

Exceptions and Limitation of Patent Rights and its Enforcement in India

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A Patent holder enjoys a bundle of exclusive rights given as an incentive for the investment in innovative activities and for the dissemination of knowledge to public. However, these rights are not perpetual and can be revoked in exceptional circumstances to balance the interests of the patent holders with those of others; there are various exceptions and limitations to these rights. Such exceptions are experimental or research use; use on foreign vessels; obtaining regulatory approval from authorities; exhaustion of patent rights and parallel imports; compulsory licensing and use or acquisition of inventions by government. Even though there are exceptions and limitations, yet the term to hold a patent remained unaltered. The current paper attempts to consolidate all the exceptions and evaluate the effects of these exceptions on the monopoly rights of a patent holder.

Keywords: Patent right exceptions, compulsory licensing, principle of exhaustion, implied licenses, parallel importation, research exceptions, foreign vessels, regulatory approval, government use, patent limitations

Exceptions to patents concept draw its root from an old concept,¹ which would render a patent void on the ground that it is prejudicial or inconvenient to King's subjects and a ground to revoke the patent if the patentee neglected to work the patent.² The TRIPS Agreement is focused on global standards for protecting and enforcing intellectual property rights, is to date the most exhaustive multilateral agreement on intellectual property and its trade.³ Many significant changes have taken place for instance post TRIPS, as earlier over 40 countries in the world did not grant patent protection for pharmaceutical products.⁴ But once they become the member of TRIPS, to comply with the provisions the countries have to make changes in their respective legislations.

The basic purpose of TRIPS is to introduce the protection of intellectual property in trade and granting of exclusive patent rights⁵ as an incentive for investment in production of knowledge.⁶ However, allowing the enforcement of the full scope of the exclusive rights in all circumstances may not always meet the ultimate goal of the patent system to enhance the public welfare. Therefore, in order to maintain the correct balance between the interests of the patent holders, third parties and the public, the exclusive rights for patents may be set to certain exceptions and limitations to patent rights.⁷

Since the socio-economic conditions and priorities of a country differ from one country to another, hence provisions in patent laws on exceptions and limitations vary as well. As India is a signatory to TRIPS, the Patent Act, 1970 has been amended from time to time to include the limitations and exceptions as per the norms of the agreement. Some of the following exceptions and limitations to the patent rights provided in the Act are: (i) experimental or research use; (ii) use of patented invention on foreign vessels etc.; (iii) for obtaining regulatory approval from authorities; (iv) exhaustion of patent rights & parallel imports; (v) compulsory licensing and (vi) use or acquisition of inventions by government. These exceptions and limitations will be discussed one by one.

Compulsory Licenses

In India, the provisions of compulsory licensing were introduced into the Patents Act pursuant to the recommendation made by the Ayangar Committee, considering the fact that the abuse of patent rights, which had become the matter of concern.⁸ Compulsory licensing is governed by Sections 82 to Section 94 of the Act. The predominant purpose for this exception is to ensure the supply of patented invention in the Indian market. Compulsory licenses can be granted to the patented invention for redressing all the situations such as, non-working or insufficient

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working; not available to the public at a reasonably affordable price; non satisfaction of reasonable requirement of the public;⁹ public health; national emergency or extreme urgency; public non-commercial use;¹⁰ export a patented medicine to a country having no-manufacturing capacity or inadequate manufacturing capacity;¹¹ refusal to grant licenses on reasonable terms; anti-competitive practice and dependent patents.¹²

The public policy objectives behind the grant of compulsory licensing are stipulated under Section 83 of the Act.¹³ The grounds of “nonworking” or “insufficient working” for the grant of compulsory licenses are not defined in the Act, hence there is an ambiguity in interpreting these terms. Whether this can be interpreted as “product must be manufactured in the territory of India”, or it can be considered as “making available for local sale as in import” needs clarity. The importation of a patented product or a product manufactured by a patented process constitute “working” of the patent is presently sub judice before the court. Every patent holder within a stipulated time needs to show the working of its patent in commercial terms otherwise the patent shall be licensed or revoked. The grant of compulsory licenses on the grounds of non-working or insufficient working, shall be refused if the patentee justifies his inaction by legitimate reasons as in the provisions as stipulated in the Section 86 of the Indian Patents Act.¹⁴

The grant of compulsory licenses on the grounds of non-working or insufficient working is provided at any time after the expiration of 3 years from the date of grant of the patent before a compulsory license can be requested. Law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”.¹⁵ According to this provision the reasonable period shall be construed as a period not ordinarily exceeding a period of 6 months.¹⁶ No explanation is being provided for the term “reasonable terms” and conditions.

