LALL & SETHI
ADVOCATES

THE PATENTS NEWSLETTER

This is an eventful time for intellectual property, in particular patents, in India. There has been a churning of sorts at the Indian Patent Office. With the start of comprehensive e-filing services, the system has become swift, transparent and more accessible than before. The on-line filing system for instance has been streamlined, though there still are errors and glitches in the process. The IPO has also taken initiative in publishing guidelines for the examination of patent applications of different technology domains and also invited stakeholders' opinion for streamlining the examination process. With India becoming an International Searching Agency (ISA) and International Preliminary Examination Authority (IPEA) under the Patent Cooperation Treaty (PCT) it is expected that the usage of the PCT system by the Indian inventors will rise. There has been a substantial increase in patent litigations post 2005 amendment with domestic generic companies fighting with big multinational pharmaceutical patentees. The dust after the Novartis judgment has now settled and the increase in filing of new patent applications and rise in IP litigation even during economic slowdown clearly suggests a healthy IP atmosphere which is striving for balancing the public health and the innovation. Additionally, the new government is taking measures for creating IP awareness through educational institution level program as well as cluster level IP awareness in association with industry associations.

This issue of Patents newsletter includes a landmark judgment by Supreme Court against simultaneous proceedings against the same patent. Further, it includes a featured article on the patent working statement. It also highlights a comparative analysis of Designs Act 2000 and The Patents Act 1970 in light of a key judgment of M.C. Jayasingh v. Mishra Dhatu Nigam Limited. Additionally, it also covers the Section 8 requirements of the Indian patent prosecution which has time and again proved to be a bête noire to the patentee/patent applicant.

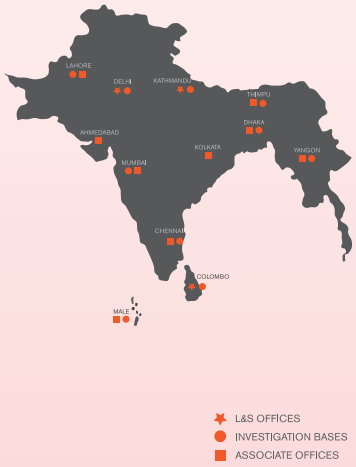
We strive to bring forward the policy issues and the key judgments passed by the Hon'ble court and other judicial bodies shaping the Indian Patent system in a remarkable manner. We welcome you to this issue of newsletter and would look forward for your feedback and inputs.

INDIA
D -17 South Extension-II
New Delhi 110 049
India
E: info@indiaip.com
P: +91 11 4289 9999
F: +91 11 4289 9900

SRI LANKA
Level 10, East Wing,
Ceylinco House,
69, Janadhipathi Mawatha,
Colombo 01
Sri Lanka
E: srilanka@indiaip.com

NEPAL
Lali Gurans Marg,
Ghatte Kulo,
P O Box No. 9760,
Kathmandu
Nepal
E: nepal@indiaip.com

www.IndiaIP.com



SC rules against simultaneous proceedings against the same patent

In a landmark judgment the Supreme Court has sought to correct the trend of simultaneous assailment of a patent in different forums. The Hon'bleCourt held that simultaneous remedies to assail the same patent are not available under the Indian Patents Act and under Section 10 of the Code of Civil Procedure (CPC), 1908 read with Section 151 of the CPC.

To give a short background, a dispute over certain Licensing agreements led to a long drawn legal struggle between Dr. Aloys Wobben and Enercon India Limited being fought in multiple forums. This long standing dispute between Dr. Aloys Wobben (Appellant) versus Yogesh Mehra (Respondent) came to the Supreme Court for resolving (2014 Indlaw SC 370). The appellant had filed 19 infringement suits, and the respondents had filed 23 revocation petitions. The respondents had also filed counter-claims to the patent infringement suits filed by the appellant.

The main contentions that the Court dealt with were concerned with the issue of a patent faced with attacks from multiple forums:

- One issue was that if a counter-claim was instituted in response to a suit for infringement of a patent in the High Court, could there be further proceeding in the revocation petition filed before the Intellectual Property Appellate Board (IPAB), whether prior to or after the filing of the suit for infringement.
- The second issue was: could the jurisdiction of a High Court to decide a counter-claim for revocation, which was exclusive, could be taken away, by initiating proceedings simultaneously, before the IPAB.

  The Court emphatically held that "if a "revocation petition" is filed by "any person interested" in exercise of the liberty vested in him under Section 64(1) of the Patents Act, prior to the institution of an "infringement suit" against him, he would be disentitled in law from seeking the revocation of the patent (on the basis whereof an "infringementsuit" has been filed against him) through a "counter-claim"".

