Local Working of Patents - Law and Implementation in India

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Inventive activity is supposed to result in innovation, which further leads to technological advancement, industrial development and economic welfare. This is possible through local working of inventions. When it comes to patented pharmaceutical drugs, local working requirement becomes more crucial for it is concerned with health issues. Historically, patents in England have been granted with an intention to encourage local application of the invention through industrial establishment. In recent years, particularly after TRIPS, tremendous growth in patent activity has been seen. Local working of patents has been the most efficient way of transfer of technology which itself is one of the primary objectives of the patent system. However, it is noticed that these patents are not necessarily worked locally. This paper aims to examine the legal framework of local working requirement, its implementation and feasibility in India. This paper argues that, though there are favourable conditions for investment, patents are not worked in India on a commercial scale. The present trend of non-working of patents in India indicates that patenting is attractive merely due to the high economic gains from the large Indian market, and patented products are often imported with no actual transfer of technology. It also shows that the present patent system has deviated from its ultimate objective of socio-economic welfare.

Keywords: Local working requirement, innovation, working patented inventions, compulsory licence, patent

In the early days, patent privileges were issued to ensure the application of inventions in local industries and to establish new industries. Patent monopoly was used as a public tool to fulfil the government’s social, economic and political objectives, such as increasing foreign trade, introducing new technologies, developing new industries and maximizing employment. In England, introduction of a new industry and local working were the primary requirements of the royal grant. The ultimate objective of the English monopoly privileges was to create a self-sufficient economy by importing new industries and technology from other nations. This royal policy of granting special privileges worked as a catalyst in the development of the state. The policy of encouraging the industrial growth through the grant of monopoly rights was also present in the 1624 Statute of Monopolies. In the later period, the patent system underwent a sea change and many aspects of the original patent system, which had a tremendous impact on development of industry, appeared to be missing or were ineffective in the modern patent system. The enormous technological growth and change in international trade policy resulted in the formulation of TRIPS Agreement, which mandated member states to change their domestic laws accordingly. During the pre-TRIPS period, patents were exclusively governed by national jurisdiction, subject to local laws framed according to the local needs and national developmental goals. There were differences among the nations in the levels of protection and fields of technology covered by patent, owing to divergent goals, values, history, culture, tradition and political climate of each country. These differences caused problems for the developed countries in patenting of inventions in foreign countries. Therefore, TRIPS came into existence. TRIPS mandate provided for certain minimum levels of IP protection to be met by the member countries.

India as a signatory to the TRIPS, complied with the requirements under it, by amending the Patent Act, 1970, from time to time. The new Patent Act has spurred tremendous growth in patenting activity. However, this patenting growth could give rise to transfer of technology and ultimately socio-economic welfare, only if the patents are worked locally on a

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commercial scale. Local working of patents is possible only when there is adequate infrastructure and a favourable environment for industrial investment. This paper aims at examining the legal framework of local working of patents, its implementation and the feasibility of working patents locally in India.

**Importance of Local Working Requirement**

Manufacture of the patented product or application of the patented process in a local industry is generally called as ‘local working of patent’. It is claimed that the local production of patented inventions would decrease transport costs, cut dependence on foreign suppliers, provide local jobs, increase expertise, cause transfer of technology and lead to innovation. It is also affirmed that it will help the nations achieve economic autonomy and sustainable development.\(^5\) Local working may be achieved by direct investment, joint venture or by issue of exclusive or non-exclusive licences. In the words of Michael Halewood:

‘Local working refers to the condition some countries impose on patentees that their patented product or process must be used or produced in the patent granting country. This condition has the effect of forcing foreign patentees to situate production facilities within the patent granting country. Such transfers of technology are desirable from the patent granting country’s point of view because they contribute to a variety of public policy goals such as employment creation, industrial and technological capacity building, national balance of payments, and economic independence.’\(^6\)

In the contemporary era, technology is among the most important determinants of economic development and its transfer and dissemination is essential for developing countries. Technology transfer is the process of sharing of skills, knowledge, technologies, methods of manufacture, samples of manufacture and facilities between governments and other institutions. It ensures that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology for new products, inventions, processes, applications, materials or services (Articles 7 & 8 of TRIPS). New technologies improve standard of living, create new jobs and facilitate change in the fabric of economy. Economic growth is largely based on advancement in technology and increase in job-oriented expertise. The success of businesses mostly depends upon the capacity of renewal and innovation. Technological and economic development worldwide leans heavily on new and competitive products and promotes general welfare. In most of the industries, intellectual property rights, especially patents, and their exploitation in the local industries, play a key role in the development and commercialization of new products. Patents are of vital importance to facilitate the transfer of technology, directly by stimulating the introduction of foreign technology and indirectly by making available the technological information through patent documents. ‘The principal way in which patents may contribute directly to the transfer of technology to developing countries is through the exploitation of the patented technology in the patent granting country by the foreign patent holder himself or with his consent by third parties. The former mainly takes place in the form of FDI (foreign direct investment) or joint ventures, while the latter chiefly occurs through a licensing arrangement.’\(^7\) Thus, local working has an unequivocal role in transfer of technology and socio-economic welfare of the state, which itself is the ultimate objective of the patent privilege.