The law provides for the grant of compulsory licenses on the ground of anti-competitive practices.¹⁷ However, unlike other exceptions, as per the Competition Act, this excludes jurisdiction of civil courts,¹⁸ as no civil court shall have jurisdiction to entertain any suit or proceeding in respect of any matter which the commission or the Appellate Tribunal is empowered to determine and no injunction

shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under this Act. It may therefore be noted that all issues relating to anti-competitive practices fall within the exclusive jurisdiction of the Competition Commission of India.

When the license is granted under a patent and the license cannot be worked without some other patent held by same patentee the Controller by order can grant license with respect to the said other patents held by the same patentee.¹⁹ The law provides a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee. There is a general policy provided in the Indian Patents Act with respect to the remuneration to be paid by the beneficiary of the compulsory license to the patentee.²⁰ TRIPS requires countries utilizing compulsory license, need to pay “adequate remuneration”, However it does not specify about calculating the same, which leads to ambiguity, and ambiguity always invites future disputes.²¹ If remuneration does not suffice high cost investment in prolonged period of R&D activities, it will be a serious disincentive in the path of innovation and development.

The law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”.²² Consent of the patent holder is not a necessary requirement for granting compulsory license. Countries are free to determine the grounds for granting compulsory licenses, yet it lists a number of conditions for issuing compulsory license.²³ Voluntary license is a basic ingredient for compulsory license, but at time of “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial use” (or “government use”) or anti-competitive practices, there is no need to negotiate for a voluntary license. The purpose is to say that the first step of negotiating a voluntary license can be by passed in order to save time. But the patent owner still has to be paid.

Under the Patents Act, 1970, there has been only one compulsory license matter which has been dealt successfully which pertains to an anti-cancer medicine. India issued its first compulsory license, by allowing Natco Pharma to sell the Bayer’s patented drug for kidney liver cancer. In *Natco Pharma Limited v Bayer Corporation*, an application filed before the Controller of Patents of Mumbai relating to grant of compulsory license under Section 84(1) of

the Act for a patented drug.²⁴ The compulsory license was granted to Natco on all three grounds of Section 84(1) including reasonable requirement of public not being met, non availability of drug on affordable prices, and non-working of the invention in the territory of India. The same was challenged in the High Court of Bombay, wherein the Hon'ble Court refused to interfere with the IPAB Order.²⁵ Bayer appealed before Supreme Court, wherein Hon'ble Court refused to entertain Bayer's appeal to set aside the compulsory license on Sorafenib (*Nexavar*).²⁶

Compulsory licensing allows countries to produce patented innovations without the consent of the patent holders. While some argue that compulsory license will weaken the economic incentives to invest to produce innovation as the innovations of others are cheaply available after paying a low licensing fee, others argue that there is no decline in innovation by patent owner companies affected by compulsory licence. Moreover, the experience with producing innovations of others could encourage the learning-by-doing.

Exhaustion of Patent Rights and Parallel Importation

Exhaustion refers to one of the limits of patent rights. It is an unrestricted sale of a patented item exhausts the patentee's control over that particular item. The flow of goods and services across borders is significantly affected by the exhaustion doctrine. Doctrine of exhaustion addresses the point at which the patent holder's control over the good or service ceases. Once a product protected by patent rights is marketed either by the patent holder or by others with his consent, the patent rights of commercial exploitation over this given product can no longer be exercised by patent holder, as they are exhausted.²⁷

A parallel importation is an import of non-counterfeit branded goods without permission of the brand owner. Parallel import takes place when a branded good sold by the brand owner in a foreign country is exported by a buyer to another country wherein the same brand, duly registered, is held by a person other than the importer.²⁸ A parallel import is an import of non-counterfeit branded goods without permission of the brand owner. Genuine goods are produced and protected by patent are circulated in one market, and then imported into a second market without the authorization of the local owner of the intellectual property rights. It is considered to be most disadvantageous for IP holders as, this lowers the

profit because of unrest authorized marketing networks. This directly affects incentives to make new innovations in the future, because lowering profits results in lower investment in R&D and therefore lower output from R&D.