  (It is pertinent to add here that section 64 of the Indian Patents Act, 1970 provides for revocation of a patent any time after grant on the grounds listed therein, either on a petition of any person interested or of the Central Government by the Intellectual Property Appellate Board (IPAB) or on a counter-claim in a suit for infringement of the patent by the High Court).

  The Court further held that "where in response to an "infringement suit", the defendant has already sought the revocation of a patent (on the basis whereof the "infringement suit" has been filed) through a "counter-claim", the defendant cannot thereafter, in his capacity as "any person interested" assail the concerned patent, by way of a "revocation petition"". This was based on the provisions of Section 10 of the Code of Civil Procedure (CPC), 1908 read with Section 151 of the CPC that provide that "where an issue is already pending adjudication between the same parties, in a Court having jurisdiction to adjudicate upon the same, a subsequently instituted suit on the same issue between the same parties, cannot be allowed to proceed"

  The third issue, in the same vein as the two above, was that the use of the word "or" in Section 64(1) demonstrated that the liberty granted to any person interested to file a revocation petition, to challenge the grant of a patent to an individual, could not be adopted simultaneously by the same person, i.e., firstly, by filing a revocation petition, and at the same time, by filing a counter-claim in a suit for infringement.

  The Court held that "though more than one remedy was available to the respondents in Section 64 of the Patents Act, the word "or" used therein separating the different remedies provided therein, would disentitle them, to avail of both the remedies, for the same purpose, simultaneously. On principle also, this would be the correct legal position".

- The fourth issue in this regard that came up before the Supreme Court was that if a patent had already been challenged under section 25(2) (opposition to the grant of patent within a year of grant) does the very same person have a right to challenge it again under section 64(1) (revocation proceedings and counter claim in infringement proceedings).

(It is pertinent to add here that section 25(2) under the Indian Patents Act, 1970 provides for opposition to a patent on the grounds listed therein, within one year of grant).

The Court averred "that if "any person interested" has filed proceedings under Section 25(2) of the Patents Act, the same would eclipse all similar rights available to the very same person under Section 64(1) of the Patents Act. This would include the right to file a revocation petition in the capacity of "any person interested" (under Section 64(1) of the Patents Act), as also, the right to seek the revocation of a patent in the capacity of a defendant through a "counter-claim" (also under Section 64(1) of the Patents Act)".

- The fifth issue was the consent order passed by the High Court wherein the respondents (as defendants) had agreed, that the suits and "counter-claims" pending between the parties should be consolidated and should be heard by the High Court itself.

The Hon'ble Court averred that "it would be open for them by consent, to accept one of the remedies, out of the plural remedies, which they would have to pursue in the different cases, pending between them, to settle their dispute.Having consented to one of the available remedies postulated under law, it would not be open to either of the consenting parties, to seek redressal from a forum in addition to the consented forum"

The Hon'ble Court concluded by saying that "We have already concluded hereinabove, that having availed of any one of the above remedies, it is not open to the same person to assail the grant of a patent by choosing the second alternative available to him".

To summarize, the Supreme Court has directed as follows:

- Once a patent has been opposed under section 25(2) of the Indian Patents Act and has been granted thereafter, it cannot be attacked again, by the same person, for revocation under section 64(1) of the Indian Patent Act, either as revocation proceedings under the Act or as a counter claim against infringement claim.
- If a revocation proceeding has been initiated against a patent by a person, the same person would be disentitled to file revocation as a counter claim in infringement proceeding against him with regard to the same patent.
- If a defendant had already availed of revocation as remedy in a counter claim against an infringement proceeding, the same person would be disentitled to file a separate revocation proceeding in front of another authority.

This judgment will have far-reaching effect upon the current scenario where the hapless patentee is attacked from multiple forums and has no choice but to either give up on his patent or fight in front of multiple authorities. It is a moot point that after years of such battles, what would be the motivation left for the patentee to innovate further and how it effects the overall innovation environment in the country in the long run. Though there are several questions left unanswered still in this context, the effect will certainly help in improving the overall innovation environment in the country.

Bombay HC dismisses challenge to Nexavar Compulsory License

The Bombay High Court dismissed a challenge by Bayer AG to the 'IPABs order to grant Natco a compulsory license to manufacture and distribute a generic version of Bayer's patented kidney cancer drug, Nexavar. The court opined that, "We don't see a reason to interfere with the order passed by IPAB and, therefore, the case is dismissed." Further in upholding the Nexavar compulsory license, generic versions of the drug can continue to be manufactured at Rs 8,800 per month, rather than the patented price of Rs. 2.8lakh per month. There still lies an appeal to the Supreme Court if Bayer wishes to take this up, which the Supreme Court will take up only if it believes a question of law is to be decided upon. Public health issues and price difference between the patented drug and its generic counterpart were taken into account while dismissing the said Writ.