**History of Patents and Local Working**

During the middle ages, patent letters were issued by the Crown to encourage tradesmen and industrialists to migrate to England to reinforce the realm’s lagging industrial development and industrial attainments.\(^8\) The Venetian statute, framed in 1337 for the protection of the new industry, was also aimed at industrial development.\(^9\) The first monopoly privilege, granted by the Crown to a foreigner Henry Smyth in the form of Letters Patent for the production of Normandy glass, was on the condition of (a) bringing the foreign trade of manufacturing Normandy glass to England, (b) benefiting the realm by lowering the price and (c) training Englishmen in its production. There were patents validly enforced even in case of a trade that was in use earlier but at that time out of use in the realm, with the purpose of re-establishing the industry. The status of ‘inventor’ was accorded to the patentee, as he was the first to establish or re-establish his respective trade, unless he took away the trade of others. The expression ‘establish new trade and industry’ was equated with the ‘new invention’, such newness being limited to the territory of the state. It was an incentive to import and establish
(or re-establish) rather than to invent.\textsuperscript{10} Section 6 of the Statute of Monopolies, 1624, demonstrated clearly that ‘the statute was an instrument of economic policy; rather than being motivated by the desire to do justice to the inventor; it was meant to encourage industry, employment and growth. The patentee’s consideration for the grant was that he would put the invention to use’.\textsuperscript{1}

The statement of Holt C J and Pollex Fen in \textit{Edge Berry v Stephens} is reminiscent of the patent policy of Statute of Monopolies:

‘If the invention be new in England, a patent may be granted, though the thing was practised beyond the sea before; for the statute speaks of new manufactures within this realm; so that if they be new here, it is within the statute; for the Act intended to encourage new devices useful to the kingdom, and whether learned by travel or by study, it is the same thing.’\textsuperscript{11}

This affirms that the objective of the royal policy in granting patent monopoly was to introduce and establish new industries in the realm. The ultimate objectives of the Statute were to encourage industrial activity, employment and economic growth, rather than to reward the ‘true and first inventor’. The Statute stated that monopolies are contrary to the ‘ancient and fundamental laws’ of the realm and exempted patent monopolies by virtue of a privilege based on their contribution to the public good.\textsuperscript{12} Local manufacturing of products was believed to be beneficial for transfer of technology and economic upliftment of the state. Therefore, it was a primary and fundamental obligation on patentees to produce the patented articles within the territory and it always remained the precondition for grant of patents. However, failure to work has always been considered a prima facie ‘abuse’ of the patent privilege.\textsuperscript{13} In this era, though the patents cannot be granted merely for establishing or re-establishing an industry, for the reason that the circumstances which were in existence at that time, are not in existence today. However, the ultimate objective of the patent system remains the same, i.e. technological advancement and economic welfare.

\textbf{Local Working under Paris Convention}

The Paris Convention, under Article 5A(2), allows the member countries to take legislative measures providing for the grant of compulsory licences to prevent abuses, namely, failure to work or insufficient working, which might result from the exclusive rights conferred by a patent for invention. What amounts to ‘failure to work’ was not provided and the member states were free to define it. However Article 5A (4) (ref. 14) did provide a timeline before the ground of failure to work or insufficient work could be evoked to grant a compulsory licence.

Since it is recognized that the immediate working of an invention in all countries is impossible, Article 5A sought to strike a balance between these conflicting interests.\textsuperscript{15} The failure to work an invention cannot result in forfeiture of the patent, except in cases where the grant of a compulsory licence would not have been sufficient to prevent the abuse, and then also, only pursuant to a proceeding instituted after the expiry of two years’ period following the grant of the first compulsory licence. However the compulsory licence under this provision shall not be granted if the patent holder is able to justify his inaction through legitimate reasons, for example, economic, legal or technical obstacles that caused the invention impossible to work, or work more intensively in the country. The grant of compulsory licence for non-working or insufficient working must be non-exclusive and non transferable and should be coupled with a share in profits earned from the compulsory licence. The patent owner should also retain the right to grant other non-exclusive licences and/or to work the invention himself. These limitations are imposed in order to prevent a compulsory licensee from acquiring a stronger position in the market than is warranted by the purpose of the compulsory licence, that is to say, to ensure sufficient local working of the invention.\textsuperscript{15}

\textbf{Local Working under TRIPS Agreement}

There is no express provision in the TRIPS Agreement regarding local working of patents; however, there are provisions which are incorporated by reference and some can be inferred from the objectives and principles. Nevertheless, the US - Brazil patent dispute that ended undecided due to the withdrawal of complaint by US raised the issue of validity of the local working provisions in domestic laws of the member states.\textsuperscript{16}

Article 2.1 of the TRIPS Agreement incorporates Article 5A of the Paris Convention thereby making it obligatory for the WTO member states to comply with the relevant requirements under Paris Convention. Article 2.2 of the TRIPS Agreement
further provides that ‘Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.’ Incorporation of these preexisting WTO administered treaties into the TRIPS Agreement suggests that, TRIPS is ‘an addition’ and not a ‘replacement’ to the earlier conventions.17

Article 27.1 of the TRIPS Agreement is regarding the subject matter of patent and extends the protection to the patented goods irrespective of the place of invention, the place of production and the field of technology. The expression ‘patents shall be available and patent rights enjoyable without discrimination’ along with ‘whether products are imported or locally produced’ imply that the patentee may either import the goods from other countries or may produce the goods locally. However this provision does not confer any absolute right in favour of the patent holder to import the patented goods from other countries.