Under TRIPS, Article 6 in view of Article 3 & 4 pertains to principle of exhaustion and parallel imports.²⁹ Application of the TRIPS national treatment provision to exhaustion doctrine suggests that members must treat foreign nationals on at least equivalent basis as local nationals regarding protection of IPRs by exhaustion rules.

In absence of exhaustion doctrine, the original IPR holder would perpetually exercise control over the sale, transfer or use of a good or service embodying an IPR, and would control economic life.³⁰ There are three types of exhaustion which a country recognizes. If a country recognizes a doctrine of "national" exhaustion, an IPR holder's right to control movement of a good or service is only extinguished by the first sale or marketing of a good or service within the territory of that country. In this movement of goods and services may be blocked by IPR holders to segregate markets. If a country recognizes doctrine of "international exhaustion", an IPR holder's right to control movement is extinguished when a good or service is first sold or marketed anywhere in the world. In this goods and services flow freely across borders after they have been first sold or placed on the market under certain conditions anywhere in the world. If a country recognizes a doctrine of "regional" exhaustion, an IPR holder's right to control movement is extinguished when a good or service is first sold or marketed in any country of the region e.g. EEA (European Economic Area).³¹

International exhaustion and parallel importation is explicitly mentioned in the Act.³² If a patented product is offered for sale in another country at a lower price by the patent holder or with the patent holder's consent, the patent holder here cannot legally stop its imports by others. A person in India may import patented products which he has purchased from any person authorized under the law, evidently of the exporting country, to sell such products. Therefore, the present provision is in full consonance with its objective making available patented products at minimum international market price.

In compliance with TRIPS, Government of India has notified in terms of Rules,³³ import of goods infringing IP right without the consent of right holder

is prohibited.³⁴ Under these rules, brand owner is required to give a notice, to the customs requesting for suspension of clearance of goods suspected to be infringing IP right, which will be registered. On registration import of all goods suspected to infringe the IP rights will be suspended and proceedings for confiscation of goods will be initiated.³⁵ The brand owner also has to bear the costs towards destruction, demurrage and detention charges incurred till the time of destruction or disposal, as the case may be. The Rules does not apply to personal baggage or small consignments intended for personal use. These provisions enable the brand owner to combat menace of parallel import in a cost effective, hassle free and timely manner. In highly competitive market where reputation of the brand decides existence of a product and the company, it is a golden opportunity to the brand owners to protect reputation of the brand and restrict damages from the parallel import.

Until recently, import of goods infringing IP rights was not prohibited or restricted either under The Customs Act, 1962 or the Foreign Trade Policy ('FTP') issued under The Foreign Trade (Development and Regulation) Act, 1992 which governs trans-border movement of goods in India, import of goods infringing IP rights was not prohibited or restricted. However, import of spurious goods is prohibited.³⁶ The policy objective is to allow importation of patented products in the country from such markets where the product has been placed in duly authorized manner. One of the important facets of parallel imports and exhaustion of patent rights is that, it does not permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country. It also facilitates import of patented goods from markets where the price is low. These also help in regulating the price of goods through market mechanism, i.e. the owner of patent forced to fix the price so as to make third party importation less attractive, which in term improves the access to goods at affordable cost.

Exhaustion of patent rights and parallel importation are economic disaster to patentees, as the products could be legally imported from wherever the respective products were produced by the patentee or with his consent, regardless of whether there was a patent or not. So in order to obtain a reward upon first sale under a patent right, the patentee would thereby

be required to apply for patents in all countries with possible future production facilities or marketing plants. Banning parallel importation would of course be the patentee's first choice. But not only would this contravene the spirit of free trade that has been advocated so vociferously in the last decade and manifested in a number of global and regional treaties, it would also have many undesirable economic side effects.³⁷

Experimental or Research Use

Research exemption permits use of a patented invention for experimental purposes without infringing the rights of the holder.³⁸ The objective is to promote research and development in the country as well as to ensure that patent rights must not impede or hinder higher education and research. The exception as provided is for the purposes of experiment or research which includes imparting instructions to pupils. There is no limitation to the scope and extent of research and experimentation.

According to the Act, there is no distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity).³⁹ The interpretation of "experimental use" or "scientific research" is exceptionally broad and is very general and there is not much clarity in this context.⁴⁰ The issue to be addressed is what is "purely scientific" because definition is purely subjective, and which might be considered as scientific for one point of time might not be considered as scientific later.

