

## THE PATENTS NEWSLETTER

In the whirlwind of events marking the patent landscape in India, we strive to keep you updated with our regular editions of the Patents Newsletter and bring you patents news from India fresh off the racks!

We begin with the news from the Indian Patent Office (IPO). First the good news! In its endeavor to deliver better services the comprehensive e-filing system has been upgraded with a new payment gateway that allows payments to be made through more than 70 banks. The IPO is also making significant strides towards its efforts to become more transparent and accessible and has started a facility called the 'Stock and Flow' that gives real time access of the work happening in all the four Patent Offices on the IPO website. It is purported to be the first of its kind amongst the IP offices across the world.

Now the bad news! The pendency of patent applications is one of the biggest challenges faced by the Patent Office. It had got a rap on its knuckles from the Chennai High Court in 2011 for inordinate delay in examination of applications but that had little effect on expediting the examination process. We bring you a snippet on another such case where a writ was filed at the Delhi High Court and the Court has given directions to the Patent Office on how to reduce such pendency.

The general trend of upswing seen in the number of conflicts in the patent arena in the past few years continues to be the same: upswing! Other technology areas now vie for this space with the pharmaceutical sector, especially telecommunications and mechanical. We bring you our analysis in a few such cases.

Not be left far behind is Design! We bring you our analysis of some important issues that the Courts have been grappling with vis-à-vis Design enforcement in India.

At Lall & Sethi we continue to explore and discover our limits and strive to overcome them. The entire office went on a three day long exploration trip to the Himalayas and discovered their adventurous side with bungee jumping, zipping, river rafting and such other activities. We share a few pictures of our adventure.

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### INFRINGED BY DESIGN

Design filings, like utility patent filings, have been growing at a rapid pace in India. The interesting part is that whereas patent filings are dominated by foreign applicants, design filings are dominated by Indian applicants<sup>1</sup>. Increase in filings invariably leads to increase in enforcement efforts and hence litigation.

In the recent past Courts have been confronted with some very interesting issues vis-à-vis design enforcement in India. We summarize here some of these issues and how they have been settled by case law. These issues that have been plaguing (amongst many others) the users and much needed clarity has been given by the Courts in this regard.

The issues can be summarized below:

- Whether a suit for infringement of a registered design is maintainable against another registered design
- Whether an action of passing off is maintainable in respect of a registered design

#### **Maintainability of a suit for infringement of a registered design against another registered design**

Section 22 of the Indian Design Act, 2000 provides for remedies available to a registered proprietor in the event of the piracy of the design. The main contention is regarding the use of the expression 'any person' and what it entails. The pertinent section reads as:

*"22. Piracy of registered design.- (1) During the existence of copyright in any design it shall not be lawful for **any person** - for the purpose of sale to apply or cause to be applied to any article in any class of articles in which the design is registered, the design or any fraudulent or obvious imitation thereof, except with the license or written consent of the registered proprietor, or to do anything with a view to enable the design to be so applied; or to import for the purposes of sale, without the consent of the registered proprietor, any article belonging to the class in which the design has been registered, and having applied to it the design or any fraudulent or obvious imitation thereof, or knowing that the design or any fraudulent or obvious imitation thereof has been applied to any article in any class of articles in which the design is registered without the*

*consent of the registered proprietor, to publish or expose or cause to be published or exposed for sale that article.*

*2. If any person acts in contravention of this section, he shall be liable for every contravention-*

*(a) to pay to the registered proprietor of the design a sum not exceeding twenty-five thousand rupees recoverable as a contract debt, or*

*(b) if the proprietor elects to bring a suit for the recovery of damages for any such contravention, and for an injunction against the repetition thereof, to pay such damages as may be awarded and to be restrained by injunction accordingly: Provided that the total sum recoverable in respect of any one design u/cl. (a) shall not exceed fifty thousand rupees: Provided further that no suit or any other proceeding for relief under this subsection shall be instituted in any court below the court of District Judge.*

*(3) In any suit or any other proceeding for relief under sub-section (2), every ground on which the registration of a design may be cancelled u/s. 19 shall be available as a ground of defence.*