A patent is not a goal in itself, rather it is a right created by the state as a means to achieve a larger social goal. Therefore, the state imposes certain restrictions on exercise of such rights in the form of exceptions so as to achieve the desired goal and also to prevent their abuse. The exceptions provided under Articles 65.4 and 70.8 are relating to the extension of patent protection to the products in the fields of pharmaceutical, agricultural and chemical technology for which there was limited or no protection in some countries prior to TRIPS; while non-patentable inventions are mentioned in Article 27.3. However, these provisions do not speak about local working requirements, and therefore it is argued that Article 27.1 is only subject to the enumerated provisions and the local working requirement is contrary to Article 27.1 of the TRIPS Agreement,17 while at the same time, one should bear in mind that there is no express provision which prohibits member states from requiring local working of patents after the grant of patent. On the contrary, Article 5(A) of the Paris Convention, which is incorporated into the TRIPS Agreement by virtue of Article 2, authorizes the member states to adopt legislative measures like compulsory licence to prevent abuses such as failure to work. These two provisions appear to be contradictory and have created confusion about the legal validity of local working requirement of patents under TRIPS. Nevertheless, the existence of provisions relating to exceptions under Article 30 and 31 suggest that Article 27.1 is not an absolute rule. Therefore Article 27.1 cannot be interpreted in isolation; rather it should be interpreted after considering other relevant provisions in the text of TRIPS in order to draw the right conclusion. Further, if Article 27.1 is considered as an absolute rule, Article 5(A) of the Paris Convention and Article 30 and 31 of the TRIPS Agreement would become meaningless. The mandate of Article 27.1 is thus qualified and subject to other provisions.

A right created under the law cannot be interpreted by ignoring the exceptions under the law and the ultimate goals for which it was created. The International Court of Justice asserts that the disputed provisions of a treaty should be interpreted in the context of treaty as a whole including objects and purposes. And if the text is ambiguous and unclear, the preparatory works, like the official record of negotiations, etc., shall be resorted to, in clarifying the intentions of a treaty or any other instrument. Therefore, interpreting Article 27.1 in isolation, ignoring the mandate of Article 5A of Paris Convention and Articles 7, 8, 30 and 31 of the TRIPS Agreement would be contrary to the principles of interpretation.18

Article 5.1 of the Doha Declaration further provides that ‘In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.’19 The objectives and principles of TRIPS Agreement are incorporated under Articles 7 and 8 wherein Article 7 provides that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare and to a balance of rights and obligations. The principles of the TRIPS Agreement under Article 8.2 affirm the importance of technological innovation and of the transfer and dissemination of technology, which in turn require local working of patents. The failure to work the patent is treated as abuse of patent monopoly and such abuse of intellectual property rights may adversely affect the international transfer of technology. Article 27.1 and Articles 30 and 31 should be interpreted in the light of the contents of
Articles 7 and 8 of the TRIPS Agreement and hence it may be concluded that the local working provision is perfectly within the purview of TRIPS Agreement.\textsuperscript{17} The TRIPS Ministerial Conference held at Doha in 2001 adopted the Doha Declaration to clarify the scope of TRIPS reaffirming the flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines,\textsuperscript{20} stating that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. It also affirmed that the agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.\textsuperscript{21} Consequently, the member states could issue compulsory licences when access to medicine is restricted due to local non-working of patented invention or importation of patented goods from other countries. The Doha Declaration further affirmed that each member was free to determine the grounds of compulsory licences.\textsuperscript{19}

Thus Article 31 of the TRIPS Agreement regulates authorization of third parties to use patents without the consent of patent holder i.e. compulsory licensing. It does not limit the grounds upon which compulsory licences may be granted, however, it requires certain minimum obligations to be fulfilled while granting of compulsory licence. Accordingly, the member states may provide for ‘local non-working of patents’ as a ground of compulsory licence or ‘licence of rights’, subject to the requirements under Article 31 of the TRIPS Agreement.

A patent holder is required to ensure that the patented inventions shall meet the reasonable expectations of society (Article 7 of TRIPS). In case the patent holder fails to fulfil such expectations even after the expiry of a reasonable period, without any reasons, such a failure needs to be addressed in order to prevent the abuse of monopoly through non-use or local non-working. Furthermore, in such an event, the state has every right to protect its interests by allowing third parties to manufacture the patented products. Therefore, while Article 27.1 of the TRIPS Agreement is a general rule, Article 30 and 31 (compulsory licence) of the TRIPS agreement and Article 5A (2) of the Paris Convention are exceptions to it.

