market potential. Therefore,
IPM takes the drivers seat in formulating strategies for Indian pharmaceutical industry in the product patent regime.

6.2.28 This question primarily addresses the issue of access to medicine. Industry professional were asked to opined on whether the present prices of medicines for life saving drugs are appropriate enough to ensure the welfare of Indian people belonging to different economic strata?

![Pie chart showing opinions]

Current drug prices are largely not affected as yet by the effect of product patent regime because majority of the product which are currently marketed in India are pre-1995 molecules which is outside the scope of product patent protection as per the amendments in Indian patent act. Therefore, 86% of the industry professional feels that the drug prices of life saving drugs are appropriate since it is not only unprotected by patent but also the prices are controlled by an authority under drug price control order (DPCO).
6.2.29 To analyse whether the Indian patent act as affected the access to medicine, it is imperative to know which are the factors which influence the access to medicine. Therefore, through this question industry profession were ask to choose the factors which affects the access to medicine.

The above result clearly shows that price is the most important factor which affects the access to medicine. Therefore, any government policies or amendment in the present act if affect the prices would in turn affect to the access to medicine.
6.2.30 The objective of this question is to evaluate industry professional perception on whether new product patent regime will affect the access to medicine particularly for life saving drugs.

Graph – 6.10 Effect of product patent regime on Access to Medicine

As shown in the above graph, 86% of industry professional surveyed perceived that the new product patent regime would affect access to medicine. However, most of them expressed that this affect would visualize in long term and not in short term. Till the time off patent molecules are in the market the effect would not be seen as critical. In the scenario which would be seen in long term when new generation molecule which are covered under product patent in India are markets by only innovator company. At that time the prices would definitely be affected since one drug which is under patent would be marketed by only one company i.e. innovator company. It is then when the real effect of new product patent regime on access to medicine would be seen. Some of the industry
professionals have also expressed that it may adversely affect the access to medicine if adequate policy measures are not been introduced by the government.

6.2.31 This question was particularly an open ended question to evaluate how the business model has changed from pre-1995 to post-1995 era. Industry professionals were asked to fit Intellectual property management in their business model.

Lots of interesting remarks are being made by the industry professionals in comparing the pre-1995 and post-1995 particularly post-2005 when the product patent regime implemented. Majority of industry professional have indeed excepted the fact that in the earlier scenario(pre-1995) when the industry was introducing copy-cat drug through copy-cat processes without even bothering about other intellectual property, the strategy was different significantly.

In the pre-1995 era, those molecules which were selected and developed which are potential irrespective of their patent situation. Very little attention was given to the research rather the focus was on production to attain high turnover to meet the high demand. But post-1995, gradually as the Indian patent act was subject to amendment, the strategic management in Indian pharma industry has witnessed a see change and a new strategic element called intellectual property management was not only recognized but gained importance very rapidly and now it is a centre point.

In the current scenario when new product patent regime is in place, any strategy starts from evaluation of patent situation and then goes on to other different element. In the
current scenario almost all the Indian pharmaceutical companies have created separate Intellectual property management cell to cater the ever increasing needs of intellectual property management.

In summary, the business model in pharmaceutical industry has been subject to change as per the change in Indian patent act and still companies are working for reformulating business model for minimizing the adverse impact and maximizing the benefits offered by the changing environment in the new product patent regime. A derived ideal business model from this study and analyzing the views expressed by industry professionals is being discussed in the concluding chapter.
6.2.32 The objective of this question was to study the strategic component incorporated in the business strategy of pharma companies follows in general to face the challenges of post-2005 era. Industry professionals were being requested to chose the strategic component they incorporated.

Graph -6.11 Strategic components of pharmaceutical business

The above results clearly depicts that there are four different strategic dimensions which the industry would like to incorporate in the future business model to face the challenges of post-2005 era.