The law also makes no distinction between "commercial" and "non-commercial" purpose for conducting research. What if experiments on a patented invention give rise to altogether a new product, as in this case research goes beyond "purely experimental" connotation.

Use of Inventions for purposes of Government and Acquisition of Inventions by Central Government

Chapter XVII of the Indian Patents Act is related to the use of inventions for the purpose of Government and acquisition of inventions by Central Government.⁴¹ Section 99 defines what constitutes "use of an invention for the purposes of government" according to which, an invention is said to be used for the purposes of government if it is made, used, exercised or sold for the purposes of the Central Government, State Government or a Government undertaking.⁴²

In this connection please note that under the powers of Central Government,⁴³ to use inventions for the purposes of Government use between the date of filing an application for patent and any time during the patent in force, if the Government decided to use the said invention either by the Government or by any person authorized by the Government to do so then the royalty to be paid to the patentee is not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent. This also provides that the Government, or any person authorized by it, is empowered to use the patented invention 'for purposes of Government'. It stipulates that in case of Central Government use of an invention the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent. However, any dispute on the amount paid can be referred to the High Court.⁴⁴ Section 101 provides for the rights of third parties in respect of use of invention for purposes of Government. Section 102 provides for acquisition of inventions and patents by the Central Government and Section 103 provides for reference to High Court of disputes as to use for purposes of Government.

There are no limitations with respect to the use by Government. The public policy objectives for providing government use in your country are to enable the Government to use any invention whenever it is so required. The law provides for the grant of government use on the ground of "national emergency" or "circumstances of extreme urgency", however these phrases are not defined in the Act.

In *Chemtura Corporation v Union of India & Ors.*⁴⁵, wherein the suit was filed before the Hon'ble High Court of Delhi relating to use by or on behalf of the Government for the purpose merely of its own use. The patent in this matter was relating to a side bearing pad assembly for absorbing and cushioning compression forces. The High Court was of the view that the Ministry of Railways qualified as 'Government', and therefore could freely use the patented invention without the risk of infringement. However, the suit was subsequently dismissed as withdrawn on 23 October 2013.

Use of Patented Invention on Foreign Vessels

The Patents Act, 1970, provides that patent rights are not infringed when used on foreign vessels, etc.,

temporarily or accidentally in India.⁴⁶ This exception is allowed to enable the entry of the foreign vessels, aircrafts and land-vehicles in the Indian territory so that patent rights do not inhibit movements of such transports.⁴⁷ The exception applies in relation to vessels; aircrafts and land vehicles. Where there is no reciprocity, then use of invention on foreign vessels shall be treated as infringement. The words "temporarily" or "accidentally" in relation to the entry of foreign transportation means into the national territory only are used in the statute. No definitions for the said words are provided in the Act.

Acts for Obtaining Regulatory Approval from Authorities

Exception for obtaining regulatory approval is embedded in Section 107A(a).⁴⁸ Act of making; constructing; using; selling; or importing a patented invention are allowed in acts for obtaining regulatory approval from authorities. The policy objective is that the manufacturing of such products should not be delayed due to time taken for obtaining marketing approval and to enable the submission of reports to a regulatory authority.

Anticipation Due to Prior Use

Prior secret trial or secret use by third parties is not considered for the purposes of anticipation or obviousness under Sections 25(5) and Sections 64 of the Act in proceedings for revocations. Similarly prior use by the patentee or applicant for patent, or any person with or without his consent shall not be deemed to be falling within anticipation subject to certain conditions. Chapter VI of the Act provides such exceptions and some of the relevant provisions are:

Anticipation by previous publication,⁴⁸ which states that the invention will not be deemed to be covered under the provision, if the publication was published before the priority date and also if the matter was published without the consent or knowledge of the rightful owner. It should be also ensured that, immediate steps should be taken to ensure the application for the invention after getting knowledge of such publication. Anticipation by previous communication to Government,⁴⁹ which states that if an invention would not attract the provision, if details are provided to the Government or to any person authorized by the Government to perform any required tasks.

Anticipation by public display,⁵⁰ which states that, an invention would not attract the provision if the invention has been displayed in an exhibition to which the provisions of the instant Section has been extended by the Central Government or the invention is described in a publication in consequence of display of the invention in such an exhibition; or the invention has been used by any person without the consent of the true and first inventor or a person deriving title from him after it has been displayed in such an exhibition; or disclosing the invention before a learned society or publishing the invention in the transaction of such society; provided the application is filed within 12 months from a fore-mentioned public display. Anticipation by public working⁵¹ which states that the invention will not be deemed to be covered under the provision, if the invention has been filed within 12 months after the invention has been publicly worked for the purpose of reasonable trial considering the nature of the invention.