In another argument it may be claimed that the patent is a privilege granted by the state in the form of contract and local working is a reciprocal requirement of the contract. Hence, legislative measures requiring local working of patent along with the remedy of compulsory licence and revocation of patent available under Article 5A of Paris Convention and Article 31 of the TRIPS Agreement are perfectly justified.\textsuperscript{22} Article 27.1 of the TRIPS Agreement together with Article 5A of the Paris Convention imply that patents are available and patent rights may be enjoyed by the patentee by producing the goods locally or by importing from the another countries; however, if there are no legitimate reasons for local non-working, he shall start local production at a reasonable extent, not later than four years from the application or three years from the grant of patent, whichever expires later. The period of three/four years as mentioned above is a reasonable period required for setting up an industrial unit and start actual production and not merely for importation from other countries.\textsuperscript{21}

**Importation of Patented Goods and Local Working Requirement**

Article 5A of the Paris Convention which is incorporated in the TRIPS Agreement by virtue of Article 2 provides for local working of patented inventions. However, it does not define ‘local working’ and leaves it for the member states to define it. This leads to conflicting interpretations about what constitutes ‘local working’ and whether mere ‘importation’ of patented goods would satisfy the local working requirement.

The key argument underlying the provisions requiring the working of an invention in the country where the patent was issued is one of promoting industrialization of that country. The patents should be used to introduce new technology into the country, for which the patent system has emerged.\textsuperscript{10} G H C Bodenhausen, former Director of the Bureau for the International Protection of Industrial Property (BIRPI), while describing local working requirement under the 1967 revision of the Paris Convention, observed that:

‘The member states are also free to define what they understand by ‘failure to work’. Normally, working a patent will be understood to mean working it industrially, namely, by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as ‘working’ the patent.’\textsuperscript{23}
If the importation of patented goods is considered sufficient to meet the requirements of local working, failure to work the invention could have been addressed by ‘parallel imports’ using the provisions relating to international exhaustion under Article 6 of the TRIPS Agreement and there would not have been any need of incorporating separate provisions of Article 5A of the Paris Convention in the TRIPS Agreement. Incorporation of such an independent and separate provision into the TRIPS Agreement indicates that the framers of Paris Convention and the TRIPS Agreement intended ‘local working’ to mean ‘local manufacturing’ in the country where the invention is patented which is to be enforced through issuance of compulsory licences and not merely parallel imports.

International Exhaustion Principle (Article 6 of TRIPS) may be invoked to import patented drugs from other countries so as to ensure availability and affordability of patented drugs, however, import of drugs from other countries may not always be an effective and adequate remedy to control the price of drugs and supply, as it always depends upon various factors such as, the taxing structure, capacity to manufacture, quality of drugs, cost of production, etc. This principle may be invoked only when the quality drugs are available in other countries at lower prices. Therefore, though the provision of parallel imports is one of the remedies available to address shortage of drugs, drug prices and issues concerning the public health, it may not be effective in all cases, particularly in developing countries which themselves have domestic capacity to produce quality goods at much lower prices as compared to developed countries. The provision relating to local working has been incorporated with the wide objective of socio-economic welfare, i.e. to ensure transfer of technology and industrial progress in addition to availability and affordability of patented goods. Such a provision is more effective particularly, in the developing countries such as India, China, Brazil, etc., having a strong industrial set up with capacity to produce quality drugs at cheaper rate.

If the importation of patented goods is considered sufficient to meet the local working requirement, it would diminish the paramount objective behind incorporating the local working provision and the patent system itself. Let one assume for the sake of argument, that the importation of goods is sufficient to fulfil the local working of invention. According to Article 5A of the Paris Convention, the patentee is bound to work the invention only after the expiration of the specified period, and is excused from this duty if there are legitimate reasons for non-working. If this interpretation is accepted, the patent holder would be entitled to exploit unrestricted and absolute monopoly over the invention for the initial three to four years and even thereafter, if he has reasons for non-working. If this were the case, international exhaustion provision would have been the proper and sufficient remedy for addressing the failure to work and there would not be any need for provision in the form of compulsory licence as in Article 5A of Paris Convention. The inadequacy of the provision relating to parallel imports as seen above and incorporation of local working provision indicates that mere importing of patented goods without local manufacturing would not be sufficient to comply with the local working condition and it requires local manufacturing of patented products to a reasonable extent in addition to the importation. It also indicates that both of the remedies are available for the member countries and may be invoked simultaneously and independently.

It may be argued that the manufacture of a product in the country where the invention is patented may not be feasible owing to inadequate infrastructure and high production cost. It may further be argued that the local applicant for a compulsory licence does not have sufficient technical and economic capability to exploit the patent. In the former case, the patent holder can opt for issuing licences to local manufacturers instead of investing huge capital; rather this is the primary demand of the local working provision. However, in the later case where it is not at all feasible to work the patent either by direct production or by issuing licences, the issue of compulsory licence may be decided on individual merits under Article 31(a).

