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THE PATENTS NEWSLETTER

The story continues..... those who have been reading our past newsletters will understand that in the patent landscape our focus has been pharmaceuticals. This is not intentional and we do try very hard to veer away from it and focus on other technology areas as well, but since so much activity is always happening in this area, we are compelled to write and focus about this technology area. Here we are again! Back with another edition with some more news in the pharmaceutical landscape. This time however it is notjust news, we have tried to collect, collate and analyze data on enforcement of pharma patents in India in recent years. Specifically we are bringing you the trend in the relief granted to plaintiffs in these disputes.

And it is that time of the year again! The deadline for filing working statements for granted patents is just round the corner. We bring you an updated article on the working of patents in India with the latest case law in this regard.

A few words patting the Patent Office on its back for bringing some much-needed transparency and efficiency in its working will complete this edition.

We wish all our readers a wonderful 2015. We hope you find the information useful. Any queries may be directed to akhanna@indiaip.com or info@indiaip.com.

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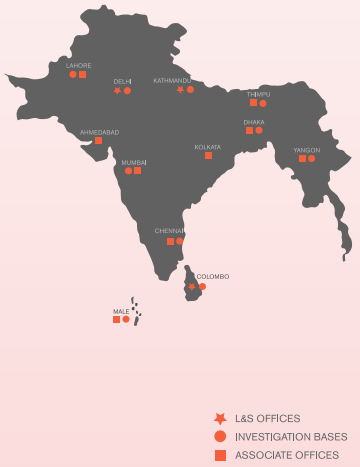

Right to Infringe?

This is the impression the world has of India in the pharmaceutical space. To the world India is a no-holds-barred country where anyone (read the generic companies) can copy your invention and live-happily-ever-after. However the reality may be quite different. With the Indian pharmaceutical market growing at double digit rates[1] competition between the innovator companies and the generic companies is predictably fierce. As the innovators and the generics fight it out, we try and bring you a realistic picture from the Ground Zero!

Patentee's Rights and Protection

The rights of the patentee[2] are enshrined in the Indian Patents Act, 1970 that gives the exclusive right to the patentee to prevent others, without his consent, from the act of making, using, offering for sale, selling or importing the patented product in India. In case of a process it is the exclusive right to prevent others, without his consent, from using that process and from using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India. The rights are however subject to conditions stated in section 47[3]. Infringement per se is not defined in the Act but flouting of these rights by a third person amounts to infringement.

The patentee can file a suit for infringement against the infringer. The Court can grant relief[4] to the patentee in the form of an injunction and either damages or an account of profits. The Court can also order seizure of infringing goods.

The injunction granted by the Court can be either temporary or permanent. For granting interim injunctions the Courts follow three criteria[5] to determine its grant: availability of a prima facie case (that a patent is valid), the balance of convenience and irreparable injury. Traditionally Courts have not been very keen on granting injunctions, either interim or permanent, in patent cases, especially in pharmaceutical disputes. Recently, however this scenario seems to be shifting.

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[1] *http://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation*

[2] *Rights of patentees.—Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee—*
(a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
(b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

[3] *Grant of patents to be subject to certain conditions.—The grant of a patent under this Act shall be subject to the condition that—*
(1) any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;
(2) any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;
(3) any machine, 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; and
(4) in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette.

[4] *Reliefs in suit for infringement.—(1) The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits.*
(2) The court may also order that the goods which are found to be infringing and materials and implements, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation.

[5] *The Supreme Court of India has provided precedential jurisprudence in SeemaArshadZaheer Case (SeemaArshadZaheer -vs- Municipal Corpn. of Greater Mumbai, (2006) 5 SCC 282) where the Court has laid down its guidelines for the grant of temporary injunction orders. The Court opined that "The discretion of the court is exercised to grant a temporary injunction only when the following requirements are made out by the plaintiff: (i) existence of a prima facie case as pleaded, necessitating protection of plaintiff's rights by issue of a temporary injunction; (ii) when the need for protection of plaintiff's rights is compared with or weighed against the need for protection of defendant's rights or likely infringement of defendant's rights, the balance of convenience tilting in favour of plaintiff; and (iii) clear possibility of irreparable injury being caused to plaintiff if the temporary injunction is not granted. In addition, temporary injunction being an equitable relief, the discretion to grant such relief will be exercised only when the plaintiff's conduct is free from blame and he approaches the court with clean hands".*

What follows below is the trend in grant of injunctions in the pharmaceutical space in recent years for the protection of various drug molecules.

Sitagliptin

Merck Sharp and Dohme (MSD) found infringement of its patent covering the molecule Sitagliptin, an anti-hyperglycemic drug of the DipeptidylPeptidase-4 (DRP-4) inhibitor class for which theyfiled infringement suits against several parties.