*(4) Notwithstanding anything contained in the second proviso to sub-Section (2), where any ground on which the registration of a design may be cancelled u/s. 19 has been availed of as a ground of defence and sub-s. (3) in any suit or other proceeding for relief under sub-section (2), the suit or such other proceedings shall be transferred by the Court in which the suit or such other proceeding is pending, to the High Court for decision. (5) When the court makes a decree in a suit under sub-section (2), it shall send a copy of the decree to the Controller, who shall cause an entry thereof to be made in the register of designs."*

As mentioned earlier Courts have been grappling with the definition of 'any person'. In a number of cases viz. *Tobu Enterprises Pvt Ltd Vs Megha Enterprises and Anr* (1983 Indlaw DEL 10173), *Asahi Glass Co. Ltd. Vs Jai Mata Rolled Glass Ltd. & Anr.* (1996(16) PTC 220 (Del.)), *Servewell Products Pvt Ltd & Anr. Vs Dolphin* (2010(43) PTC 507 (Del.)), Courts have taken the view that a suit of infringement does not lie against a subsequent registration and that the term 'any person' would not include a subsequent registrant.

<sup>1</sup>[http://ipindia.gov.in/cgpdtn/AnnualReport\\_English\\_2012\\_2013.pdf](http://ipindia.gov.in/cgpdtn/AnnualReport_English_2012_2013.pdf)

There is equal number of cases where the Courts have taken an opposite view viz. *Tobu Enterprises (P) Ltd Vs M/s Joginder Metal Works and Anr.* (1982 Indlaw DEL 125), *Alert India v. Naveen Plastics* (1996 Indlaw DEL 363), *Vikas Jain v. Aftab Ahmed and others* (2008 (37) PTC Del), *Dabur India v. Amit Jain and another* (2008 Indlaw DEL 2232), the Courts have held that a suit of infringement is maintainable against a later registration and that the term ‘any person’ would also include a subsequent registrant.

In *Micolube India Limited vs. Rakesh Kumar Trading As Saurabh Industries & Ors* (CS (OS) No.1446/2011) the Court was again confronted with this issue. Justice Manmohan Singh, while concluding that a suit of infringement does not lie with a subsequent registrant, however referred the matter to a larger bench while himself being a member of the Bench.

The Division Bench of the Delhi High Court (*Mohan Lal and another vs Sona Paint and another* (2013 Indlaw DEL 1319)) sought to clear the air regarding this issue. The majority judgment of the Full Bench held that “A holder of a registered design could institute a suit against a defendant who is also in possession of a registered design”. The Full Bench stated that the previous judgments that held otherwise “failed to appreciate that the registration of a design is *prima facie* evidence of the fact that the design is unique, novel or original or that it is significantly distinguishable from any known design or combinations of designs. Thus, the registration in that sense creates a monopoly in favour of the registrant for the period prescribed under Section 11<sup>2</sup> of the Designs Act. The registrant thus has, in our opinion, the right to assert this monopoly against all and sundry, including a subsequent registrant. There are no words of limitation in Section 4<sup>3</sup>, 11

and 22 which would exclude institution of an action against the subsequent registrant. Therefore, in our opinion, the rationale supplied in *Tobu Enterprises* that the only remedy available to the plaintiff against a subsequent registration would be to seek cancellation of the registration, is flawed.” Hence the Full Bench held that **the expression “any person” found in the Section 22 of the Design Act would not exclude a subsequent registrant as no such words of limitation were found in the said Section.** The dissenting Judge however held that a suit for infringement of a registered design could not lie against another registered proprietor.