It may also be argued that local working is not possible in all the cases as all inventions may not prove economically efficient due to lack of demand/market or interest; in such cases the patent holder cannot be burdened by requiring the local working of invention. However, such a scenario falls under the exception to work an invention if there are legitimate reasons. Furthermore, a demand for compulsory licence from local manufacturers is expected only when the invention is economically efficient since the grant of such licence is also subject to payment of royalty. Therefore, the question of burden and inconvenience to the patentee does not arise in case of the local working requirement.
Indian Patent Regime and the Local Working Requirement

The Indian Patent Act, 1970 (hereinafter the Patent Act) under Chapter XVI (Sections 82-99), provides for certain obligations on patentees, proposed to ensure local working of the patent and avoid misuse of monopoly by mere import the product. Section 83 of the Patent Act stipulates the cardinal principles of patent privilege. It provides that the patents are granted to encourage inventions and to ensure that these inventions are worked in India on a commercial scale and not merely for benefitting from the monopoly. The protection and enforcement of patent rights should contribute to the promotion of technological innovation and to the mutual advantage of producers and users of the technological knowledge. The Act also intends that patents granted do not impede protection of public health and nutrition and act as instruments to promote public interest especially in sectors of vital importance for socio-economic and technological development of India. It further lays down that the patentee or his assignee shall not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. Finally, it states that patents are granted to make the patented invention available at reasonably affordable prices to the public. This provision reiterates the fundamental objectives of the patent system and attempts to prevent the abuse of patent. Such abuses are restrained under Section 84 of the Patent Act.

According to Section 84(1) of the Patent Act, any interested person may, after the expiration of three years from the date of the grant of a patent, apply for the grant of compulsory licence on the grounds that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at reasonably affordable price or that the patented invention is not worked in India. As per the Section 84(7) of the Patent Act, the ‘reasonable requirements of the public’ shall be deemed not to have been satisfied if inter alia the patented invention is not being worked in the territory of India on a commercial scale to the fullest extent that is reasonably practicable or if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article. Though there are three different grounds provided for issuing of compulsory licence, all are aimed to ensure that the patents are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable. Furthermore, under Section 85 of the Patent Act, 1970, a patent may be revoked if the patent holder fails to comply with the requirements under Section 84(1). These provisions clearly reflect the policy objective of the patent system. The Indian Patent Act has imposed a duty on the Controller of Patents to ensure the local working of patents. Under Section 146 of the Patent Act, the Controller may require the patentees to furnish to him information/statements regarding the working of patented invention on commercial scale in India. If any person refuses or fails to furnish such information to the Controller, he shall be punishable with fine which may extend to ten lakh rupees or if knowingly submits false information, he shall be punished with imprisonment which may extend to six months or fine or both (Section 122 of the Act). The Controller of Patents may also publish periodically, the information submitted under Section 146 of the Patent Act.

In the compulsory licence case of Natco Pharma, the Controller General of Patents approved the legality of these provisions holding that, ‘When the Article 27(l) of TRIPS Agreement is read with the aforementioned provisions of TRIPS Agreement and the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory licence is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility that the Parliament have invoked in Chapter XVI of the Patents Act, 1970 by incorporating a provision for grant of compulsory licence upon failure to work the invention within the territory of India.’

Though there are various provisions requiring the patentee to submit information regarding local working of patents, there has been no mention about local working of patented inventions in the annual reports of the Controller of Patents till 2007. The data regarding the local working of patents provided in the annual reports for the year 2007 to 2009 is based merely on the information provided by the patentees and reveals that, only 3499 patents were working commercially out of 29688 patents in force in 2007-08 while only 4752 patents were working...
commercially out of 30822 patents in force in 2008-09 (ref. 25). It indicates that about 85 – 90 per cent patent holders either failed to work the invention on a commercial scale in India or failed to submit the information regarding working of invention. In either case, it is breach of the duty under the Patent Act and the patent holder is liable for action of compulsory licence, revocation or/and fine.

In spite of having severe liability under the Indian Patent Act for non working of patents, the situation of local working of patented inventions is miserable. Primarily, it is the duty of the Controller of Patents to implement these provisions. Nevertheless, it is only twice or thrice that such information was called for while no action has been yet taken against those who have not submitted such information.

Recently, the Indian Patent office, for the first time after implementation of TRIPS, issued a public notice dated 24 December 2009, directing all the patentees and licensees to furnish information working of patents, as prescribed by the law. However, there is not much information on whether any action has been taken on those who have not provided such information. Only one compulsory licence has been granted by the Patent Office in the patent history of India for failure to work the invention locally. In Natco Pharma Ltd v Bayer Corporation, the Controller General of Patents, after being satisfied with the claim of the applicant Natco Pharma Ltd, granted compulsory licence to manufacture and market the anti-cancer drug Nexavar proposed to be sold by Natco at a rate of Rs 8880/- for a dose of one month as against Rs 2,80,428/- by the German pharmaceutical giant, Bayer Corporation. However, the order of Controller of Patents is based on three grounds viz., reasonable requirements of the public with respect to the patented invention are not satisfied, the patented invention is not available to public at reasonably affordable price and that the patented invention is not worked in India. The Controller of patents held that ‘working’ does not mean ‘importation’ and ‘worked in the territory of India’ implies manufactured in India to a reasonable extent.

