Empirical data was collected through a questionnaire based survey. The main aim of the survey was to collect opinion of the professionals and experts working in the IP and pharmaceutical fields over various contentious issues in the regulations for patenting of pharmaceuticals in India.

The questionnaire was comprised of total 14 questions, each question having choice of answering either in agree/disagree or yes/no format. Further, for each question option was provided to draw open ended answer in the form of “any other comments”. The questions were drafted based on the issues on the current patenting system in India identified during review of literature. A copy of the questionnaire is enclosed at Annexure-2.

A list of 100 respondents was prepared and responses were collected online as well as in-person. Out of the 100 respondents contacted, 73 respondents provided their responses by filling the questionnaire. The responses received in the survey are presented and discussed below. Further, opinion was also collected from few international delegates on the patent laws of their countries, during my participation in Second Mediterranean Symposium on Medicinal and Aromatic Plants (MESMAP-2), at Antalya, Turkey in April, 2015.

Q.1 The main responsible factor for India’s consistently poor annual FDI (Foreign Direct Investment) inflows is its weak national IP environment as compared to the other BRIC (Brazil, Russia and China) and middle-income countries.

Result: Shown in Figure 8
Discussion:

IP environment in the country comprises of its policies and regulations on all major IP rights including patents, copyrights, trademarks, trade secrets, etc. In the context of developing economies such as India, the strength of national IP environment depends not only on how effectively it can protect the rights of the IP owners, but also on how efficiently it can prevent the possible abuses of the IP rights. The IP environment therefore should strike a balance between the interests of IP owners and need of the public. The present survey was directed towards assessing the strengths/ weaknesses of the current patent environment in India. The responses received on the first question of this survey indicate that the respondents believe that there lie some issues/ concerns in the current IP and patent environment in India, which are needed to be addressed. An effective resolution of these issues would therefore aid in strengthening the national IP environment and improving FDI inflows in the country. The subsequent questions would throw light on the particular issues/ concerns in the current patenting system/ patent environment in India, and respondents’ view on these issues.
Q.2 Inclusion of compulsory licensing in India’s National Manufacturing Policy, 2011 as a mechanism for government to effectuate technology transfer in certain sectors indicates that in India compulsory licensing provisions are being used merely as a tool to achieve government’s industrial policy goals rather than towards the protection of public health in the country.

Result: Shown in Figure 9

<table>
<thead>
<tr>
<th>Agree</th>
<th>38.36%</th>
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<tbody>
<tr>
<td>Disagree</td>
<td>57.53%</td>
</tr>
<tr>
<td>Didn't answer</td>
<td>4.11%</td>
</tr>
</tbody>
</table>

Figure 9: Response to the Question 2

Discussion:
TRIPS provide flexibility for the grant of compulsory license as a measure to prevent abuse of the patent rights in the country. In the above question, majority of the respondents refuted the argument that Indian government is using compulsory licensing provisions inappropriately to achieve its industrial policy goals rather than for protecting country’s public health. The respondents therefore denied the allegation raised by the multinational companies that the compulsory licensing provisions in India are aimed primarily to extend undue benefits to the local generic drug manufacturers instead to address public health problems. The respondents’ view can be reinforced by taking into consideration the fact that only one compulsory license has been issued in India till date. Subsequently two more applications filed for the grant of compulsory license on the patents held by multinational...
companies were rejected by the India Patent Office for not satisfying the regulatory requirements for the grant of compulsory license (see Chapter 3: Judicial Review). Further, India’s National Manufacturing Policy document clearly mentions “[s]uch compulsory licenses will be issued only within the provisions of TRIPS. Reasonable royalty will be paid to the patent holder”. It is thus clearly evident that grant of compulsory license in India is in accordance with the TRIPS compliant regulations, and not influenced by any government policy.

Q.3 Article 27 of TRIPS enlists the subject matter that can be excluded from the patent coverage. Section 3 (d) of the Indian Patents Act, which excludes from patentability any new forms of known substances lacking enhanced efficacy, is inconsistent with the TRIPS Agreement because subject matter of Section 3(d) is not included in the permissible list of exclusions for patentability mentioned in the Article 27. Furthermore, Section 3 (d) also conflicts with the non-discrimination principle provided by the Article, as this Section sets a higher threshold of patentability specifically for the pharmaceutical inventions.