It was against this background that this issue again came up in *Whirlpool of India Ltd. vs Videocon Industries Ltd* (2014 Indlaw MUM 594) in the Mumbai High Court where the Plaintiff had filed a case against the defendants for two of their registered designs of washing machine for infringement, passing off and damages. The Plaintiffs had also taken out a Notice of Motion in the Suit (in 2012) and had moved for an ad-interim injunction in the Mumbai High Court that was granted to them in respect of both infringement and passing off July 2012. The decision was challenged by the Defendant that was rejected by the Appeal Court on 13<sup>th</sup> August 2012. In the interim period between the filing of the Suit by the Plaintiff the Defendant had applied for registration of their design applied to their washing machine, “Videocon Pebble” to which registration was granted. On 2nd November, 2012, the Defendant preferred a Special Leave Petition (SLP) against the decision of the Division Bench dated 13<sup>th</sup> August, 2012. In the SLP the Defendant contended that no suit for infringement of design could lie against them since they had secured design registration and also that an action for passing off could not lie in respect of a registered design. As mentioned above,

<sup>2</sup> 11. (1) When a design is registered, the registered proprietor of the design shall, subject to the provisions of this Act, have copyright in the design during ten years from the date of registration.

(2) If, before the expiration of the said ten years, application for the extension of the period of copyright is made to the Controller in the prescribed manner, the Controller shall, on payment of the prescribed fee, extend the period of copy-right for a second period of five years from the expiration of the original period of ten years.

<sup>3</sup> 4. A design which

(a) is not new or original; or

(b) has been disclosed to the public anywhere in India or in any other country by publication in tangible form or by use or in any other way prior to the filing date, or where applicable, the priority date of the application for registration; or

(c) is not significantly distinguishable from known designs or combination of known designs; or

(d) comprises or contains scandalous or obscene matter shall not be registered

these issues had been taken up by the Full bench of the Delhi High Court which had held that a suit for infringement would lie against a registered proprietor. The dissenting Judge had however differed. At the hearing of the SLP these issues were again contended and the Hon'ble Supreme Court held that it was appropriate to await the decision of the Mumbai High Court inter alia these questions since the Notice of Motion was yet to be decided and deferred the hearing of the SIP.

Analyzing the expression 'any person' the Mumbai High Court held that "S. 22 of the Act thus gives the registered proprietor a right to relief against "any person" who applies the design of the registered proprietor to any article of the class of articles in which the design is registered. The words "any person", which are used without any words of limitation, ordinarily must be given their plain and natural meaning - namely, any person whosoever - unless the statute compels by reason of the context in which the words "any person" are used or by reason of the other provisions of the Act to restrict the meaning of the words to "any person other than a registered proprietor".

The Court found the submission of the Defendant that a Court could only examine the validity of the Plaintiff's registration but not examine the Defendant's registration "conceptually illogical". The Court explained that if both the plaintiff and defendant are registered proprietors, the defense of provisions of section 19<sup>4</sup> as available to the defendant against the claims of infringement of the plaintiff's design was also available to the plaintiff as defense against claims of infringement of defendant's design. The Court averred that "*The Defendant - proprietor would have a complete defence to the Plaintiff - Proprietor's action only if his (the Defendant's) registration is prior in*

*point of time, since such prior registration is a ground for cancellation of the Plaintiff's registration. A Defendant proprietor, who holds a subsequent registration cannot plead his subsequent registration in defence to an action under Section 22, since a subsequent registration is no defence within the meaning of S. 22 (3) read with S. 19. That is an obvious consequence of S. 22 from the defendant's point of view. Just as a Plaintiff cannot claim a right to relief under S. 22 against a prior registered proprietor on the basis of his (the Plaintiff's) registration, the defendant cannot successfully defend an action under S. 22 by a prior registered proprietor on the basis of his (the defendant's) registration. It, therefore, cannot be argued that S. 22 (3) has implications only for the Plaintiff's registration and not for the Defendant's registration. The Court may consider both the Plaintiff's and the Defendant's registrations in the light of S. 22 (3) and grant or reject the relief to a Plaintiff depending on whose registration is prior in point of time".*

Differentiating between the reliefs obtained from section 19 and section 22, the Court held three points of differences between them:

- While section 19 could be invoked to seek cancellation of a registration of a design, section 22 of the Act could be invoked where a registered design of a proprietor was infringed by any person and the registered proprietor sought reliefs in the form of damages, injunction, etc. against the infringer.
- Section 19 entitled a party to move the Controller for cancellation of a design even where the registered proprietor was not using the design while section 22 of the Act afforded a cause of action only where a registered design was being

<sup>4</sup>19. (1) Any person interested may present a petition for the cancellation of the registration of a design at any time after the registration of the design, to the Controller on any of the following grounds, namely:-

(a) that the design has been previously registered in India; or  
(b) that it has been published in India or in any other country prior to the date of registration; or

(c) that the design is not a new or original design; or

(d) that the design is not registrable under this Act; or

(e) it is not a design as defined under clause (d) of section 2.

