6. SUGGESTIONS TO STRENGTHEN PATENT REGULATIONS IN INDIA

Based on the findings of the present research work, following measures are proposed for strengthening the patent regulations in India.

6.1 Patent office administration
In order to improve the efficiency of patent office administration in India, measures such as hiring more patent examiners, training of the officials, improving working conditions of the patent examiners and digitalization of the patent databases and procedures at the patent offices are required to be taken (See Question 11 in the Chapter 5: Empirical Aspects).

6.2 Encouragement of patent filing by Indian citizens
To encourage patent filing by the Indian citizens there is a need to increase awareness about the benefits/role of patents and IPR in India (See Question 9 in the Chapter 5: Empirical Aspects), for which more number of patent/IPR awareness workshops, seminars, camps and training programmes may be organized on regular basis by both the state and central governments in India. As adopted in China, representative offices of the Indian Patent Office may also be opened in all state capitals and district headquarters in India. Indian government may provide subsidy in the patent filing/examination fee to the Indian applicants to encourage patent filing by them (See Where to file the patent application? (2.4.4) in 2.4: Patent law in China).

6.3 Patentability of polymorphs/new forms
In the Novartis Glivec case, the supreme court of India provided meaning of the term “efficacy” as “therapeutic efficacy”. However, it has been argued that it is a very restrictive interpretation of the term “efficacy” (See Criticism of the Supreme Court’s decision (3.1.1.1) in the Chapter 3: Judicial Review). It is
therefore suggested that the meaning of the term “efficacy” may be defined in the Patents Act in a broader way to encompass other relevant aspects such as decreased toxicity or side effects; increased bio-availability; improved physicochemical properties or any other unexpected effect/property etc.

6.4 Compulsory licensing

Compulsory licensing is an effective mechanism to prevent the abuse of patent rights. TRIPS allows the member countries to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Through the comparative study, it was concluded that compulsory licensing provisions in India are fully TRIPS compliant. Only one compulsory license has been granted in India till date, and it was in full compliance with the existing international trade rules (See Compulsory licensing (3.2) in the Chapter 3: Judicial Review; and Compulsory licensing (4.7) in the Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China).

To further strengthen the compulsory licensing provisions in India, following measures are proposed:

(i) **Detailed guideline on compulsory licensing**: A detailed guideline on compulsory licensing may be issued by the Indian Patent Office. The guideline covering various aspects of the compulsory licensing would help in removing any ambiguities in the interpretation and implementation of the compulsory licensing provisions in India.

(ii) **An Act similar to Bayh-Dole Act in the U.S. may be enforced in India**: This Act aims to encourage innovation through protection and utilisation of intellectual property generated through government funding. This Act also authorizes the government to issue compulsory licenses on the patents.
acquired on inventions made through the government funding in certain circumstances.

(iii) Mandatory cross-licensing: Provisions relating to mandatory cross-licensing between the owners of patented biotechnology inventions and registered plant variety can be implemented in India under Patents Act or Protection of Plant Varieties and Farmers’ Rights Act, 2001. Such provisions aim to encourage innovation in the biotechnology sector.

(iv) Alternative mechanisms: Before making a decision of the grant of a compulsory license, the government may consider alternative mechanisms such as putting pressure on the patent holder to reduce price of the concerned product; regulating the drug prices through Drug Price Control; or direct government purchases of the patented drugs from the manufacturers at negotiated prices.

(v) Direct dialogue with the MNCs: Indian government should make more aggressive efforts to establish direct dialogue with the multinational companies and involve them in government’s healthcare mission as equal partners. This would encourage the companies to fulfil their corporate social responsibilities in a proactive manner and would also reduce the chances of patent abuse.

6.5 Patent opposition

Opposition system is an important tool for controlling poor quality patents. However, as patents have a limited term, a weak patent opposition system may lead to undue loss to the innovators due to delays in the patent grant. Concerns have been raised over the efficiency of patent opposition system in India. Further, statistical data collected during the present research work indicated that highest number of opposition cases have been filed against the pharmaceutical patents, therefore as compared to fields of technology, the pharmaceutical field is most affected by the opposition system in India. See Patent opposition (4.6) in the Chapter 4: Comparison of the Indian Patent Law
with the Patent Laws in U.S., Europe and China; and Question 6 in the Chapter 5: Empirical Aspects.

Following measures are proposed for strengthening the patent opposition system in India –

(i) **Adoption of ex-parte prior art submission system**: U.S., Europe and China follow ex-parte prior art submission process at the pre-grant stage. However, India is among a limited number of countries which still permit inter-partes pre-grant opposition. In order to avoid undue delays in patent grant, it is suggested that inter-partes pre-grant opposition be abolished in India and ex-parte prior art submission process may be adopted in its place. The ex-parte prior art submission is advantageous as it permits speedy prosecution of the patent applications, yet allowing third parties to bring the most relevant prior art to examiner's attention at an early stage of the prosecution.