A report by Basheer that surveyed the top-selling drugs in India for the period 2007-2010 concluded that the pharmaceutical companies in India were not serious about the local working provisions of the Patent Act. The provisions of law have been breached either by non filing of the local working information, or by filing incomplete information. The information provided is often either not available, or inadequate to show whether the product is imported or produced locally. Although the study undertaken and the conclusions drawn are of very limited nature due to lack of adequate information on local working of patents owing to so called ‘confidentiality’ of third party information, stringent requirements and rigid approach of the Indian Patent Office in disclosure of information; the findings are enough to show the pharmaceutical companies’ disregard towards their duties under the Patent Act, 1970. The information about the working of patents provided by the patent holder under Form 27 is of utmost importance; rather it can be the basis for grant of compulsory licence under Section 84(1) of the Patent Act, 1970. Non-availability of the information relating to working of patent on commercial scale in India is a basic obstacle in claiming compulsory licence under Section 84(1). The provision of ‘licences of rights’ (Sections 87 – 89) which existed under the Patent Act, (prior to amendment in 2002) perhaps would have been more appropriate in these circumstances.

Import of pharmaceutical drugs is likely to have an adverse impact on public access to medicine. The quality of imported drugs, unreliable suppliers, the high production costs and transportation costs, scarcity of drugs and shortage of supply are matters of concern in the importation of drugs. Local production of drugs is an attractive solution for such problems. Local production ensures price reduction, increases supply and competition and, consequently, ensures better access to medicines. It also brings self-sufficiency in medicines, cuts dependence on foreign suppliers, increases domestic expertise in the production of medicines for key local diseases, increases transfer of technology and knowledge, increases employment, opens a new export market and improves foreign exchange flows. India has low development costs, complex synthesis capabilities, growing experience with good manufacturing practice (GMP) compliance and a large local market in which to gain experience. India is also known for having a large number of strong chemists, many with Ph.D.s from the U.S. and Europe, providing rapid, and creative, process development. India is the most viable place for production of quality drugs at comparatively lower cost. However, the pharmaceutical companies have failed to follow the local working requirements, thereby affecting access to medicine which is a derivative of the right to health.
Under the belief that price is the primary barrier to accessing effective drugs in developing countries, the international community has actively pressed for more competitive, efficient and transparent drug-procurement practices for lowering of prices, by encouraging more producers, increasing drug supply and driving prices down. Nevertheless, public access to medicine has remained one of the most pressing global public health concerns in developing countries.  

With regard to the role of patents in transfer of technology, it is seen that the technology transferred to developing countries through patents, accounts for less than 2 per cent of the total technology transferred. The technology transferred through the FDI or joint venture is negligible, as almost none of the foreign-owned patents are exploited in developed countries. This is because a majority of the patented inventions have not been used by patent owners in most developing countries. 

**Problems in Local Working of Patents**

Local working condition requires the patentee to manufacture the patented product or product of patented process in the country where the patent has been granted. This needs initial capital investment, technological support, adequate infrastructure, cost effective labour and favourable environment. Inadequate infrastructure, such as shortage of water and electricity, shortage of skilled and non-skilled labour, bad condition of roads, lack of transport facilities and inadequate technological support are factors that may hamper production and also affect the cost and quality of product. Among other factors, political and social instability, lack of political will, indifferent public attitude, inapt tax structure, electricity costs, transport costs, cost of raw material, instability of foreign exchange, availability of market, market growth and the regulatory framework of that State are crucial in the smooth functioning and progress of the industry. 

Local working of patent would not be feasible in a country where these factors are not favourable.

In case patents have been granted in multiple countries for the same invention, it may not be possible for the patentee to establish separate industrial units in all such countries due to administrative and financial reasons. In such cases, licensing to local firms is a better option for the patentee. However, the patentee may not get a local firm, which is economically and technologically capable of working the patent. The local working of the patent cannot be forced when it is not feasible.

In particular cases, bulk production of patented goods from an existing plant and importing the goods to the country of patent grant may be more convenient for the patentee, rather than to establish a new industrial unit. It saves the start-up costs, manpower, maintenance cost, administrative expenses and other infrastructural expenses, including electricity, water, etc. The price of imported products might be lower than the locally manufactured products. This happens particularly, when the market is very small in that country or the demand for the product is very low. The patentee shall not be subjected to a compulsory licence when there are legitimate reasons for his inaction or local non-working.

Where it is evident that the patentee prefers importing from other countries even when all factors are favourable for the establishment of an industrial unit, compulsory licensing is justified as an essential remedy to prevent misuse of monopoly. Such an action may result from the intention to earn higher profits by creating shortage and selling at higher rate, even without investing any capital.