PATENT WORKING STATEMENT

The submission of a working statement of 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 (pre-grant or post-grant) or revocation of an application, 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 require 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 of the Patent Rules 2003 provides 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.

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."

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)*

While granting the compulsory license to Natco Pharma 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.

The discussion regarding whether 'working' would mean actual manufacturing in India or being imported and merely sold in India was taken up in detail in the challenge to the compulsory license by Bayer in the Intellectual Property Appellate Board (IPAB) (2013 Indlaw IPAB 20).

The IPAB, in its detailed order, first clarified 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 is required to show that 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/

So far it has been observed that the statements of working are of utmost importance and have been taken seriously in the pharmaceutical industry more than any other sector presently in India.The publishing of working statement information opens various doors of licensing, compulsory licensing which again have their advantages and disadvantages. A strategic approach to the filing of Form 27 i.e. the statement of working of patent is required to bear profits out of not so economically profitable inventions in India.

Section 8 Requirements at the Indian Patent Office

Recent Court, IPAB (Intellectual Property Appellate Board) and Patent Office decisions in India vis-à-vis compliance with Section 8 requirements under the Indian Patents Act has brought this section into a sharp focus and has created trouble many applicants/patentees. This section requires the applicant to inform the Patent Office regarding filings in other jurisdictions corresponding to the same or substantially the same invention as filed in India. There is a stipulated time frame for filing such information. In addition to that the applicant is required to keep the Patent Office informed about the processing of such applications during the pendency of the application in India up till the grant. Keeping in view the gravity this issue has attained, we have prepared a short note that will help explain the requirements under this section.

Section 8 of the Indian Patents Act is reproduced hereunder:

"8. Information and undertaking regarding foreign applications.—

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow—

(a) a statement setting out detailed particulars of such application; and

(b) an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed."

There are two aspects to Section 8 filings. One is the voluntary disclosure as required under section 8 (1) and the other is disclosure as per request from the Controller under Section 8(2).

It is pertinent to add here that failure to disclose information under Section 8 is a ground for revocation of a patent under section 64(m) that reads as:

"64. Revocation of patents.—(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say—

.....

(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;"

It is a ground for pre-grant opposition under section 25(1)(h) that reads as follows:

"25. Opposition to the patent. – (1)Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground—

.....

(h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to

his knowledge;"

It is also a ground for post grant opposition under section 25(2)(h) that reads as follows:

"*25. Opposition to the patent :--(2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:—*

.....

(h) that the patentee has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;"

The issue of non-compliance or partial compliance with the requirements of this section has come before the Courts in a number of cases (Chemtura Corporation vs. Union of India, Roche vs. Cipla, Tata Chemicals vs. Hindustan Lever, Richter Gedeon vs. Cipla, Koninklijke Philips Electronics ... vs Maj. (Retd) SukeshBehl&Anr.) and a few patents in India have been revoked in the recent past for partial non-compliance of such requirement.

The disclosure under **section 8 (1a)** requires that the applicant, while filing Patent application in India, within the prescribed time limit of six months (Rule 12 (1a)), file the details of the applications filed in other countries pertaining to the same or substantially the same invention.

Under **Section 8 (1b)** the applicant undertakes to furnish the **detailed particulars** from **time to time** up to the grant of the patent, within six months of filing in any other country (Rule 12(b)). It may be noted that even if the invention is assigned to another entity in another country, still the applicant is required to keep the Patent Office informed of such an application.

Section 8(2) disclosure is, however under the instructions of the Controller, which normally arises during the examination of the application in the examination report. This disclosure includes information relating to objections, if any, in respect of novelty and patentability of the invention and any other information as may be required by the Controller.

In Chemtura Corporation vs. Union of India, 2009 Indlaw DEL 1705, the Court refused to grant an interim injunction to the Plaintiff (claiming alleged infringement of its Patent No. 213608) on the grounds of non-compliance with sections 8(1)(b) and 8(2). This was a landmark decision and one of the first ones to bring this section into sharp focus. This was the beginning of the hardening of stance requiring strict compliancewith respect to this section by other Courts and forums. The Court in this case asserted that it was the applicant's duty to keep the Controller informed periodically regarding the status of the applications filed in other countries. The periodic update was interpreted by the Court as informing the Patent Office the stage at which application was and *"not a mere furnishing of information whether the application is pending or dismissed"*.With regards to section 8(2) non-compliance, the Court added that "*It cannot be said that the omission to comply with the requirement of Section 8 (2) was not serious enough to affect the decision of the Controller to grant the patent to the Plaintiff."*

Hearing the revocation petition for the same patent (213608) in a separate proceeding at the Intellectual Property Intellectual Board (IPAB) in VRC Continental vs. Uniroyal Chemical Company, Chemtura Corporation and others, 2012 Indlaw IPAB 82, the IPAB revoked Chemtura's patent on the grounds of non-compliance of section 8 and obviousness. The patentee had filed the ISR but had failed to file subsequent USPTO and EPO prosecution details. The IPAB held that mere filing of the ISR initially was not sufficient and that the patentee had specifically withheld the information from the Patent Office by giving in writing that there were no further developments since the initial filing of Form 3 (prescribed form for filing section 8 details).