The Court granted interim ex-parte injunction against eight defendants, while refused injunction against Glenmark. In case of infringement suit against Glenmark[6], the Court held that since the plaintiff (MSD) had failed to prove that Sitagliptin Phosphate was identical in its properties to Sitagliptin, hence the product (Sitagliptin Phosphate) of the defendant (Glenmark) would be outside the purview of the plaintiff's patent. The Court averred that the plaintiff had not submitted any pleadings with regards to the fact that that Sitagliptin Phosphate was merely a new form of Sitagliptin, and did not result in the enhancement of its efficacy and was a mere combination of other derivatives of Sitagliptin. The fact that the plaintiff had obtained patents on Sitagliptin Phosphate in the US and Europe by showing that it was a new product worked against them. The patent application for Sitagliptin Phosphate had been earlier rejected by the Indian Patent Office. The matter had been referred for mediation, however since attempts to settle disputes have failed, matter is into the trial phase.

Erlotinib:

Roche filed several infringement suits between 2008 and 2010 against a number of generic drug companies namely Cipla, NatcoPharma, Dr. Reddy's, Glenmark, Oncare Life Sciences, Aureate Healthcare, Innova Life Sciences, Mylan Laboratories Inc, Fresenius Kabi, Accura Care Pharmaceuticals and Intas Pharma for its patent on a drug molecule "Human Epidermal Growth Factor Type-I/Epidermal Growth Factor Receptor (HER/EGFR)" inhibitor which is known as 'Erlotinib' for treatment of cancer. However, in nine of the ten cases the Court decided only on jurisdiction part and main issue of injunctive relief remains open. Only in Cipla's case Court rendered its decision[7], denying permanent injunction to Roche. In this case Roche was denied permanent injunction based on the Court view that Cipla did not infringe on the patent, though patent was held valid by the Court. Appeals were filed by both the parties against the Court decision.The defendant also filed revocation application for the same patent before Intellectual Property Appellate Board. Later in the case, the two parties agreed to work with the Court direction to provide mediation. The mediation also has however failed, and the both the parties are back in the Court.

Sorafenib:

The patent covering the famous drug of Bayer used for treating kidney, liver and radioactive iodine resistant advanced thyroid cancers was the subject of the first Compulsory License granted to NatcoPharma Ltd. In December 2014 Supreme Court rejected Bayer's Special Leave Petition (SLP application) that challenged a July, 2014 order of the Bombay High Court that upheld the grant of the Compulsory License to produce a cheaper version of its patented drug Sorafenib[8].

Bayer had filed infringement suit against Cipla in 2010 for the infringement of its patented drug Sorafenib.The Delhi High Court did not grant interim injunction to Plaintiff in 2010 suit which is still pending with the Court.

Dasatinib:

Bristol-Myers Squibb's (BMS) patent covering the drug molecule Dasatinib survived the Compulsory License grant by the Patent Office in 2013. Dastanib is a multi-BCR/Abl and Src family tyrosine kinase inhibitor for first line use in

[6] *CS(OS) 586/2013, High Court of Delhi*

[7] *CS(OS) No. 89/2008, CC 52/2008 & CM No.6436/2013 in RFA(OS) 92/2012 in High Court of Delhi*

[8] *SC 30145/2014*

patients with chronic myelogenous leukemia (CML) and Philadelphia chromosome – positive acute lymphoblastic leukemia (Ph+ ALL).

Earlier BMS had filed infringement suits against several parties for infringing its patent covering the drug molecule Dasatinib. It managed to get interim injunctions against Dr. BPS Reddy, Hetero Drugs, BDR Pharmaceuticals and Natco to restrain them from infringing its patent. Delhi High Court however refused granting an interim injunction against Shilpa Medicare for the same drug.

Vildagliptin:

Novartis filed several suits of infringement against parties infringing its drug molecule Vildagliptin, an anti-hyperglycemic agent of the Dipeptidyl Peptidase-4 (DPP-4) inhibitor class of drugs.

In seven separate suits for infringement filed by Novartis in the Delhi High Court in 2014 against the various Indian Generic companies like Ranbaxy Laboratories, Wockhardt Ltd, Biocon, Alembic Pharmaceuticals, Glenmark Generics, Cadila Healthcare and Bajaj Healthcare, *quia timet* ex-parte interim injunctions were granted to Novartis. The Court granted permanent injunction to Novartis against Bajaj Healthcare.

Atazanavir:

Bristol-Myers Squibb (BMS) was denied an interim injunction by Hyderabad Trial Court in a suit against generic manufacturer Matrix (owned by Mylan) regarding the export of HIV Drug Atazanavir to Venezuela. While BMS had no product patents in either India or Venezuela, they had brought the suit on the basis of two secondary process patents.