These dimensions are investment in Basic Research in developing new molecules, creating strong IP portfolio before entering in developed market, understanding the IP
scenario of respective target market before entering, creating the wealth by selling or licensing Intellectual Property created by the company, Wealth maximization of creating and valuating intellectual property. Out of these above elements understanding the IP scenario of respective target market before entering is extremely important since it recognized by all the industry professional surveyed.
6.3 Key findings

Following is the gist of perceived implications of the impact of product patent regime on the business model and strategic shift in the Indian Pharmaceutical industry as well as access to medicine from the industry professionals derived from the study done of industry professionals:

❖ Overall awareness level in the industry on intellectual property has taken a shift post-2005 since everyone was anxious about the implication on pharma industry and lots of activities are being done not only by various institutions but also by government organizations which helped tremendously in improving the overall awareness level of the industry.

❖ Importance to intellectual property as strategic element was not that much pre-1995 and the importance has gain momentum specially in the period between 2000 to 2005 when India has beginning to get closer to implement the product patent regime. Still many companies are ignoring IP protection as an important strategic element.

❖ Intellectual protection is an extremely important element in business strategy for pharmaceutical industry in the new product patent regime.

❖ Investment in research and development is inevitable in the current scenario which helps in building intellectual assets. The current era demands the focus on
research and development which lead to creation of substantially portfolio of IP which help firm not only survive but grow in post-2005 scenario.

❖ The image of a pharmaceutical company is directly proportion to the intellectual property owned by the company.

❖ Partnership can be a strategy which would help building a strong intellectual portfolio.

❖ Under current scenario the strategy of an Indian pharma company should Intellectual property Management driven.

❖ Product patent can create monopolistic environment. Therefore, the policy measures taken by the government in order to restrict this effect would be extremely important according to professionals surveyed.

❖ Product patent regime can have negative impact on competitive environment.

❖ Government's role would be extremely critical in negotiating with WTO for TRIPs compliance as well as minimizing the adverse impact on drug prices.
❖ Product patent regime would adversely affect the small scale industry in particular because of the non or less availability of huge funds which are required for R & D investment and building up in intellectual property portfolio.

❖ It would be easier for the company to be able to enter in the developed markets which has proper Intellectual property protection.

❖ Indian pharma companies can compete more effectively in the global scenario by giving strategic importance to Intellectual property management.

❖ Drug prices would likely to increase post introduction of product patent regime specially in the long run. However, if adequate measures are being taken by the government and industry then this impact could be minimize at least for essential medicines.

❖ Government is indeed successful in protecting the interest of domestic industry. However, MNCs interest is not properly addressed and they are not very satisfied with the current Indian patent act.

❖ Government should provide more and more benefits for R&D incentive such as tax benefit, recognition in the form of award, government funding facility etc. They have also said that strong intellectual property regime would also force the
companies to stop copying other molecule and create and innovate their own molecules and their synthesis processes.

❖ The strategic management in Indian pharmaceutical industry has witnessed a see change and a new strategic element called intellectual property management was not only recognized but gained importance very rapidly and now it is a centre point.

❖ The business model in pharmaceutical industry has been subject to change as per the change in Indian patent act and still companies are working for reformulating business model for minimizing the adverse impact and maximizing the benefits offered by the changing environment in the new product patent regime. A derived ideal business model from this study and analyzing the views expressed by industry professionals is being discussed in the concluding chapter.

❖ There are four different strategic dimensions which the industry would like to incorporate in the future business model to face the challenges of post-2005 era. These dimensions are investment in Basic Research in developing new molecules, creating strong IP portfolio before entering in developed market, understanding the IP scenario of respective target market before entering, creating the wealth by selling or licensing Intellectual Property created by the company, Wealth maximization of creating and valuating intellectual property. Out of these above
elements understanding the IP scenario of respective target market before entering is extremely important.

In summary, is abundantly clear from the above finding that intellectual property is one of the core elements of strategic element particularly in the product patent regime. Any pharmaceutical company has to take strong measure to incorporate intellectual property management function in order to cope with the paradigm shift which has been ignited by the introduction of product patent regime after 1st January 2005 by the Indian patent act. This finding are strongly in support of the hypothesis laid down in the beginning for the impact of intellectual property on Indian pharmaceutical business.

The next chapter relates to analyzing the impact of changing Indian IPR regime on Access to medicine from the Medicos perspective. It would elaborate the primary data analysis with respect to evaluating the said objectives in relation to access to medicine. The chapter would also conclude with key finding in this regards and correlating the same with the predefined objective and hypotheses.