(2) An appeal shall lie from any order of the Controller under this section to the High Court, and the Controller may at any time refer any such petition to the High Court, and the High Court shall decide any petition so referred.



applied or caused to be applied to any article for the purposes of sale or in relation to or in connection with such sale. Consequently if a registered proprietor did not apply his design to an article for sale or in connection with such sale, another registered proprietor could not have recourse to S. 22 of the Act.

- While section 19 was applicable to ‘any person interested’, section 22 was available only to a small segment of such person viz. registered proprietors.

The Court further averred that it was important to see the Legislative intent behind using the phrase ‘any person’ in section 22 as against the phrase ‘any person other than the proprietor of the design’. Section 29<sup>5</sup> of the Indian Trademark Act for instance unequivocally mentioned the phrase “a person who, not being a registered proprietor....” while enumerating infringement of registered trademarks and limits on effect of registered trademark. Additionally, at various other places in the Design Act different expressions had been used where the Legislature wanted to expressly wish to exclude the registered proprietor. The Court concluded that “I am of the considered view that a registered proprietor of a design can under S. 22 of the Act file a suit for infringement against a registered proprietor of a design”.

### **Maintainability of action of passing off in respect of a registered design**

The debate about the remedy of passing off being available in respect of a registered design has been catching the attention of Courts. In *Micolube India Limited vs. Rakesh Kumar Trading As Saurabh Industries & Ors* (CS (OS) No.1446 /2011), Court held that passing off remedy was not available in respect of a registered design. It held that “Therefore, the prima facie conflict between the two inconsistent remedies can be resolved by applicability of doctrine of election and limited right of passing off exists under the law of trademark wherein the definition of trademark includes shape and configuration of the article but the same cannot be pressed into service when the suitor

*opts for remedy under the Designs Act where there is no such saving of common law remedy nor is there any common law pre-existing which has been continued under the law. Thus, the relief sought by the plaintiff cannot be granted*”. The Court however referred the matter to a Larger Bench which gave the majority judgment in favour of passing off action being maintainable in respect of a registered design.

The Larger Bench held that a “*design could be used a trade mark and if by virtue of its use, goodwill was generated in the course of trade or business, it could be protected by an action in the nature of passing off. The plaintiff would then not have to look to the Designs Act for instituting such an action.*” The Court found the argument that the Legislature by not incorporating a similar provision in the Designs Act, such as Section 27(2)<sup>6</sup> of the Trade Marks Act had by necessary implication excluded the availability of such a remedy, untenable. “*However, if such an action was instituted, the onus to demonstrate, that the registered design was used by him as a trade mark which, in the minds of the purchasing public was associated with his goods or services which had acquired goodwill/reputation which was worth protecting, was on the plaintiff*”. The Court held that a plaintiff would be entitled to institute an action of passing off in respect of a design used by him as a trade mark provided the action contained the necessary ingredients to maintain such a proceeding and this did not mean that such a suit could be instituted only after the expiry of the statutory period provided under Section 11 of the Designs Act. The reason the Court gave for this was that while the Section 2(d)<sup>7</sup> of the Designs Act excluded any trademark from the definition of design, “*however the use of the design as a trademark post its registration is not stipulated as a ground for cancellation under Section 19 of the Designs Act.*” The Court held that The Trade Marks Act did not specifically exclude a design and in fact “*shape of goods*” could be registered as a trademark. Explaining its stand further the Court asserted that this logic was based on the principle that trademark is something which is extra,

<sup>5</sup>29 (1) A registered trade mark is infringed by a person who, not being a registered proprietor or a person using by way of permitted use, uses in the course of trade, a mark which is identical with, or deceptively similar to the trade mark in relation to goods or services in respect of which the trade mark is registered and in such manner as to render the use of the mark likely to be taken as being used as a trade mark:.....

which is added on to the goods to denote origin, while a design forms part of the goods. Hence, while it may not be possible to register simultaneously the same matter as a design and a trade mark, however, post registration there could be no limitation to its use as a trademark by the registrant of the design. The dissenting Judge however differed and held that the action of passing off would not lie with a registered design.