The plaintiff appealed in the Hyderabad High Court against the trial Court decision that was rejected and thereby denying the interim injunction application, noting that the applicants failed to demonstrate a prima facie case and balance of convenience in its favour.

Glatiramer Acetate:

Teva Pharmaceutical Industries Ltd (Teva) was denied interim injunction against Natco Pharma Ltd by the Delhi High Court in an infringement suit for infringement of two patents covering the process of making Glatiramer Acetate for want of appropriate jurisdiction. Glatiramer Acetate is an immunomodulator drug used to treat multiple sclerosis. Natco is manufacturing Glatiramer Acetate in India on behalf of Mylan for sale outside India. The Court refused the application on the basis of Delhi High Court not being the correct jurisdiction as the patents in question were process patents and not product patents.

Saxagliptin:

Astra Zeneca AB sued Glenmark Generics Ltd for infringing its patent on its anti-diabetic drug Saxagliptin monohydrate which is co-developed by Bristol Myers Squibb. The plaintiff alleged that Glenmark exported the Saxagliptin. The Delhi High Court has passed a status quo order that allows Glenmark to continue export of Saxagliptin Monohydrate only.

Linezolid:

Symed Laboratories Pvt. Ltd. (Symed) filed suits of infringement against several parties for infringement of its patents covering Linezolid intermediates and process for the perpetration of Linezolid and related compounds. Linezolid is a synthetic antibiotic.

The court granted ex-parte injunctions against Sharon Bio-Medicine and Optimus Pharma and permanent injunction against Alken Laboratories.

Imatinib Mesylate:

Novartis AG sued several generic manufacturers over the strength of its EMR (Exclusive Marketing Right) obtained for its drug, the beta crystalline form of Imatinib Mesylate in the Madras High Court. The Court issued an ex-parte injunction against six generic manufactures (which includes Cipla, Ranbaxy, SunPharma, Emcure, Hetero Drugs, Intas) preventing them from producing the drug. However, in another parallel litigation, the Bombay High Court refused to grant injunction against Meher Pharma, while ex-parte injunction granted in favour of plaintiff in

Adarsh Pharma case.

Entecavir

Bristol - Myers Squibb filed a suit for infringement of its patent covering Entecavir, an antiviral drug used in the treatment of Hepatitis B virus (HBV) infection.The plaintiff prayed for permanent injunction to restrain Ranbaxy Laboratories from infringing its patent at Delhi High Court but injunction was not granted by the Court.

Sunitinib

Pfizer and Sugen were granted an injunction preventing Cipla from launching Sunitinib that flouted their patent for the drug molecule by the Delhi High Court. Sunitinib is a multi-targeted receptor tyrosine kinase (RTK) inhibitor for the treatment of Renal Cell Carcinoma (RCC) and Gastrointestinal Stromal Tumor (GIST). Injunction was also granted against Natco and two other defendants.

Indacaterol

Novartis filed a suit for permanent injunction against Cipla Ltd and got restraining orders against Cipla for infringing its patent covering its drug molecule Indacaterol, an ultra long-acting Beta 2- agonist approved for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

Others:

Vifor (International) AG obtained ex-parte interim injunction against Symed Laboratories for violation of its patent which is related to process for preparation of water soluble iron carbohydrate complex of a particular weight.

In Cadila vs Instacare Laboratories related to patent for process for amoxicillin formulation, the Ahmedabad High Court vacated the Trial Court's order of rejecting ex-parte ad-interim injunction to Cadila.

In K Ramu vs. AdayarAnandaBhavan and Muthulakshmi Bhavanthe Madras High Court granted interlocutory injunction for its patent which is related to low glycemic sweets.