In Tata Chemicals vs. Hindustan Unilever Limited (HUL),

MANU/IC/0091/2012, the IPAB held that section 8 was not

complied with since IPER and EPO opinions were not revealed to the Patent Office. The word 'processing' was construed as being one "*which would include within it the series of actions or steps to be taken in order to achieve a particular end and would include PCT applications and they would come under the purview of Section 8(2)*".

In Richter vs. Cipla, the Controller rejected the patent application in an opposition proceeding since the patent applicant had failed to reveal to the Patent Office the details of the corresponding applications in the JPO and the USPTO. Applicant's contention that those applications had been abandoned in the said jurisdictions did not hold any ground with the Patent Office. The Patent Office hence must be informed about the prosecution history of every application, even if it is abandoned.

The same theme was repeated in Sugen Inc. vs. Controller General of Patents, Design, Trademark and Geographical Indications,2013 Indlaw IPAB 30, when the IPAB emphasized that "*what has been furnished by the Patentee/Appellant is alone relevant to decide this issue and not what is available on the internet*" (emphasis by the IPAB).

In AjanthaPharma Limited vs. Allergan Inc., 2013 Indlaw IPAB 135, the IPAB asserted that the Section 8 requirements must be complied with and "*the law does not say that the failure to furnish the S.8 details must be deliberate and willful or that the failure must be in regard to material particulars*". In a series of subsequent decisions the IPAB has upheld the importance of section 8 compliance and reiterated time and again that "*S.8 destroys a patent which is otherwise patentable on grounds which have nothing to do with the invention, but only with the Inventor's lapse during the grant proceedings*" (Fresenius Kabi Oncology Limited vsGlaxo Group Limited, 2013 Indlaw IPAB 149). In the same decision IPAB also made it clear that "*we are of the opinion if in any of the foreign offices the patentee had made a division or was required to make a division, in respect of the same or substantially the same invention or had amended or was required to amend in respect of the same invention or substantially the same invention such information regarding division or amendment would also be information required to be furnished under Section 8*".

In a few cases a marginally lenient approach has been adopted by the Courts. In F. Hoffman-La Roche Ltd. vs. Cipla Ltd., MANU/DE/4182/2012, while the Court agreed that Section (8) provisions had been violated, it refused to consider it as a ground for revocation averring that the use of word 'may' in the section 64 gave it the discretion of not revoking the patent on this ground and proceeded not to consider this as a ground for revocation of patent. Section 64 (please see above), while elaborating on the grounds on which a patent can be revoked, uses the word 'may'. In Fresenius Kabi Oncology Limited vsGlaxo Group Limited, 2013 Indlaw IPAB 148, the IPAB averred that "*S.8 of the Act is not intended to be a bonanza for all those who want an inconvenient patent removed*"and that the facts must be pleaded and the Petitioner would need to show how the particular application was for the same or substantially the same invention. A bald statement in this regard would not suffice. In Koninklijke Philips Electronics N. V. v Maj. (Retd) Sukesh Behl and another, 2013 Indlaw DEL 2591, the Court introduced the concept of 'willfulness' in suppressing the Section 8 disclosure to the Patent Office. The Court held that it was not possible for the Court to decide, since it was a triable issue, if the patentee had willfully suppressed information form the Patent Office by filing only partial information under Section 8 and dismissed defendant's application.But these cases are far and few and not the norm.

In most of the cases the Courts have shown zero tolerance for non-compliance with the Section 8 requirements.

We elaborate below the scheme of compliance with Section 8 requirements:

The prescribed form for filing Section 8 details is Form 3 under the Indian Patents Act. The details of the same or substantially the same invention including those that may have been assigned to another person are required to be given. The details are enumerated below:

- Name of the country (in which the application is filed)
- Application number
- Date of filing the application
- Status of the application
- Publication Number
- Publication Date
- Date of grant
- Patent number

Compliance with Section 8(1)(a):

- For compliance with Section 8(1)(a),Form 3 with details as mentioned above is first filed at the time of filing the application.
- Since at the time of filing the application, no details (except for the PCT and/or priority application, if any) or very few may be known to the applicant, the Patent Office has prescribed a limit of six months from the date of filing to submit such details. The second time an updated Form 3 is filed within six months of the date of filing. We request our clients to adhere to this deadline as any delay in such filing can be condoned only with a petition. In the light of Sugen and others we also advise our clients to file any IPER, written opinion, search report etc. that may have been generated.