The patentees may take a defence that it is not feasible to work the patent in India. Now the question is whether the industrial infrastructure and other conditions necessary for industrial investment are favourable for local working of patents in India. Answer to this question, to some extent, is case specific and to be answered on merits of each case. However, the general industrial conditions necessary for the establishment of an industrial unit and the feasibility to work the invention in a broad sense are common for all cases. The following few paragraphs are focused on the industrial policy and investment climate in India.

**Availability and Affordability of Pharmaceutical Drugs in India**

Indian drug industry has witnessed a significant growth in the last two decades and is now recognized as one of the leading global players in the manufacture of pharmaceuticals. It is ranked at the top in making generics at low prices worldwide, with wide ranging capabilities in the complex field of technology, quality and the vast range of medicines that are manufactured. India’s pharmaceutical industry is now the third largest in the world in terms of volume and 14th in terms of value. India tops the world in exporting generic medicines worth US$ 11 billion and currently
the Indian pharmaceutical industry is one of the world's most developed industries.\textsuperscript{31} India has been supplying life-saving drugs at affordable cost to a number of developing countries and least developed countries and today, it is recognized as the pharmacy of choice of the developing world. However, high quality medicines within India appear to be overpriced, unaffordable and inaccessible, driving many patients to misery. Often Indians have to pay comparatively significant amounts of their wages, or borrow money, for purchase of medicines. Also, the majority of medicines used are not accessible through public health outlets and, have to be borne as out-of-pocket expense.\textsuperscript{32} According to an estimate, about 25 lakh people in India suffer from cancer and most of them are not financially capable of affording the high cost of anti-cancer medicines. Further, India reportedly has the highest number of HIV/AIDS patients in the entire South Asian region.\textsuperscript{33}

A look at the recent restructuring of ownership in the pharmaceutical sector shows that many strategic alliances are being forged by some large Indian players. For instance, during the last few years, six leading Indian companies, namely Matrix Labs, Dabur Pharma, Ranbaxy Laboratories, Shanta Biotech, Orchid Chemicals, Piramal Healthcare, were taken over by Mylan Inc, Fresenius Kabi, Daiichi Sankyo, Sanofi Aventis, Hospira, and Abbot Laboratories, respectively. The Department of Industrial Policy and Promotion (DIPP) while commenting on this trend warned that, ‘Most of these companies are export oriented. There is a concern that their [Indian generic drug manufacturing companies’] takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them. This may weaken competition leading to headroom for increase in domestic drug prices’\textsuperscript{34} thereby worsening both, the availability and the affordability of pharmaceutical products.\textsuperscript{33} Furthermore, these foreign companies are taking over domestic drug companies in other countries also. For example, Sanofi Aventis took over Medley in Brazil and Zantiva in the Czech Republic, GSK took over BMS in Egypt and Pakistan. If this trend of takeover continues, it may establish hegemony of bigger companies, allowing them to dictate the prices of those drugs critical for addressing public health concerns. Such monopoly is also likely to weaken the Government’s ability to address such challenges through compulsory licensing measures. If large Indian generic companies with the capability to manufacture drugs based upon compulsory licensing are themselves taken over, then the regime of affordable and accessible drugs would be in serious jeopardy. Another consequence would be that such large Indian pharmaceutical companies, if taken over by foreign companies, may not be willing to apply for a compulsory licence, even if eligible, for obvious reasons. With the recent acquisitions of Indian pharmaceutical companies by overseas firms, there is a well justified concern that it may lead to the reduced local availability of patented drugs and an increase in prices, including those of generics.\textsuperscript{34}

**Initiatives to Attract FDI and Impact on Local Working**

The Indian government launched its market-oriented economic reforms through its liberal investment policy in 1991. Since its inception, promotion of foreign direct investment (FDI) has been an integral part of India’s economic policy and it has proved to be very effective in attracting FDI inflow.\textsuperscript{35} Efforts have continually been made to progressively rationalize it further, so as to encourage and facilitate FDI. Presently most of the FDI activities are covered under the automatic approval route and the FDI limit has been raised to 100 per cent for activities in Special Economic Zones (SEZs). Also, it has been raised considerably in other parts.\textsuperscript{36} Huge human capital, size of the market, market growth rate, cheap labour cost, lower country risk and political stability are the factors that attract FDI in India.\textsuperscript{37} India, the second fastest developing country in the world, with transparent, liberal and efficient investment norms and strong market potential, offers abundant opportunities for FDI and has emerged as the second most attractive FDI destination globally.\textsuperscript{38}

However the status of local working of patents in India is far from satisfactory. The rat race of inventors to file patent applications throughout the world appears to be merely for acquiring control over the market. Due to the potential threat of losing novelty, patent applications are frequently filed without properly evaluating the economic viability of the invention. Therefore, the patents which are not worked locally or whose local working is interrupted, should be subjected to compulsory licensing and, subsequently, to revocation, except in cases where local working is not feasible.
Conclusion

The concept of patent has emerged as a concession conferred by the State for transfer of technology, innovation and industrialization. Industrial development, economic welfare and technological advancement are the prime objectives of the patenting system and these objectives cannot be achieved without local working of patents. Therefore, a patent right is always coupled with a reciprocal duty to work the invention in the local industry.