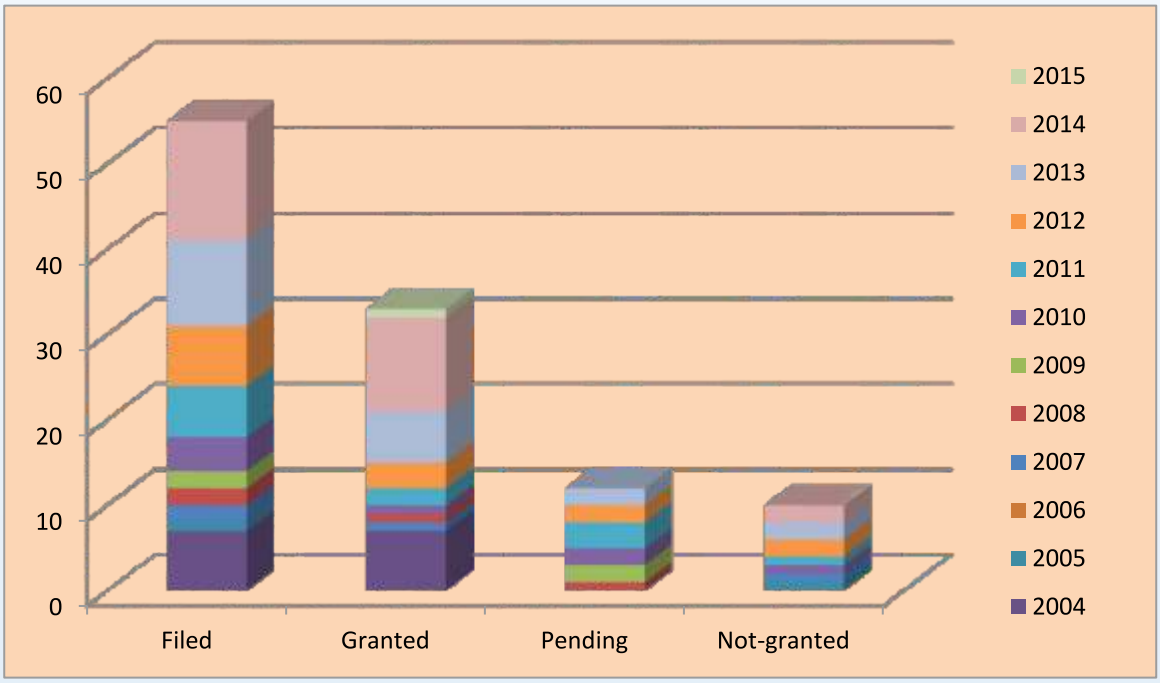

Figure 1: Year-wise trend in the grant of injunctions in India

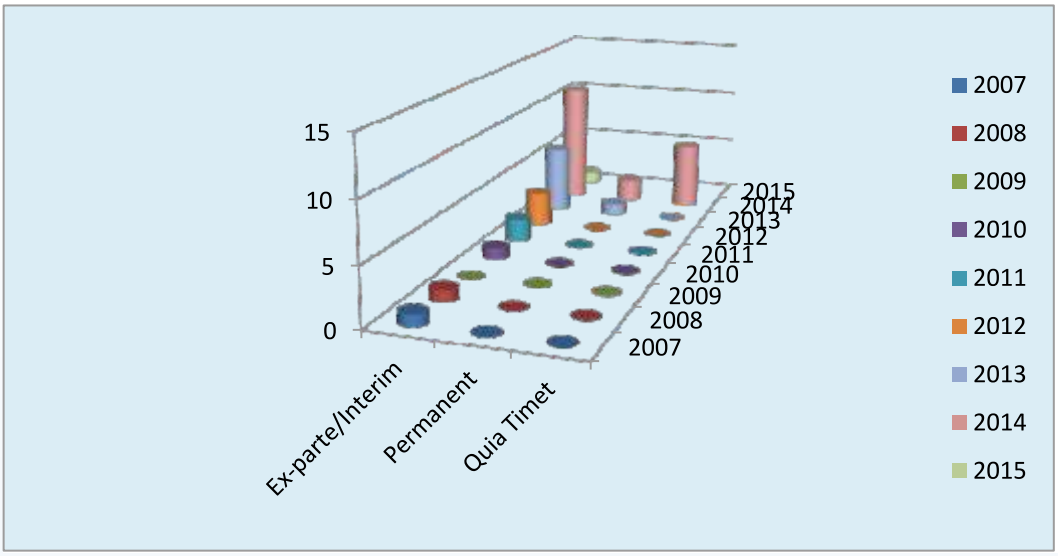

Figure 2: Year-wise trend in the grant of ex-parte/interim and permanent injunctions and *quia timet* actions in India

Conclusion

The data above reflects that nobody in the country has the 'Right to Infringe' and that the Indian Judicial System is proactive in protecting the rights of proprietary pharmaceutical companies in India. The balance in fact is much tilted in favour of innovator companies. This is good news for innovation in India. As we struggle to find solutions to our unique problems in the health sector, an innovator friendly environment will go a long way in steering our industry towards it. Besides the life threatening diseases like AIDS and cancer, we have also seen the prevalence of lifestyle related diseases taking a huge toll of lives and resources in the country. Innovation supported by a conducivelegal environment is perhaps the key to a healthy India.

Disclaimer: The data presented above may not be exhaustive as it is based on internet search albeit a comprehensive one. The purpose of this article is to project to our readers a general trend vis-à-vis grant of injunctions in the pharmaceutical sector in India.

Notes: We can provide the details of cases related to each case on request.