Section 8(1)(b) compliance:

- This section requires that if there is any other application filed after the six months' period of Section 8(1)(a) compliance up to the grant of the application, detailed particulars of such an application are also required to be filed within six months of such filing. The 'new application' includes any continuity application, CIP, patent of addition, divisional etc. We advise that such an update be filed at the Patent Office within the prescribed limit. In the light of Chemtura, TATA Chemicals, Fresenius and others, the details of divisional, child continuity applications must also be submitted at the Patent Office. In the absence of any clear guidelines from the Patent Office in this regard, we advise our clients that an updated Form 3 be filed every six months from the date of filing of the application. This will also cover any related application that may also have been filed in the interim period.

Section 8(2) compliance:

- As mentioned above, this is in response to the Controller asking for details of processing of the corresponding applications filed in other jurisdictions. The word processing has been construed as including copies of all search and examination reports, office actions, claims as allowed in respect of any family applications including CIPs, divisional applications, patents of addition etc.It is pertinent to add here that in the Examination Report the Examiners always require the applicant to submit the above-mentioned documents including the translations of the granted applications if the same are in a language other than English.

Accordingly, we require our esteemed clients to furnish the aforesaid details to comply with the requirements of Section 8.As a matter of policy we seek periodic updates from our clients in this regard and send constant reminders. For a PCT application, we also check the foreign filing particulars from the National Phase Data available on the Patentscope website and report to our clients with regards to any anomaly that we may find. This helps us in minimizing errors at all stages.

COMPARATIVE ANALYSIS OF DESIGN ACT 2000 & THE PATENTS ACT 1970,

in light of M.C.Jayasingh v. Mishra Dhatu Nigam Limited (2014 Indialaw MAS 305)

The facts in brief are as follows:

The Appellant – Plaintiff had filed an infringement suit against the Respondents – Defendants namely: Mishra Dhatu Nigam Limited (MIDHANI), Apollo Hospitals and Cancer Institute (W.I.A.), Regional Cancer Centre, Adayar, Chennai,

Grounds for filing suit

That the respondents were infringing his patents for prosthesis, more specifically, Custom Mega Prosthesis – Knee Joint Prothesis (subsequently referred to as 'CMP-KJP'). The prosthesis, made of titanium alloy or medical grade stainless steel, were manufactured and marketed by the Appellant as CMP – KJP and were used in limb salvage surgery.

The Court in a comprehensive order citing various precedents from various jurisdiction upheld the validity of the patent and design but also found no infringement by the defendants. The case is important for it lays down the distinction between rights and liabilities under the Patents Act vis-a vis the Design Act which is presented below in the tabular form.

Also the court lays down distinction between section 64 and 107 of the Patent Act:

"75. In other words, there is a distinction between the area of operation of Section 64(1) and the area of operation of Section 107(1). If a defendant wants the plaintiff's patent to be revoked, he must file a counter claim in a suit for infringement. If he is not interested in the revocation of the patent, but is interested only in defending himself against an action for infringement, it is not necessary for him to file a counter claim. Section 107(1) is an enabling provision. This is why it uses the expression 'defence'. A petition for revocation of patent in the form of a counter claim is an offensive action and not a defensive action."

	Patent Act, 1970	Designs Act, 2000
RIGHTS GRANTED	Section 48(a) of the Patent Act, 1970 entitles the proprietor of a patent, to prevent others not merely from making or offering for sale or selling, but also from using or importing the product which is the subject matter of the patent. SECTION 50(2) READ WITH SECTION 48 enables each of the grantees or proprietors of a patent to seek redressal or to enforce the rights conferred under Section 48, for his own benefit even without accounting to the other person or persons.	Does not contain any prescription, indicating the rights conferred upon the registered proprietor of a design. Section 11(1) of the Designs Act, merely indicates that the registered proprietor of a design, shall have copyright in the design, subject to the provisions of the Act. Section 11(1) of the Act, confers a copyright in the registered design, upon the registered proprietor of the design.