The public policy objectives are (a) to provide a reasonable grace period to the applicant from his disclosure or reasonable trial etc. to the date of filing (b) to provide immunity to the applicant from the unlawful disclosure by a third party (c) to provide immunity to the applicant when he discloses his inventions to the Government and (d) power of the central government in case prior use.

Other Exceptions and Limitations

Apart from the exceptions as discussed above, there are additional exceptions which are worth mentioning. Revocation of patent can be done by the Central Government in the public interest if the patent or the mode in which it is used is found to be mischievous to the state and also revocation of patent or amendment of complete specification can be made on directions from Government in cases relating to atomic energy.⁵² Central Government also has wide power to revoke a patent in the interest of security of India.⁵³

There are other mechanisms for the limitation of patent rights external to the patent system exist in India,⁵⁴ which enumerates the anti-competitive agreements, however, it also states that nothing restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under the Patents Act. The public policy objectives for these

exceptions are that the holders of the respective IPRs shall enjoy their rights as long as the conditions imposed by them are not unreasonable and are detrimental to competition.

In addition to the anti-competitive practices as said in the context of the compulsory licensing, the following Sections need special mentions as they deal with anti-competitive practices. The Patents Act seeks to ensure that the patentee is not able to widen the scope of the statutory monopoly by incorporating restrictive conditions in contracts relating to the use of his patent by way of sale, lease or license. The Act does it by declaring certain conditions as restrictive and prohibiting their incorporation in contracts relating to sale or lease of patented articles and licenses to use a patent.⁵⁵

Other Exceptions (World)

Extemporaneous preparation of medicines-this is one of the limitations which are not in India. Many countries have this exception as well in their patent laws. Many countries have added to their legislation an exception with regard to the manual preparation of medical products or drugs according to an individual medical prescription by pharmacists or doctors. Many member states whose laws provided for such exception⁵⁶ specified that the “extemporaneous” preparation of a medicine in a pharmacy according to a medical prescription is excluded from the scope of the rights conferred by a patent.⁵⁷ The applicable laws of many of those member states state that such preparation should also be for “individual cases”. In addition, the “acts”, “actions”, “treatment” or “procedures” relating to the medicine so prepared are also considered to be within the scope of the exception in many member states.⁵⁸

Conclusion

There are many exceptions to patentee's rights, however these exceptions are limited to only specific situations and are not exhaustive, the motive to inculcate these exceptions is to mend a balance between the rights of the inventor and the user so as an undue monopoly is not created in the market. However an undue implementation of these exceptions may hamper the very objective of granting a patent hence should be exceptionally and judiciously used. If we see from an inventor's point of view, it seems a bit unjust to limit the number of years of the monopoly but adding various exceptions as and

when needed. However a check over the usage of these exceptions is needed so as to ensure its proper working. The exceptions are not age old and a recently added therefore neither a proper and universally accepted definition is present nor the courts have had the situations to analyze it to the core. However these exceptions have proved to be bliss for the developing countries, also developing countries have adopted a very liberal approach to these exceptions so as to promote research and technology in their countries unlike the developed countries that follow a very narrow interpretation.