NEW DEVELOPMENTS AT THE INDIAN PATENT OFFICE

The end of the year 2014 and the beginning of the year 2015 have seen a series of welcoming developments undertaken by the Controller General of Patents Design & Trademarks with an aim to improve the working of the Patent Office.

- Electronic Mail Intimation of the Patent Examination Reports

  The Controller General (CG) of the Indian Patent Office launched the service of electronic mail intimation of the issued Patent Examination Reports on real time basis. The CG suggested that the applicants/authorized agentsupdate their email IDs against the respective applications in case they had not been already provided.

- Explore IP INDIA

  The Controller General launched an umbrella service that is a one stop information portal for data related to the Intellectual Property Office in India. Data related to patents, designs, trademarks and geographical indications can be accessed from a single page at http://www.ipindia.gov.in/explore_ipindia_f.htm. Data that was spread across the Patent Office website has now been consolidated under one head that also includes the Controller's decisions. Information also includes particulars regarding working of the Patent Office as the International Search Agency (ISA) and International Preliminary Examination Agency (PEA) and the Rajiv Gandhi National Institute of Intellectual Property Management (RGNIIPM). It is hoped that this will give a boost to the transparency drive undertaken by the IPO in India. The portal is comprehensive and useful that contains all the information that is needed by an IP practitioner.

- Cause List for Patent hearings

  Hearing appointments at the Delhi Patent Office will now be notified in a Cause List on the IPO website and can be accessed at http://ipindiaservices.gov.in/rqstatus/Cause_list.ASPX .

PATENT WORKING STATEMENT

The working of an invention in India is a requirement under the Indian Patents Act, 1970.This requirement has come into sharp focus since the issuance of the first Compulsory License in India.While non-working of an invention is not a ground for opposition or revocation of a patent, it is a ground for the grant of a compulsory license. This requirement is hence virtually intertwined with the compulsory license conditions. We explain the requirements under this section, and also analyze in detail as to what exactly this requirement is and what it entails as per the Act and judicial precedence.

Background

Section 146 of the Patents Act, 1970 read with rule 131 of the Patents Rules, 2003 requires the submission of working statement by every patentee. The pertinent section reads as:

146. Power of Controller to call for information from patentees.—

(1) The Controller may, at any time during the continuance of the patent, by notice in writing, require a patentee or a licensee, exclusive or otherwise, to furnish to him within two months from the date of such notice or within such further time as the Controller may allow, such information or such periodical statements as to the extent to which the patented invention has been commercially worked in India as may be specified in the notice.

(2) Without prejudice to the provisions of sub-section (1), every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India.

(3) The Controller may publish the information received by him under subsection (1) or sub-section (2) in such manner as may be prescribed.

The consequences of non-compliance to this section are covered by section 122 of the Indian Patents Act, 1970 and reads as:

"122. 1) If any person refuses or fails to furnish—

(a) to the Central Government any information which he is required to furnish under sub-section (5) of section 100;

(b) to the Controller any information or statement which he is required to furnish by or under section 146, he shall be punishable with fine which may extend to ten lakh rupees.

(2) If any person, being required to furnish any such information as is referred to in sub-section (1), furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both".

There are two aspects to this provision. Section 146(1) of Indian Patents Act provides that the Controller has the power to call for information or periodical statements as to the extent to which the patented invention has been commercially worked in India from a patentee or patent licensees. The patentee or the patent licensee is required to furnish such information to the Controller within two months from the date of such notice or such further period as the Controller may allow.

Section 146(2) of the Act and Rule 131(2) of the Patent Rules 2003 provide that every patentee and patent licensee should furnish the details of working of the patented invention in Form 27 in respect of every calendar year within three months of the end of each year. A patentee or patent licensee can file such information for a given calendar year latest by 31st March of the following year.

The Patent Act repeatedly refers to the 'working' of a patent. We enumerate below what is the expectation from the patentee in this regard.

What is meant by 'working'

The issues being discussed are:

- Does working mean only local manufacture
- Does working include imports

- Does working mean sale on a commercial scale, whether locally manufactured or imported

Before taking up each issue, we would like to enumerate various provisions and/or requirements in this regard under the Indian Patents Act, 1970. We also touch upon the provisions under the TRIPS and the Paris Convention in this regard.

The working requirement has been covered in the Patents Act, in section 83 that expostulates the general principles applicable to working of patented inventions.

Section 83 reads as:

"83. General principles applicable to working of patented inventions.—Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely;—

*(a)**that 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;***

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."(emphasis ours)

While this section enumerates only guiding principles, it more or less sets the tone of the Act and the intention of the Legislature in postulating the Patents Act in India.