(ii) **Fee for filing pre-grant opposition**: Presently, Indian patent office does not charge any fee from the person filing a pre-grant opposition. Since, in India the current pre-grant opposition is an inter-partes procedure involving hearings of the parties, an appropriate fee may be charged from the person filing pre-grant opposition for utilizing services of the patent office. Charging of fee will also put a check on the filing of frivolous or misleading oppositions.

(iii) **Estoppel provision**: Estoppel prevents the opponent from challenging validity of the same patent in any subsequent opposition proceedings on the ground(s) already raised by him in the previous proceeding. In India the same person is allowed to challenge a patent through both pre-grant and post-grant oppositions even on the same ground(s). This may lead to undue lengthening of the patent grant. Further, a particular patent can be targeted purposefully by the competitors, causing substantial loss of effective patent term to the patent owner. To avoid this, estoppel
provision may be incorporated in the Indian patent law at the pre-grant stage. At the post-grant stage the Supreme Court has already clarified that estoppel shall be created that would allow an interested person to pursue only the first initiated revocation proceeding. This provision of estoppel may now be explicitly incorporated in the Patents Act, 1970.

(iv) **Threshold requirement**: Threshold to institute the opposition proceeding puts a check on filing of frivolous or misleading oppositions. Threshold requirement to institute post-grant opposition is included in the U.S. patent law. Threshold requirement may also be laid down in the Indian patent law to fix threshold to institute both pre- and post-grant oppositions.

6.6 **Duty to disclose information regarding foreign applications**

Regulations in India in this context seem to be much more strict and difficult to comply with (See Duty to disclose information regarding foreign applications (4.5) in the Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China; and Question 13 in the Chapter 5: Empirical Aspects). Following suggestions are proposed with respect to the requirement of submitting information regarding corresponding foreign patent applications in India:

(i) **Clarification of meaning of the term “detailed particulars”**: Duty to disclose information regarding foreign applications is laid down under Section 8 of the Patents Act in India. The Section 8 mandates the patent applicants to submit “detailed particulars” related to the corresponding foreign application(s) at the Indian Patent Office. However, meaning of the term “detailed particulars” has not been provided under the Act, which makes this provision ambiguous and difficult to comply with. It is suggested here that the meaning of the term “detailed particulars” may be clarified under the patent guidelines in India. It could be defined as “copies of the priority search/examination reports of the corresponding foreign
application(s)” It would remove the ambiguity by limiting the submission of information to the search/ examination reports of the corresponding foreign application, as the same is required by the patent laws in Europe and China also. Search/ examination reports are the most crucial documents which help in bringing out the relevant prior art and throw light on the patentability of the claimed invention as judged by the corresponding foreign patent office.

(ii) **Penalty for failure to comply with the requirement:** In India failure to comply with the requirement of Section 8 is a ground of pre- and post-grant oppositions under Section 25 and patent revocation under Section 64 of the Patents Act. It is suggested that the ground of patent revocation in such cases may be limited in the situation of counter claim for infringement only.

6.7 Expedited patent examination

U.S., Europe and China provide various procedures to expedite the patent examination, whereas, no such option is currently available in India. The Draft Patent (Amendment) Rules, 2015 has proposed to add the provision for expedited patent examination in India. The proposed rules for expedited examination have however been criticized by various organizations viz. American Intellectual Property Law Association (AIPL), Sinapse and Intellectual Property Owners Association (IPO) on different grounds *(See Expedited patent examination (2.1.8) in the Chapter 2: Patent Laws in India, U.S., Europe and China)*. Following suggestions have been proposed to strengthen the proposed rules for expedited examination in India.

(a) Condition of manufacturing the invention in India may be replaced with the condition of commercializing the invention in India.
(b) The fees for natural persons/ small scale industries may be reduced.
(c) The fee may be split into two parts - the first part at the time of making the request, and the second part to carry out the expedited examination, if the application meets the requirements.

(d) Proof of necessary capital and facility may be required at the time of the patent grant.

(e) Due to limitation in the infrastructure facilities at the patent office, for conducting expedited examination priority can be given to applications related to some specific technologies such as drugs & pharmaceuticals, dairy & food, agriculture, green technology etc.

**Patent Prosecution Highway (PPH):** India is currently not a member of Patent Prosecution Highway (PPH) program (See Patent filing and prosecution (4.4) in the Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China). India may join the PPH program to which U.S., Europe and China are members. Joining PPH program can help in significantly accelerating the patent examination process, and improving the patent quality in the country. Through PPH program examination of the patent applications of even those applicants who do not opt for the expedited examination can be accelerated.