References

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- 2 Wyndham H, *On the Consideration of Patent Grant, Past and Present*, 13 LQR 313 p. 316.
- 3 *Overview: The TRIPS Agreement*, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed on 14 April 2015).
- 4 *WHO and The Trips Agreement*, http://www.who.int/medicines/areas/policy/wto_trips/en/ (accessed on 14 April 2015).
- 5 Article 28 of the TRIPS Agreement establishes basic rights of the patent holder, which is to preclude others without consent from the acts of making, using, selling, offering for sale or importing the patented product, or using the patented process (including importing products made with the process).
- 6 *Report on the International Patent System*, WIPO, Geneva, Standing Committee on the Law of Patents, Twelfth Session, June, 2008.
- 7 Article 30 of TRIPS allows Members to provide for limited exceptions to the exclusive rights conferred by a patent, that is, to define acts that would not be deemed as infringing when made without the authorization of the patent owner. Such exceptions may include, for instance, acts of experimentation and the request for marketing approval of a pharmaceutical product before the expiration of the patent (known as the “*Bolar Exception*”).
- 8 Justice N Rajagopala Ayyangar, ‘*Report on the Revisions of the Patent Laws*’, September 1959, para 125-167.
- 9 Section 84 of the Patents Act, 1970. This exception is available only if the reasonable requirement of the public is not met or patented invention is not available to the public at a reasonably affordable price or the patented invention is not worked in India.
- 10 Section 92 of the Patents Act, 1970. This exception is available only In circumstances of national emergency, circumstances of extreme urgency or in case of public non-commercial use at any time after the grant of the patent, upon satisfaction of the Central Government. However, if a circumstance of national emergency or extreme urgency or in a case of public non-commercial use arise due to the epidemics like HIV/AIDS, TB, malaria or other such epidemics, the compulsory license can be granted any time after the grant of the patent pursuant to the notification by the Central Government.
- 11 Section 92(A) of the Patents Act, 1970. Pursuant to DOHA declaration on TRIPS and Public Health, the provision has been incorporated in the Indian Patents Act to grant a compulsory license for manufacture and export of patented pharmaceutical products to the countries with no-manufacturing capacity or insufficient manufacturing capacity in the pharmaceutical sector to address the public health problems.
- 12 Section 91 of the Patents Act, 1970. Any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply on the ground that he is prevented or hindered without such license from working the other invention efficiently or to the best advantage possible.
- 13 Section 83 (a) states that the patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. Further, Section 83 (b) clearly states that the patents are not granted merely to enable the patentees or patent licensees to enjoy the monopoly for importation of the patented article. Section 83 (c) and Section 83 (f) also talk about promotion of technology innovation, technology transfer and prevention of abuse of patent rights to unreasonably restrain international transfer of technology.
- 14 Section 86 of The Patents Act, 1970. This provides that the Controller may adjourn hearing of applications on this ground by up to 12 months if he is satisfied that adequate time was not available to the patentee to work the patent in the territory of India.
- 15 Definition for reasonable period is provided under explanation of Clause (iv) of Sub-Section 6 of Section 84 of the Indian Patents Act.
- 16 Section 84 (6) of the Patents Act, 1970. “Reasonable period” shall be construed as a period not ordinarily exceeding a period of six months.
- 17 The anti-competitive practices relating to patents may lead to the grant of compulsory licenses provided in Section 84 (6) of the Patents Act, 1970.
- 18 Section 61 of the Competition Act, 2002.
- 19 Section 88 (3) of The Patents Act, 1970, Where two or more patents are held by the same patentee and an applicant for a compulsory license establishes that the reasonable requirements of the public have not been satisfied that the applicant cannot efficiently or satisfactorily work the license granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a license in respect of the other patents also to enable the license to work the patent or patents in regard to which a license is granted under Section 84.
- 20 Section 90 (1) (i) of the Patent Act, 1970. Controller shall try to secure that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors while granting compulsory licenses.
- 21 Mercurio B C, TRIPS, patents, and access to life saving drugs in the developing world, *Marquette Intellectual property Law Review*, 8 (2) (2004) 211, 242, 243.