As per section 84 of the Indian Patents Act non-working is a ground for granting a compulsory license. The pertinent section reads as:

"84. Compulsory licences. (1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:—

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied,or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

*(c)**that the patented invention is not worked in the territory of India"**(emphasis ours)*

84(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

……

(e) 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 by—

(i) the patentee or persons claiming under him or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement."

Section 89 explains the purpose for granting compulsory license and reads as:

"89. General purposes for granting compulsory licences.—The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,—

(a) that patented inventions are worked on a commercial scale in the territory of India

without undue delay and to the fullest extent that is reasonably practicable;"(emphasis ours)

Article 5 of the Paris Convention states that:

"Article 5

A. Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses. —B. Industrial Designs: Failure to Work; Importation of Articles. — C. Marks: Failure to Use; DifferentForms; Use by Co–proprietors. — D. Patents, Utility Models, Marks, Industrial Designs: Marking]

A.—(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work……."

Article 27 of TRIPS :

"1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions,whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.Subject to paragraph 4 of Article 65, paragraph 8 ofArticle 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable withoutdiscrimination as to the place of invention, the field of technology and whether products are importedor locally produced……."

Article 30 deals with the "Exceptions to Rights Conferred" and Article 31 to "Other Use Without Authorization of the Right Holder" (not being reproduced here).

While granting the compulsory license to NatcoPharma Ltd.for Patent Number 215758 covering 'SorafenibTosylate' a proprietary drug manufactured by Bayer Corporation, the Controller General(of the Patent Office)refused to accept Bayer's argument that the meaning of the word 'worked' would mean supplying to the Indian market and using it in the sense of actual manufacturing in India would be beyond the scope of the Act. The Controller said that this provision was in consonance with both the TRIPS Agreement and the Paris Convention.Pondering further on this point the Controller was of the view that a patentee is obligated to transfer and disseminate technology both nationally and internationally to balance the rights of the patentees with its obligations. Despite having manufacturing facilities in India, including for Oncology drugs, the patentee had failed to manufacture the same in India and therefore attracted the provisions of this sub-section.

In Novartis AG vs Cipla Ltd, I.A. No.24863/2014 IN CS(OS) 3812/2014, the Court held that *"……With regard to the argument of the Defendant that the Plaintiff is not manufacturing the drug in India is concerned, the requirement of law is limited to working the patent in India so that the same is available to public at large. It is not essential that the patent must be worked by manufacturing the patented product in India……The Act does not mandate that no patent protection would be granted to a patentee unless the local manufacture is undertaken"* The Court emphatically noted that non-working of a patent could not be taken as a defence to a suit of infringement in a civil Court. The Court averred that the appropriate forum for taking up the issue of non-working of a patent would be to seek compulsory license before the relevant authority.

In the challenge to the compulsory license by Bayer in the Intellectual Property Appellate Board (IPAB) (2013 Indlaw IPAB 20) the IPAB, held that the working requirement would be met only if the invention is worked on a commercial scale in India, even if it constituted only import, and subsidized programmes would not constitute 'working the invention on a commercial scale'. Expostulating further on this, the IPAB held that *"in a given case there may be an invention which cannot be manufactured in India and it is also possible that there is an invention where the*

reasonable requirement of public itself is small in number and setting up a factory just for the said purpose is not practicable……Therefore, we cannot decide that "the working" totally excludes import, or that "working" is synonymous to "import" and that if there is no manufacture in India, then there is no working…… So, with regard to S. 84(1)(c), we find that the word 'worked' must be decided on a case to case basis and it may be proved in a given case, that 'working' can be done only by way of import, but that cannot apply to all other cases. The patentee must show why it could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence ……Working cannot mean that the requirement of working would be satisfied by having import monopoly for all patented inventions……Therefore, 'working' could mean local manufacture entirely and 'working' in some cases could mean only importation. It would depend on the facts and evidence of each case."

While coming to the above conclusion IPAB considered the Article 27 of the TRIPS and Article 5 of the Paris Convention that states that importation by the patentee of the articles for which patent has been granted will not be a ground for forfeiture of the patent. However Articles 30 and 31 give exceptions to the member countries and to consider this on a case to case basis.

It is pertinent to add here that as per section 84(7) of the Indian Patents Act, the working requirement is not met by importation only under the conditions that it is being hindered by importation from abroad.

The working requirement in India can be summarized as follows;

- Working requirement would be satisfied only if the invention has been sold on a commercial scale and would not include that which is distributed/made available to the public under subsidized or other programmes.
- The working requirement would be dealt with on a case to case basis as in some cases it would mean only importation and in others it would mean local manufacture
- The patentee may be required to show why it could not be manufactured locally.