Result: Shown in Figure 10

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<table>
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<tr>
<th></th>
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<tbody>
<tr>
<td>Agree</td>
<td>36.99%</td>
<td></td>
</tr>
<tr>
<td>Disagree</td>
<td>61.64%</td>
<td></td>
</tr>
<tr>
<td>Didn't answer</td>
<td>1.37%</td>
<td></td>
</tr>
</tbody>
</table>

Figure 10: Response to the Question 3
Discussion:
On the issue of TRIPS non-compliance of the Section 3(d), majority of the respondents (61.64%) disagreed as they believe that Section 3(d) is fully compliant with the Article 27 of TRIPS. India’s position of this issue was well defended by the Indian government during the proceedings in Novartis case in the Supreme Court. Indian government asserted that TRIPS agreement coupled with the Doha Declaration permits the member countries to set higher standards of patent protection for pharmaceutical and health related products, and therefore there is no question of TRIPS non-compliance of Section 3(d).
We can support the view of Indian government by refereeing to the relevant cases on patentability of polymorphs/ new forms in other countries such as U.S. and Europe. In U.S. and Europe also courts have set higher threshold of patentability for the inventions related with the polymorphic forms, salts, active metabolites etc. (see Chapter 3: Judicial Review).

Q.4 India’s current IP policy is inducing barrier to trade and is an obstacle in the business environment in India for the companies of foreign countries such as U.S. and Europe.

Result: Shown in Figure 11

![Figure 11: Response to the Question 4](image_url)

- Agree: 34.25%
- Disagree: 63.01%
- Didn't answer: 2.74%
Discussion:
Majority of the respondents (63.01%) believe that India’s IP policy is not against the trade and business of foreign/multinational companies. Although, the respondents recommended taking measures for improving overall IP environment in India (see response to the Question 1), yet in the response of this question the respondents refuted the contention that IP policy in India is particularly discriminatory towards the foreign/multinational companies.

Q.5 India should implement patent term restoration provision as available in a number of countries such as US, Europe and Australia, which aims at restoring a portion of the patent term granted to innovative pharmaceutical products that is lost, due to the prolonged research, development, and regulatory approval periods of such products.

Result: Shown in Figure 12

![Bar Chart]

Figure 12: Response to the Question 5

Discussion:
Patent term restoration is currently not available in India. It aims to compensate the loss of patent term of pharmaceutical patents due to delays in product approval by the national drugs control agency. In respondents view,
implementation of patent term restoration in India would help in strengthening the patent environment in the country.

Q.6 Current patent opposition procedure in India causes undue delay in the patent grant and is a burden on the applicants because same person may, at minimal cost can challenge a patent on the same grounds through both pre-grant and post-grant oppositions. To avoid such undue delays in patent grant, the pre-grant challenge should be limited to third party submission of relevant printed prior art to the patent examiner, allowing oral hearings of the interested third parties at the post-grant opposition stage only.

Result: Shown in Figure 13

![Figure 13: Response to the Question 6](image)

Discussion:
Unlike in other countries such as U.S., Europe, China, India follows an *inter-partes* pre-grant opposition system. Majority of the respondents (71.23%) agreed that this *inter-partes* pre-grant opposition leads to undue delay in patent grant in India. Therefore, at the pre-grant stage, current *inter-partes* pre-grant procedure should be replaced with the *ex-parte* third party prior art submission process.
Q.7  India has a large number of inventions that may not satisfy the criteria of patentability but are novel, utilitarian and inventive in their own spheres. Such petty patents or “utility models” has been successfully applied in many countries but is not available in India. This leaves out a large number of inventors particularly the MSMEs from protecting their inventions. India should therefore, introduce provisions for patenting of utility models.