On the question if conception of passing off as available under the Trade Marks could be joined with the action under the Designs Act the Full Bench stated that *“The two actions cannot be combined in one suit”*. The Court was of the opinion a composite suit for infringement of a registered design and a passing off action would not lie. The Court could, however, try the suits together, if the two suits were filed in close proximity and/or it is of the view that there are aspects which are common to the two suits. The discretion of the court in this matter would necessarily be paramount.

In *Videocon Industries Limited vs. Whirlpool of India Limited (MANU/MH/1248/2012)* which was an appeal against injunction, the Court rejecting the appeal against injunction held that *“...to sustain the action of passing off, something more than mere similarity between the goods is needed. Merely selling the similar goods without making false representation, no action of passing off can be sustained. Also there must something unique and distinctive in the design which the consumer associates with the product.....that even though Videocon **may not have actively misrepresented to the consumer, it has nevertheless knowingly created a tool for deception and thus is guilty of passing off. According to us, action of passing off is clearly made out.** The design registered by Whirlpool has been a success and according to them, about three lakh machines have been sold in a short span. The design registered by Whirlpool is very similar to the impugned product. No reason is placed on record as to how*

*the Videocon thought of designing the washing machine with same distinctive shape in June, 2012. To our mind it was to take advantage of popularity of the design of Whirlpool washing machine.”* The Court hence held that passing off action was maintainable for a registered design.

The Courts were again confronted with this issue in *Whirlpool of India Ltd. vs Videocon Industries Ltd (2014 Indlaw MUM 594)* (supra). The Court found the Defendants guilty of passing off their goods/products as that of the Plaintiff. The premise on which this was held was that the shape and configuration of the Plaintiff’s design of washing machine was unique and hugely popular and the Defendant’s design of washing machine was identical. The Court held that *“reason of the fact that no other washing machine with a similar or comparable shape existed in the market prior to the introduction thereof by the Plaintiff, the said novel shape and/or configuration and/or get up and/or overall appearance has come to be identified and/or associated exclusively with the Plaintiff. The existence of the goodwill and/or reputation in the shape of the products stood established”* With regards to novelty *“The first impression has to be of a person with average intelligence and/or imperfect recollection.”* So there was every possibility that such a person would be confused between the two designs and would mistake the Defendant’s product for that of the Plaintiffs. *“Such a person would purchase the Defendant’s product on the belief that it was the Plaintiff’s product or was associated with the Plaintiff. This clearly constitutes passing off.”*

From above analysis it appears that the Courts have tried to give some clarity with regards to the twin issues of maintainability of a suit of infringement against registered proprietor and maintainability of action of passing in a registered design. The Courts have given the view in the affirmative. Now it will be interesting to see how the Hon’ble Supreme Court settles this issue.

<sup>6</sup>27(2) Nothing in this Act shall be deemed to affect rights of action against any person for passing off goods or services as the goods of another person or as services provided by another person, or the remedies in respect thereof.

<sup>7</sup>d) “design” means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything which is in substance a mere mechanical device, and does not include any trade mark as defined in clause (v) of sub-section (1) of section 2 of the Trade and Merchandise Marks Act, 1958 or property mark as defined in section 479 of the Indian Penal Code or any artistic work as defined in clause (c) of section 2 of the Copyright Act, 1957

## **RECENT PATENT INJUNCTIONS IN PHARMACEUTICAL SECTOR IN INDIA**

Under the Indian Patent law injunction is a relief granted against infringement. An injunction is important and is issued as mere award of damages at the end of a trial would not be satisfactory and effective, and may lead to a greater harm or injustice since patent is granted for a limited duration i.e. 20 years.