	Patent Act, 1970	Designs Act, 2000
DEFENCES AVAILABLE	Section 107 of the Patent Act, 1970 enables a defendant, in a suit for infringement, to invoke any of the grounds under Section 64 as a defense. Section 64 lays down (i) various grounds for revoking a patent (ii) the persons, at whose instance, a patent can be revoked (any 'person interested' and the central government) and (iii) the Authorities competent to revoke a patent (the IPAB and the High Court 'on a counter-claim in a suit for infringement'). *The court read Section 107 and 64 together and held that since Section 107 is an enabling provision which allows defendants to use grounds mentioned in Section 64 as defenses, the absence of a counter-claim would not vitiate the defendant's arguments and therefore proceed to deal with the validity of patent on THREE TEST basis.*	In a suit for injunction, damages and , for the infringement of a registered design, the defendants are at liberty, by virtue of section 22 (3), to raise every ground on which the registration of a design may be cancelled under Section 19, as a ground of defense. *The defendants did not challenge the validity of the design in their written statement, therefore court went on to assess whether the design was infringed.*
VALIDITY & CERTIFICATE OF REGISTRATION	There is no statutory presumption of validity of a patent. To be valid an invention has to satisfy following 3 criteria i.e. *Novelty, inventive step and industrial applicability.* Under Section 13(4) of the Patents Act, *certificate of registration* provides no *warranty of validity* of the patent. This is why the certificates of registration of patent also contain a disclaimer to the effect that the validity of the patent is not guaranteed	A comparison of Sections 4 and 19 would disclose that two requirements which are very fundamental to the existence of a copyright in the registered design are as follows: (i) *novelty and originality* and (ii) *disclosure in prior art*. However, there is no provision in the Designs Act, 2000, which is analogous to Section 13(4) of the Patents Act, 1970. Similarly, the certificates of registration of design also do not contain any disclaimer as is found in the certificates of registration of patents
INFRINGEMENT:	In analyzing infringement, the plaintiff has to establish that there is *no distinguishing feature* between the defendant's product and that of the plaintiff's product. The distinguishing features of the product of the defendant, in an action for infringement need not necessarily pass the test of inventive step, even to escape liability of infringement. *On the basis of above, in the present case, court held that, defendant's prosthesis is dissimilar to that of plaintiff, therefore no infringement.*	In order to establish infringement, the plaintiff has to establish (i) that the shape and configuration of the prosthesis manufactured by the defendant is similar to the shape and/or configuration of the registered design of the plaintiff's product; and (ii) that the similarities between the features of both products in terms of shape and configuration strike the eye of the observer. This is in view of the fact that though a registered design can be in respect of an application to an article, of various features

	Patent Act, 1970	Designs Act, 2000
		such as shape, configuration, pattern or ornamentation or composition of lines, the plaintiff's claim of novelty is restricted only to shape and configuration and not to others. . If a design has in it a striking feature which catches and holds the eyes and which is the one thing that strikes the eye when one looks at the design, a design which otherwise may be like a registered design, but it eliminates the striking feature or alters it so that it is not recognizable, in such a case, it is impossible to say that one is an imitation of the other. The main consideration to be applied is whether the broad features of shape, configuration, pattern etc., are the same or nearly the same. If they are substantially the same, then it is a case of imitation. *In the present case, the court observed that every prosthesis takes the shape and configuration of the bones and knee joints and there is no other shape a distal femoral prosthesis can take, if it is intended to replace a bone affected by tumor. Therefore, infringement was not established*
INJUNCTION	The court applied the three parameters of (1) Prima Facie case (2) Irreparable Injury and (3) Balance of Convenience to the facts and concluded that the *Appellant failed to satisfy any of the criteria therefore no injunction granted.* Further the court decided the issue of prima facie case on visual similarity rather than on functional elements which are normally predominant factors in deciding patent infringement suits. Because of the following reasons: a) The public interest involved and b) The fact that a determination on the basis of functional similarity would grant the Appellant a very wide patent.	Plaintiff has failed to establish infringement and that therefore, he is *not entitled to a permanent injunction* restraining the defendants in any way making, manufacturing, using, selling, offering for sale, marketing or advertising with regard to any prosthesis or any variation thereof by using or utilizing the plaintiff's Design.

MEDIATION A RECENT TREND IN PATENT INFRINGEMENT CASES

Mediation as a procedure to settle patent infringementdisputes has been adopted by many countries. In India two recent cases of patent infringement dispute, mediation has been adopted as a means of settlement:

(i) ROCHE VsCIPLA

(ii) MERCK VsGLENMARK.

After Roche-Cipla (which was India's first post-trial pharma patent ruling)initiated mediation in the recent case involving the Erlotinib patent after a long court battle, Merck and Glenmark follow suit as they attempt to resolve the issue involving Januvia. Whereas Roche-Cipla moved to the path of mediation only following court orders, it was Merck who initiated this surprising move and applied to the courts earlier in July this year to refer the case to the mediation center. As the Defendant, Glenmark also agreed to end the long dispute outside of court, the application was allowed by the court. In both the above cases court refer the matter to Delhi High Court's Mediation and Conciliation Center.