Conclusion

The working statements submitted by the patentees may be used while deciding on applications for compulsory license on patents. It is pertinent to add here that in case of suits of infringement, these working statements may be used for calculating the account of profit on one hand and on the other hand in case of non-availability of said information, may give the infringer an argument that the patent owner might not have encountered any damages.

Patent Office has made available all of the "Statements of Working" filed by the respective Patentee on the Patent office website dated June 27, 2014 and can be accessed at http://ipindiaonline.gov.in/workingofpatents/

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ADVOCATES

THE PATENT TEAM

Chander M Lall is the Founder Partner of Lall &Sethi and heads up the Litigation Department of the firm. He is one of the most renowned IP litigators of the country having argued several cases on virtually all aspects of IP law in the Delhi High Court as also the High Courts of Bombay, Madras and Calcutta and the Supreme Court of India. As the Founding Partner, he pioneered the concept of outsourcing of patent drafting work to India. This was done in collaboration with a US Law firm. His knowledge of IT and related services helped the firm develop one of the most efficient IP Management Software which the firm currently markets under the name of ClickIPR. Chander Lall has served on the Board of Directors of the International Trade Marks Association (INTA). He is also the current President of Intellectual Property Attorneys Association.

Dr. Anju Khanna is heading the Patents Department at Lall & Sethi. She has approximately 14 years' experience in execution of Patents, other Intellectual Property Rights and scientific research with exposure at institutions of excellence like the Indian Institute of Technology, Delhi, the Indian Institute of Science, Bangalore and the National Institute of Fashion Technology, Delhi.

Anju, a Partner with the firm, is handling the entire array of Patent matters involving patent drafting and filing, PCT Applications in national & international phases, prosecution, oppositions, enforcement strategies, assignments and other legal issues arising thereto. Currently Anju also handles Patent matters in Bangladesh and will be handling the entire range of Patent matters for other SAARC countries (Pakistan, Sri Lanka, Nepal and Bhutan).

Anju is a PhD from the Indian Institute of Technology (IIT), Delhi in Chemistry with post doctorate in Polymer Chemistry. She has also worked briefly on a short project in Bioinformatics from IIT Delhi. She has worked extensively in the area of organo-Tellurium and organo-Selenium compounds and the area of conducting polymers. She has handled synthesis and analysis of both small and big molecules using the several scientific techniques.

Anju is registered with Indian Patent Office as a "Registered Patent Agent". She is a member of INTA and APAA.

Anju has five publications in the field of chemistry to her credit in international and national peer reviewed journals of high repute. She has also been writing in the field of IPR and has created 'IPR Manual' for the benefit of students and faculty of NIFT. She has also formulated the IPR Policy and the Trade Marks Management Policy of NIFT and made significant contribution towards research and other policies of the institute.

Mohit Kumar Choudhary is a Patent Attorney and an associate at Lall & Sethi. He holds an Electrical & Electronics Engineering degree and a law degree from Delhi University. Mohit represents clients in the field of electrical & electronics, telecommunication, mechanical, packaging engineering, mechatronics, IT/software, medical devices & diagnostic equipments, healthcare and related subject matter with the Indian Patent Office and other foreign Patent Offices.

He deals in all matters and procedures relating to patent law and practice, such as patent prosecution, opposition, revocation etc. He handles the technical aspects of patent prosecution, patent analytics, patent enforcement, drafting the specifications, searching, freedom to operate analysis and provides technical expertise during invention evaluation. His area of work includes matters involving Intellectual Property Rights and related laws including Patents, Trademarks, Copyrights, and Designs etc.

Mohit is a registered Indian Patent Agent and also registered with the Bar council of Delhi. He is an active member of ISHRAE, Indian Society of Heating, Refrigeration and Air Conditioning Engineers which is an International Associate of ASHRAE, the American Society of Heating, Refrigerating and Air Conditioning Engineers.

Dr. Priti Aggarwal is a PhD in synthetic organic chemistry with 8 years of experience in managing intellectual property in the pharmaceutical sector.

Priti has worked extensively in the pharmaceutical sector having worked in the Patents Divisions of TEVA and RANBAXY. At TEVA she was a Senior Manager in Global Legal and Patent Group and at RANBAXY she was a Senior Research Scientist in the API group.

Priti'stechnical skills include: chemistry, patentability, cheminformatics, patent designing, drafting, prosecution, litigation, infringement & invalidity opinions, German language landscaping and opposition. She has a sound knowledge of patent databases and drug regulatory approval process. Skilled in Patent laws of various countries and implementation of these laws to patent related matters.

