7. SUMMARY & CONCLUSION

7.1 Summary

U.S., Europe, China and India grant patents for inventions fulfilling the three general criteria of patentability (as per TRIPS Article 27) viz. newness/novelty, inventive step/non-obviousness, and industrial applicability/usefulness. Indian patent law puts specific restrictions on the patentability of polymorphs and other new forms of the known drug substances through Section 3(d). A raised standard of inventive step and novelty requirements for the same have been set under the case laws/patent examination guidelines in U.S., Europe and China.

To felicitate patent filing by the Chinese citizens, SIPO has established its representative offices at all state capitals and district headquarters. Few differences exist in the patent prosecution in the U.S., Europe, China and India. The U.S. patent law provides the option to opt-out of the publication of the patent application in certain cases. This option is not available in Europe, China and India. During patent prosecution, EPO issues a search report & opinion on patentability on the claimed invention; however, U.S., China and India do not have such provision. Patent laws in U.S., Europe and China provide various procedures to expedite the patent examination, whereas, no such procedures are currently available in India. Option for supplemental examination after the grant of a patent is provided only under the U.S. law. Continued examination/re-examination is possible in the U.S. and China but not in Europe and India.

Patent laws in U.S., Europe, China and India require the applicants to disclose information regarding corresponding foreign patent applications. However, regulations in India in this context are much more strict and difficult to comply with.
U.S., Europe and China fallows *Ex-parte* preissuance submissions at the pre-grant stage, whereas, India has adopted an *Inter-partes* pre-grant opposition procedure. Threshold to institute the post-grant opposition proceeding is applicable only in U.S. Estoppel provision during post-grant opposition is applicable in U.S. and China.

Both U.S and India may grant compulsory license on the grounds of government use, anti-competitive practice and non-working of the patent. Further, in the U.S compulsory license may also be granted under Bayh-Dole Act. Provisions for the mandatory cross-licensing between the owners of biotechnology patents and registered plant varieties are currently not available in India, as provided in the European regulations. China has prescribed detailed guidelines on compulsory license. No similar guidelines are available currently in India.

As mandated in the Indian patent law, requirement for reporting of working of patents is not prescribed under the EPC and the patent laws of U.S. and China. U.S. law provides an extensive frame work for patent linkage. China follows only a basis structure of patent linkage. However, Patent linkage is not available in Europe and India. Regulations for service/ employee inventions are prescribed under EPC and Chinese patent law. No specific regulations for the same are provided in the U.S. and Indian laws. IP/ patent specialized courts have been set up in U.S., Europe and China. In India currently there are no such types of courts are established for specifically adjudicating matter related with IP rights. Newly created Commercial Courts in India will handle IP disputes worth > Rs 1 crores.

In the questionnaire based survey, 73 respondents provided their responses by filling the questionnaire. In the respondents’ view there lie some issues/concerns in the current IP and patent environment in India, which are needed
to be addressed. Majority of the respondents however believed that the use of compulsory licensing and Section 3(d) provisions in India are as per the internationally accepted standards laid down under the TRIPS agreement. They also refuted the charges that India’s IP policy is inducing barrier to trade and business of foreign/multinational companies. Majority of the respondents suggested that India should implement patent term restoration, adopt patent linkage system, and apply utility model patent. To avoid undue delays in patent grant in India, respondents suggested to replace current pre-grant opposition procedure with third party prior art submission process. 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. Respondents emphasized on improving working efficiency of the Indian Patent Offices and to strengthen IPR enforcement mechanism in India. Respondents agreed that there is a need to streamline the provisions for reporting on “working of patents” in India. In the respondent’s view Section 8 requirement needs amendment so as to align it with the regulations in other countries. Majority of the respondents did not recommend signing of Patent Law Treaty by India.

Based on the comparison of the Indian patent regulations with the relevant regulations in U.S., Europe and China, and empirical data collected through the survey, measures to strengthen the Indian regulations were proposed. Suggestions were made to improve the patent office administration and to encourage patent filing by Indian citizens. Further, measures were also proposed to strengthen provisions for polymorph patenting, patent opposition, Section 8 requirements, compulsory licensing and reporting of working of patents in India. It was suggested that India should adopt provisions for the expedited patent examination, patent term restoration, patent linkage, and utility model patents. Specialized IP/patent courts should be established and regulations for service/employee inventions be adopted in India.
7.2 Conclusion

The present research work was aimed to find out areas of improvement in the existing Indian regulations for patenting of pharmaceuticals. The patent laws of India, U.S., Europe and China were studied thoroughly and Indian regulations were compared with the patent regulations of U.S., Europe and China. Empirical data was collected through research questionnaire. Important case laws were also reviewed. Based on the comparative study, review of the case laws and analysis of the collected empirical data, suggestions for strengthening the patent regulations in India were proposed.

7.2.1 Limitation of the present work

To draw meaningful conclusions in the available time frame during this research work, only salient provisions in the patent regulations of the countries were studied and compared.

Looking at the specific subject area of the research i.e., pharmaceutical patenting, the sample size in the questionnaire based survey was limited to 100 respondents. Due to the availability of limited number of respondents, convenience sampling method was used and therefore subjectivity in the survey results cannot be ruled out completely.

7.2.2 Future scope

In the present research only one developing country i.e. China has been taken for the comparison. To get a broader perspective on the subject area, other emerging Asian markets such as South Korea, Malaysia, Philippines etc. can also be included in the study.

Majority of the respondents in the survey conducted during this research were Indians. To get a broader view, responses may also be collected from the respondents of other countries included in the research.