Result: Shown in Figure 14

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<tbody>
<tr>
<td>Agree</td>
<td></td>
<td>84.93%</td>
</tr>
<tr>
<td>Disagree</td>
<td></td>
<td>13.70%</td>
</tr>
<tr>
<td>Didn't answer</td>
<td></td>
<td>1.37%</td>
</tr>
</tbody>
</table>

Figure 14: Response to the Question 7

Discussion:
Utility models patents are effectively implemented in China. The draft of the “National IPR Policy” released by Government of India emphasized on the need to adopt utility models patents in India. Respondents of this questionnaire also endorsed the same. If implemented, utility models patents will be a boon for MSMEs in India. In pharmaceutical sector MSMEs involved in the manufacture of medical and diagnostic devices will be benefitted by this.

Q.8  India should sign and become member of the Patent Law Treaty [administered by the World Intellectual Property Organization (WIPO)], that aims to harmonize and streamline formal procedures in respect of national and regional patent applications and patents.
Result: Shown in Figure 15

![Bar Chart](image1.png)

**Figure 15: Response to the Question 8**

Discussion:

Majority of the respondents (56.16%) do not recommend signing of Patent Law Treaty by India.

Q.9 Currently, more than 75% of the patent applications filed in India belong to foreign citizens. In your opinion, the prime reason behind the low rate of patent filing by Indian citizens in India is -

Result: Shown in Figure 16

![Bar Chart](image2.png)

**Figure 16: Response to the Question 9**
Discussion:
In respondent’s view lack of awareness about the benefits of IPR and patents in India is the major reason behind the low rate of patent filing by Indian citizens. Active measures should be taken by the Indian government to educate the scientific community, industry personnel and public in the country about the benefits of IP and patenting system and its role in country’s economic development. Few such measures are suggested in the next chapter.

Q.10 Do you agree that courts in India are overburdened, leading to long delays in case processing, therefore there is an urgent need to strengthen IPR enforcement mechanism in the country by increasing judicial efficiency and reducing court backlogs through measures such as - electronic case management, fast-track procedures, IP specialized judges and separate patent benches in the High Courts?

Result: Shown in Figure 17

![Figure 17: Response to the Question 10](image)

Discussion:
In the respondent’s view, there is a need to take measures to strengthen IPR enforcement mechanism in India. In this context, few suggestions are provided in the next chapter.
Q.11 Do you agree that there is a need to improve working efficiency of the Indian Patent Offices, and therefore measures such as - hiring more patent examiners, training of the officials, and complete digitalization of the patent databases and procedures at the patent offices are utmost necessary?

Result: Shown in Figure 18

![Response to the Question 11](image)

**Figure 18: Response to the Question 11**

**Discussion:**
All respondent unanimously agreed that there is a need to improve working efficiency of the Indian Patent Offices. Few suggestions are proposed in the next chapter.

Q.12 Do you agree that the current provisions for “working of patents” and its formal reporting in India are vague and require clarity on the aspects such as - whether importation of the patented products amounts to local working of a patented invention; use of words like partly, adequately and fullest extent in the Form 27; and disclosure and publication of sensitive and confidential business information like quantum and value of the patented product worked in the country?

Result: Shown in Figure 19
Discussion:
Respondents agree that there is a need to streamline the provisions for reporting on “working of patents” in India. Few suggestions are proposed in the next chapter in this context.

Q.13  Do you agree that the Section 8 requirement of the India Patents Act relating to information and undertaking regarding foreign applications is unnecessarily burdensome and targets the foreign patent applicants in a discriminatory manner? Further, the penalty for failure to comply with this Section is extreme in India as compared to that of the other countries with similar but less onerous administrative requirements?

Result: Shown in Figure 20
Discussion:
In the respondent’s view Section 8 requirement needs amendment so as to align it with the regulations in other countries. In the comparative study also it was found that the regulation in India in this context is much more strict and difficult to comply with (see Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China). Further, patent can be revoked due to failure to comply with this provision, which is extreme as compared to other countries viz. U.S., Europe and China.

Q.14 Do you agree that India should adopt the patent linkage system that provides a transparent pathway for adjudication of patent validity and infringing issues before the marketing of a generic drug or biosimilar product?

Result: Shown in Figure 21


**Discussion:**

To strengthen the patent enforcement mechanism, respondents recommended adoption of the patent linkage system in India.