**6.8 Reporting of working of patents**

Indian Patents Act requires each patentee and licensee of the patent to submit information about the extent to which the patented invention has been worked on a commercial scale in India. Such information shall be submitted each year to the Controller of Patents, in Form-27 (copy enclosed at Annexure-3). Many defects were observed in the format of the Form-27 (See Reporting of working of patents in India (1.3.8) in 1.3: Review of literature; and Question 12 in the Chapter 5: Empirical Aspects). A new format of Form-27 (copy enclosed at Annexure-3) has also been proposed in the Draft Patent (Amendment) Rules, 2015.
Following corrections/ modifications are suggested to improve the Form 27:

(i) The form asks to mention the quantum and value (in Rs.) of the patented invention/ product. However, it is not clear how the value is to be calculated, as it may be calculated based on the manufacturing cost; ex-factory price; MRP of the product etc. To remove this ambiguity, it may be specified in the form to calculate the value of the product by multiplying quantity of the product with its MRP.

(ii) The form requires furnishing the “details of products commercialized by utilizing the patent”. Particulars of details to be submitted such as name/ brand of the product; name of the manufacturer; marketed by etc. may be specifically mentioned in the form.

(iii) The patentee/ licensee may be asked to mention the estimated demand and actual sale of the patented invention/ product in the current year. Based on this information, it could be ascertained that whether the requirement of the public with respect to the patented invention/ product have been satisfied. As non-working and not meeting requirement of the public with respect to the patented invention are the grounds of the grant of compulsory license. For pharmaceutical patents in addition to the above information, the patentee may be asked to furnish details of the pack size, recommended dosage and units of product sold in the Form-27. This information can be utilized to assess the percentage of patients are being served through the supply of the patented product.

6.9 Patent term restoration

Many countries including U.S. and Europe provide patent term restoration. This provision is currently not available in India (See Extension of patent term (4.9) in the Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China). It is suggested that India may also implement the patent term restoration provision for the pharmaceutical patents, to compensate any loss in the effective patent term due to delays in
the product approval by the drugs control agency i.e. Central Drugs Standard Control Organization (CDSCO), India (Question 5 in the Chapter 5: Empirical Aspects).

### 6.10 Patent linkage
Currently, Indian law does not have a patent linkage system. India may adopt a basic framework of patent linkage system as provided in China (See Patent linkage (2.4.12) in 2.4: Patent law in China; Patent linkage (4.10) in Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China; and Question 14 in the Chapter 5: Empirical Aspects). Under this system, the innovator drug company would submit a list of relevant patents to the drugs control agency (CDSCO in India), and the agency will publish such list on its website. A generic drug applicant will be required submit a letter to CDSCO stating that the generic drug will not infringe on the patent rights of the innovator company. The innovator company then would have the right to institute an infringement proceeding against the generic drug company in the court of law.

### 6.11 Specialized IP/patent courts
As in U.S., Europe and China, no specialized IP/patent courts have been set up in India yet. However, the newly created Commercial Courts in India are entrusted to handle IP disputes worth > Rs 1 crores.

Following measures are proposed in this context (See Specialized IP/patent courts (2.4.13) in 2.4: Patent law in China; and Question 10 in the Chapter 5: Empirical Aspects):
(i) Since the judges who have experience to handle commercial disputes in other sectors like banking or insurance may not be fully equipped to handle the IP/patent cases, judges of the Commercial Courts may be
imparted adequate training to handle the disputes related with IP/patents.\(^{243}\)

(ii) Technology investigators may be appointed in the Commercial Courts to assist the judges in the cases involving complex technologies such as pharmaceutical or biotechnology.

(iii) Separate patent benches may be designated at the Commercial Courts.

(iv) To strengthen IP enforcement mechanism, modern techniques such as electronic case management system may be adopted in the Indian courts.

(v) The Commercial Courts will deal with the IP disputes worth > Rs 1 crores only, and the cases worth below Rs 1 crores shall be continued to be dealt in the district courts where judges may having no specialization to deal with the IP/patent cases. Further, looking at the growing number of IP/patent disputes in the country, need still exists to establish separate courts which are specialized in the area of IP/patents. Therefore, in order to further strengthening the IP enforcement mechanism in the country, government of India may consider establishing specialized IP/patent courts in future.

**6.12 Regulations for service/ employee inventions**

Currently, there are no regulations/ guidelines prescribed under the Indian law to protect the interest of the employees who accomplish an invention (service invention) during the course of their employment. Regulations for service/employee inventions are prescribed under EPC and Chinese patent law. (See Regulations for service/ employee inventions (4.11) in the Chapter 4: Comparison of the Indian Patent Law with the Patent Laws in U.S., Europe and China). Pertinent rules/ guidelines on service invention may also be issued in India. It would aid in strengthening the environment for innovation and fostering technological development in India.
6.13 Utility model patent

As recommended in the draft of the “National IPR Policy” released by the Government of India, the Indian Patents Act may be amended to include the provisions related to the utility model patents (*See* Question 7 in the Chapter 5: Empirical Aspects).