Priti has worked on several molecules like Odanacatib, Simprenavir, Ibrutiib, Afatinib, Sofosbuvir, Ledipasvir etc. She has provided opinions related to products like Ingenol, Rifaximin, Romidepsin, Dabigatran, Telmisartan, Fosamprenavir, Rosuvastatin etc. She has successfully worked on pre-grant and post-grant oppositions in India for molecules like Fosamprenavir, Imatinib, Valacyclovir, Valgancyclovir, Azilsartan etc. She has worked with customers like Mylan, Lupin, Hetero and Glenmark for various small molecules and biopharmaceutical products and finished dosage forms.

Priti has three publications in the field of chemistry in Indian and international, peer-reviewed journals of high repute. She actively participates in seminars and workshops related to the pharmaceutical industry across the country.

Ms. Manika Arora is a Masters' in Biotechnology and holds a law degree from the Indian Institute of Technology, Kharagpur. She is an Associate with Lall & Sethi.

Manika has worked closely with pharmaceutical and life sciences clients and has drafted Biotechnology as well as pharmaceutical patents relating to API's, formulations, methods and kit claims. In her earlier stint at a law firm, she has handled patent portfolio of several pharmaceutical clients like Fresenius Kabi and worked on their revocations and oppositions against a line of various oncological molecule and salt patents and applications (Tyrosine Kinase Inhibitors). She has represented her client in disputes involving molecules like Bimatoprost, Timolol (*Allergan v. Ajanta*) and Erlotinib (*Hoffman La Roche v. Mylan)*.

Manika completed her Master's dissertation thesis at the National Center for Biological Sciences, Bangalore on the Projected Entitled 'Regulation of apoptosis during salivary glands development in *Drosophila Melanogaster'*

Pankaj Aseri is an IP attorney and an Associate at Lall &Sethi Advocates. He pursued his Bachelor of Law and Sciences from the National Law University, Jodhpur. His work profile involves Trade Marks, Patent, Design prosecution and enforcements including Customs recordals. He represents clients in the field of IT and software, telecommunication, mechanical and allied subject matter with the Indian Trade Mark and Patent Office and other foreign IP Offices. He also keeps keen interest in healthcare sector. He advises several fortune 500 healthcare companies with legal opinions on complex IP issues arising from emerging technologies and brands.

In addition to his professional obligations, he has also been invited as guest lecturer and Judge for Moot Court Competition organized by various organizations and institutions.

Subhash Bhutoria is a practicing lawyer and is working with Lall and Sethi as Senior Associate – Litigation. Subhash pursued his Bachelor of Law and Sciences from the National Law University, Jodhpur and joined the Bar in the year 2009. His work profile primarily involves IPR related litigation and enforcement, which entails his regular appearances before the Delhi Courts, IP Tribunals and Forums. Subhash is well versed in Procedural laws, Court filing requirements and has also conducted several Anti-Counterfeiting raids and commissions.

In addition to his professional obligations, Subhash has authored several articles and publications and is also invited as guest lecturer and Judge for Moot Court Competition organized by various organizations and institutions. He is also selected by the National Internet Exchange of India for the 2014 Fellowship program.

Nancy Roy is a practicing lawyer and is working with Lall and Sethi as an Associate – Litigation. Nancy has an LLB (Hons) Degree from the Guru Gobind Singh Indraprastha University, New Delhi and joined the Bar in the year 2010. She also is a Gold Medalist in the Post Graduate Diploma Course in Intellectual Property Rights from the Indian Society of International Law with a specialized paper on Patent Cooperation Treaty. Prior to joining Lall &Sethi Nancy has worked as a Judicial Clerk with Justice V.K. Shali of the Delhi High Court and has an in-depth knowledge of the working of the Delhi High Court. Her work profile at Lall &Sethi primarily involves IPR related litigation and enforcement, which entails her regular appearances before various Courts. Nancy has assisted Mr. Lall in arguments before the Supreme Court of India, Delhi High Court, Calcutta High Court, IP Tribunals and Forums. Nancy is well versed in Procedural laws, Court filing requirements and has also conducted several Anti-Counterfeiting raids and commissions.

Anuj Nair is a practicing lawyer and is working with Lall &Sethi as a Junior Associate- Litigation. Anuj has a double degree as a Bachelor of Business Administration and Law by way of an integrated BBA.LLB program completed at Symbiosis Law School, Pune and has joined the Bar in the year 2012. Prior to joining Lall &Sethi, Anuj has worked with an independent legal practitioner and has extensive experience in the aspect of prosecution of Trade Marks along with litigation experience . He has also interned with Senior Advocate Mr. MukulRohatgi who is the current Attorney General of India.

His work profile at Lall &Sethi primarily involves IPR related litigation and enforcement, anti-counterfeiting raids . In addition to being well versed with Procedural Laws and matters at court, he also includes his regular appearances before various Courts and assistance to Mr. Lall at Litigation Proceedings.