- 22 However, sub-Section 3 of Section 92 of the Act describes certain situations of exigency under which Compulsory Licensing can be applied in a quicker manner bypassing the detailed procedure of notifying the patentee or inviting oppositions as provided under Section 87 of the Act.
- 23 Article 31 of TRIPS. It specifically allows compulsory licensing, albeit under a different title; 'other use without authorization of the right holder.' This article sets down several conditions on a case-to-case basis, regarding when national authorities can permit a person other than the patent holder to make available the patented product, including 'the right holder shall be paid adequate remuneration' and that 'such use shall be authorized predominantly for the supply of the domestic market'.
- 24 *Natco v Bayer*, Compulsory license Application 1 of 2011 before Controller of Patents.
- 25 Writ Petition No.1323 of 2013, Bombay High Court.
- 26 SLP 30145 of 2014, Supreme Court of India.
- 27 Christopher H, *Parallel Imports and International Trade*, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich, Rep. Annual Meeting of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP), July 1999.
- 28 Agrawal D K, Combating Parallel Import, http://www.taxindiaonline.com/RC2/print_story.php?newsid=6084 (accessed on 2 March 2015).
- 29 Dispute Resolution and Parallel Importation (International Exhaustion of Intellectual Property Rights): For purposes of dispute settlement under this Agreement (other than regarding national treatment and most favored nation obligations), nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.
- 30 Singh R, *Exhaustion Under TRIPS and Parallel Importation: Challenges and Opportunities*, L.L.M Project, National Law University, Jodhpur, Rajasthan, 2012.
- 31 *Exhaustion of Rights*, in Resource Book on TRIPS and Development, New York, Cambridge University Press, 2005, Chapter 5, Section 1 & 2, 94 - 96.
- 32 Section 107A (b) of The Patents Act, 1970. Certain acts not to be considered as infringement. For the purposes of this Act, (b) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.
- 33 Intellectual Property Rights (Imported Goods) Enforcement Rules 2007 *vide* Notification Number 47/2007-Cus. (N.T.) dated 8 May 2007.
- 34 Section 11 of the Customs Act 1962.
- 35 Section 111(d) of the Customs Act 1962.
- 36 Notification No. 1/Cus. (N.T.) dated 18 January 1964 issued under Section 11 of the Customs Act.
- 37 http://www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf.
- 38 Section 47(3) of the Patents Act, 1970 provides exemption to experimental use and/or scientific research. Any machine or apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.
- 39 Patent Office of India, http://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/india_2.pdf (accessed on 12 April 2015).
- 40 Basheer S and Reddy P, The 'experimental use' exception through a developmental lens, *IDEA: The IP Law Review*, 50 (4) 2010, SSRN: <http://ssrn.com/abstract=2216850>.
- 41 It comprises 5 Sections starting from 99 and ending with 103.
- 42 Sub-Section 2 of Section 99 states that no provision of chapter XVII would be applicable to any act which falls under the conditions specified under Section 47 of the Patents Act.
- 43 Section 100 of the Indian Patents Act.
- 44 Section 100 (3) of the Indian Patents Act.
- 45 CS(OS) No. 930 of 2009.
- 46 Section 49 of the Patents Act, 1970: Patent rights not infringed when used on foreign vessels etc., temporarily or accidentally in India.
- 47 Section 107A (a) of the Patent Act, 1970: Certain acts not to be considered as infringement.
- 48 Section 29 of the Patents Act 1970.
- 49 Section 30 of the Patents Act 1970.
- 50 Section 31 of the Patents Act 1970.
- 51 Section 32 of the Patents Act 1970.
- 52 Section 64 & 65 of the Patents Act.
- 53 Section 157A of the Patents Act
- 54 Section 3 (5) of the Competition Act, 2002.
- 55 Section 140 of the Act - Avoidance of certain restrictive conditions.
- 56 38 Member States and one regional patent office provide a specific statutory provision on this matter. However, in Vietnam, while there was no specific provision regulating the act of preparation of medicines in pharmacy, such act was considered to fall under the exception on non-commercial use. Similarly, while the response from Indonesia indicated that the applicable law did not provide for such an exception, it referred to a government use exception for public health reasons. In China, medical prescriptions and preparation of medicines based on those prescriptions were not considered as being industrially applicable, and therefore not patentable. In addition, the response from the United Republic of Tanzania referred to the methods for treatment which were excluded from the patentable subject matters.
- 57 Article 38 of Law No. 9947 on Industrial Property of Albania; Section 27(3)(iv) of the Patent Law of Cyprus; Article L613-5 of the French Intellectual Property Code; Section 11 no. 3 of the Patent Act of Germany; Section 75(c) of 514 Patents Ordinance of Hong Kong, China; Article 55 of Law No. 17-97 on the Protection of Industrial Property of Morocco; Article 69 (1) (v) Industrial Property Law of Poland; Article 22 of the Law 50/2008 on the Protection of Inventions of the Republic of Moldova; Article 52.1(c) of the Law on Patents of Spain; Section 60(5)(c) of the Patents Act of the United Kingdom; Rule 19 of Patent Regulations under the Eurasian Patent Convention.
- 58 Article 73 of the Patent Law of Bosnia and Herzegovina; Article 63(3) of the Patent Act of Croatia; Section 18(c) of the Patent Act of the Czech Republic; Section 3(3)5 of the Patents Act of Finland; Article L613-5 of the French Intellectual Property Code; Section 11(3) of the Patent Act of Germany; and Article 19 of Act XXXIII of 1995 on the Protection of Inventions by Patents of Hungary.