ON PERUSAL OF ROCHE-CIPLA & MERCK-GLENMARK CASES:

In India there is no codified procedure which is to be followed in case of mediation in patent infringement proceedings.Patent infringement cases can be referred for mediation at any stage even post-trial.Mediation can be of 2 types:

a) Court-directed mediation- In this court, by passing an order, gives parties opportunities to settle the matter through mediation, as ordered by Delhi high court in Roche and Cipla case. Court appointed two “seasoned and experienced”

Delhi HC grants injunction to Roche against Biocon and Mylan over biosimilar version of Herceptin

Roche earlier this year filed a suit for injunction against Drug Controller General of India (DGCI) the first respondent, Biocon and Mylan challenging the regulator's approval given to the jointly developed biosimilarTrastuzumab known as Herceptin.

The Plaintiff had raised two specific issues in the suit.

- That the Defendants (Mylan and Biocon) *had not satisfied the requirements for a biosimilar drug* in accordance with the guidelines.
- that the *defendants were seeking to pass off their products as being equivalent in quality and class* to Herceptin® by referring to their products as “biosimilar version of Trastuzumab/Herceptin.

The court considered the second argument (passing off) and granted an interim injunction restraining the defendants from claiming any similarity to Herceptin.

In October 2012, Guidelines on Similar Biologics were released and addressed the regulatory pathway regarding manufacturing process and quality aspects for biosimilars in India. Plaintiff contended that the defendant's protocol and study design for CANMAb™ was filed and approved prior to the release of guidelines. It was further contended that Biocon was conducting the penultimate phase of Clinical trials for their product CANMAb before the guidelines became effective. Accordingly it was pleaded that the defendants be restrained from referring to their products as a “biosimilar product” until appropriate tests and studies as prescribed under the said Guidelines has been conducted. Further the Plaintiff also stated that Indian drug regulator's approval for biosimilars couldn't have come about in 'such a short period' when its 'prescribed procedure' in the guideline is so long.

The court on this issue did not grant any injunction however stated that it is imperative and necessary for defendants to disclose the nature of the approvals of biosimilar product to the Court on the next hearing.

DRAFT GUIDELINES FOR PHARMACEUTICAL INVENTIONS BY PATENT OFFICE

The Patent office issued the guidelines of examination of pharmaceutical patent on ***25th February, 2014***, with the objective to help the Examiners and the Controllers of the Patent Office in achieving consistently uniform standards of patent examination and grant. In case of any conflict between these Guidelines and the Patents Act, 1970 and the Rules made thereunder, the provisions of the Act and Rules will prevail.The draft guidelines try to establish a linkage between the Patents Act and the Biological Diversity Act, 2002 without any force of Law.

Inventions undersection 2 for examination of pharmaceutical patents:

As per sec-2 only products and/or processes for making pharmaceutical compounds are considered to be inventions under the said clause.However there are certain claims which neither pertains neither to product nor to process. Further, an objection with regard to Section 3(i) would be invoked. Necessary care should be exercised to examine those cases in which claimed inventions relate to the second use of already known compounds which have fallen in the public domain [Section 2(1)(j)].

Factors for assessing NOVELTY during the examination:

- Combining of prior arts is not allowed while assessing Novelty
- An application published after the priority date of an application under examination is not considered a prior art
- In product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product. In other words the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process.
- Implicit disclosure & Inherent anticipation of the claimed subject-matter amounts to lack of novelty, rendering the patent to be invalid.
- Claims of combination of pharmaceutical products which has already fallen in the public domain should be dealt under novelty & not under the inventive step.

Factors for assessing INVENTIVE STEP

- Guidelines provide difference between 'a person skilled in the art" (obviousness person) and "a person having average skill in the art" (enablement person).
- ***Hindsight analysis*** i.e. 'obviousness' has to be strictly and objectively judged
- Obviousness exists if, there is ***reasonable expectation of success***, embedded in the prior art which motivates the skilled person to reach to the invention.In the matter of pharmaceutical inventions structural and functional similarity of the product provides this motivation to combine the teachings of the prior arts.
- ***Common general knowledge***: The prior art needs to be judged on the date of priority of the application and not at a later date.

INDUSTRIAL APPLICABILITY for pharmaceutical patent

In order to qualify as being industrially applicablepharmaceutical invention, in addition to use in the respective industry, also has to show "usefulness" in a "distinct and credible manner".