Tremendous growth has been seen in patent applications and grants in India, particularly, during the post-TRIPS period, although most of the patents are owned by inventors of foreign origin. However, these patents are not worked in India on a commercial scale. The huge patenting activity without local working is does not serve the purpose of society; particularly in the field of pharmaceuticals. It seems the patent holders are using Indian market only for economic gain with no actual benefits in the form of transfer of technology from inventive activity. The increased rate of patent grants has not achieved the desired aim and, hence, it appears that the new Indian patent regime has not been able to stimulate innovation and foster industrial growth in real sense.

The time has come to reconsider the patent system in the light of original objectives for which the patent system was designed. Otherwise, it will continue to facilitate the exploitation by multinational corporations.

The Patent Act provides remedies, including compulsory licence, revocation and fine, if the patent holder fails to comply with the provisions of law relating to local working of patent. However, these remedies are rarely enforced. The ‘Controller’ of patents needs to take his role of ‘monitoring’ patents more seriously rather than merely ‘registering’ patents. These provisions have become lifeless and, hence, there is a need to revive the mechanism for monitoring the local working of patents.

The unavailability of information about working or non-working of patents and unfavourable and rigid approach of Patent Office towards disclosure of such information is a major obstacle in claiming compulsory licence. The authors propose a revival of the ‘ licences of rights’ provision which was in existence under Sections 87, 88 and 89 of the Patent Act, 1970 prior to amendment in 2005 with necessary modifications, which would be helpful in this regard. The Controller of Patents should enlist those patents in force, which are not working locally on a commercial scale, or are susceptible to compulsory licence/licences of rights. Such patents should be endorsed with ‘ licences of rights’ and the list published periodically on the official website with complete details, so that interested persons may apply for compulsory licence/licences of rights.

The problem of non-feasibility in working the patent has not been addressed by the Patent Act, 1970. All the inventions cannot be forcibly worked; there may be legitimate reasons such as economic, legal or technical obstacles causing the invention impossible to work, or work more intensively in the country where it is patented. Therefore the Indian Patent Act, 1970 should be amended to this effect.

Patenting of an invention is not an end in itself; rather it is a means to achieve the gigantic social goal. The Indian state has achieved the technical goal of harmonizing the patent system with TRIPS. However, it appears to have failed to achieve the ultimate goal of patent system, i.e. socio-economic welfare. India needs to stress upon the local working of patents and to implement the provisions relating to compulsory licence in cases where patent monopoly is abused affecting availability and affordability of drugs or unreasonably restrains trade or adversely affects the international transfer of technology or affects the commercial or industrial development in the country of sectors of vital interest provided, there are no legitimate reasons for failure to work. The conflicting provisions under Article 27.1 of TRIPS Agreement and Article 5A of the Paris Convention have created confusion about the legality of local working requirement. Therefore, the Article 27.1 needs to be amended to the effect that it is subject to Article 30 and 31 of TRIPS Agreement and Article 5A of the Paris Convention. The Indian State should act to further strengthen infrastructure facilities and other determinants of FDI, so as to attract more FDI in India. It should also support the local inventors in converting their invention into innovation. What has been done is a mere formality and what needs to be done is a real, honest and visionary effort towards development through the available resources and new channels.

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References


2. For example, in India the term of patent in case of food, medicine or drug was five years from the date of sealing of patent or seven years from the date of patent, whichever is shorter, while it was fourteen years in case of other subject matter, Section 53 of Indian Patent Act, 1970 prior to the amendment of 2002.


14. A compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence, except with that part of the enterprise or goodwill which exploits such licence.


16. Bird Robert & Cahoy Daniel R, The Impact of compulsory licensing on foreign direct investment: A collective bargaining approach, American Business Law Journal, 45 (2) (2008) 1-40. United States filed a complaint with the WTO against Brazil on the ground that Article 68 of the Brazilian Patent Law is inconsistent with the obligations of Brazil under Article 27 of the TRIPS Agreement. Article 68 of the Brazilian Patent Law requires the patent holder to manufacture the subject matter of the patent within the territory of Brazil, within three years of obtaining a patent, unless the patent holder can show that local production is not economically feasible or reasonable, failure to which the Brazilian companies may apply for compulsory licence, see WT/DS199/1, G/L/385, IP/D/23, 2000. Brazil immediately filed a counter complaint against United States challenging Section 204 and 209 of the US Code Title 35- Patents, requiring the licensees of the state funded small business firms and NGOs or federally owned inventions to manufacture the patented product or the product of the patented process, substantially within the US. Brazil’s counter complaint, global criticism from the NGOs and activists and mounting public pressures throughout the world forced the United States to withdraw its complaint from the WTO, see WT/DS224/1, G/L/437, IP/D/24, G/TRIMS/D/18, 2001, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds224_e.htm).


43 Enactment of the National Innovation Act, The Protection and Utilization of Public Funded Intellectual Property Bill, etc., may be helpful in this regard.