GUIDELINES FOR INVENTIONS NOT PATENTABLE (U/S.3)

- In the context of the pharmaceutical patenting the 'efficacy' u/s.3(d) should be understood as '***therapeutic efficacy***'.The onus is on Applicants to furnish adequate proof of enhanced efficacy of a claimed substance compared to the known substance.
- Whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data.
- Section 3 (e) applicable on patenting of combination inventions in the field of chemical as well as biotechnological sciences.
- In view of sec- 3(i) it is noticed that method of treatments are often claimed in the guise of composition claims. Sometimes, such claims are converted to product claims during examination procedure. Such amendments shall be examined as per Section 57 read with Section 59 of the Act.
- Sec. 3 of the Indian Patents Act defines what constitutes non-patentable subject matter in India, which includes the "mere discovery [...] of any living thing or non-living substance occurring in nature".The draft Guidelines have gone further by stating that any "***compound*isolated *from nature***" falls foul of Sec. 3 and is therefore ***not patentable***However, processes of isolation of these compounds can be considered subject to requirements of Section 2(1)(j) of the Act.
- In order to attract Section 3(d), the subject invention must be a new form of a known substance having established medicinal activity.
- The draft Guidelines addresses the patentability of known compounds for the treatment of new diseases.

MARKUSH STRUCTURE

The draft guidelines suggests that when claiming compounds in the form of Markush claims, the ***complete specification*** of an invention ***should disclose all possible embodiments covered under the claimed Markush formula, and it should provide details of the tests conducted with regard to each embodiment.*** If draft Guidelines be adopted, the IPO is likely to issue pharmaceutical patents of limited scope compared to rights that would be acquired in corresponding patents in other jurisdictions which do not adopt such an onerous stance for Markush claim support. In Markush claims the ***unity of invention [U/S.10(5)]*** shall be considered to be met when the alternatives claimed are of a similar nature. Paragraph 12.16 states that to satisfy unity of invention the intermediate and final products should not be separated, in the process by an intermediate which is not new

DEPOSITION OF BIOLOGICAL MATERIAL

As per the draft Guidelines, in addition to the requirements under section 10(4), nowthe Applicant also has to disclose the "source and geographical origin" of the biological material used in the invention. Not only does this requirement lack legal basis in the Patents Act, it also leaves the Applicants guessing as to how the source and geographic origin is to be determined.

The patent office invited the stakeholders to provide their comments on the proposed guidelines and after the said comments were submitted below provided issues emerged.

SECTION 3(b)

- Inventions contrary to morality to be clarified
- Allowing Patenting of stem cells & other modified cells for therapeutic purposes.
- separate national agency/authority for assessing & deciding on safety matters & banning technologies that have adverse environmental impact

SECTION 3

- Statutory limitations under this clause has been ignored as it only excludes discovery of living/non-living thing/substance and the entire sub-clause is qualified by the word 'mere'
- Medicaments containing non-living substance occurring in nature for an altogether new use to be patentable.
- Applying the Biotech Guidelines to Pharmaceutical inventions is not appropriate

SECTION 3(d)

- Amended Section 3(d) sets up a second tier forqualifying chemical substances/pharmaceuticalproducts to be patentable & also sets an additionalpatentability criterion, which violates TRIPS
- Efficacy should be "therapeutic efficacy" as perNovartis Judgment and No explanation on therapeutic efficacy has beenprovided
- "Mere discovery" is not clarified
- Examples do not cover all the aspects of Section 3(d)

SECTION 3(e)

- Clarity on the requirements of demonstrating synergy is to be given
- More examples where more than one active ingredients are involved to be provided
- Format of "kit" claims to be clarified

SECTION 3(i)

- Exclusion appears on face of Section 3 (i) is broader than the exceptions to patentability under TRIPS
- In-vitro diagnosis & treatment must not be read under the provision
- Method of diagnosis per se is not excluded from patentability because it doesn't amount to 'treatment' and requires medical care that cures certain condition/illness/ injury
- Cosmetic treatments are not the same as surgical methods and do not form part of the prohibitions under Section 3 (i) and the terms "cosmetics" & "purely cosmetic purposes" require explanation

SECTION 3(j)

- Isolated pure culture to be patentable since it is not available in nature as such & the term "genetically" modified is restrictive for patenting of microorganisms

Ø Exception to the provisions of Section 3(j) is genetically modified microorganisms & hence, the same should be applicable in respect of animals as well.

SECTION 3(p)

Ø The guidelines determined the scope of Section 3 (p) way beyond its de facto scope and implication and thereby proving to be detrimental to the Applicants, especially as regards the Guiding Principle 3.

The Patent office will now provide an updated proposed guidelines which will then be open up for further discussion.

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. 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.