There are several types of injunctions:

1. Interlocutory granted provisionally before a trial to maintain the status quo until the court hears both sides before granting a permanent injunction.
2. Permanent: granted after the hearing of a trial.
3. *Ex parte*: granted after hearing only one party (in case of a great urgency).
4. Interim: granted to restrain the accused until a certain date.
5. *Qua timet*: granted to prevent a threatened wrong or injury.

Section 108 of the Indian Patents Act enumerates the reliefs available in a suit of infringement and reads as:

*108. 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.*

Ever since the Indian patent law became TRIPS compatible in January 2005 and product patent regime came into being, litigations relating to patent matters have become common. Two trends have been noticed in the field of patent litigation in India. First is that most of the patent litigation in India that had been concentrated in the pharmaceutical sector is now broadening its reach in the past two to three years with telecommunication and mechanical sectors vying for this space. Second is that where in the past, Courts were averse to granting injunctions, especially in the pharmaceutical field, this trend is also slowly reversing. In the pharmaceutical sector while the earlier battles were fought mostly for life-saving and oncology drugs such as Imatinib and Erlotinib, the shift can now be seen to such injunctions being granted for lifestyle drugs such as diabetes.

We bring a short note on injunctions in the pharmaceutical filed.

One of such cases is for anti-hyperglycemic drug Sitagliptin. Merck Sharp and Dohme (MSD) holds a patent no: IN209816 for Sitagliptin (trade name: Januvia, Januvet (phosphate salt of sitagliptin)). MSD had filed a separate application on Sitagliptin phosphate Indian application No. 5948/DELNP/2005 which was rejected and abandoned by Merck.

MSD filed several infringement suits to protect its monopoly over Sitagliptin. The description defines pharmaceutical acceptable salts of Sitagliptin made from non-toxic acids that includes amongst others phosphoric acid.

MSD filed infringement suits against a number of companies as mentioned in Table 1 and was granted interim injunctions against Aprica Pharmaceuticals, Shilpex Pharmysis & Ors, NMC Biopharm & Ors and Vetri Vadivelan and Ors.

However an injunction against Glenmark to prevent it from launching its Generic products Zita (generic version of Januvia) and Zitamet (generic version of Janumet, combination of Sitagliptin + Metmorphin) was denied on the following grounds:

- MSD had filed a separate application on Sitagliptin phosphate Indian application No. 5948/DELNP/2005 which was rejected and abandoned by them. This fact was essentially concealed from the knowledge of the court as also relied upon in the Erlotinib matter in *F. Hoffmann - LA Roche Ltd. and Anr. v. Cipla Ltd., 2009 (40) PTC 125 (Delhi)*,
- MSD had obtained separate US and EP patents on Sitagliptin phosphate wherein it had admitted that Sitagliptin Phosphate was a new discovery over the main product patent by describing the salt as “novel salt”. Further if Sitagliptin phosphate had been not a distinct product from Sitagliptin, MSD would not have applied for or obtained a separate patent.
- MSD’s IN209816 patent is for Sitagliptin Hydrochloride only and not for Sitagliptin Phosphate since there are no illustrations for the phosphate salt and there are only data for the Hydrochloride salt.

It is interesting to note that even though the parent includes phosphoric salt as particularly preferred compound the same was not taken into account by the Courts.

**Table: 1 Infringement suits relating to Sitagliptin for IN209816**

Sitagliptin				
S.No	Case	Suit No.	Injunction	Status and comments
1.	Merck Sharp and Dohme & Anr Vs. Aprica Pharmaceuticals	CS(OS) 1236/2013	Ex-parte injunction granted based on the arguments of Merck that Aprica Pharma plans to launch the medicine with content which is an identical salt covered by IN209816	Pleadings are completed matter is at the final argument stage. The injunction still persists.
2.	Merck Sharp and Dohme & Anr vs. Glenmark	CS(OS) 586/2013	Injunction application by MSD was rejected as Glenmark took the argument that they are manufacturing the Phosphate salt of Sitagliptin which is not covered by IN209816. Since MSD themselves had filed a separate patent application for the phosphate salt 5948/DELNP/2005 corroborated this point further. Further the court acknowledged the prosecution history estoppels, that since the plaintiff had abandoned the said application during prosecution they can no longer claim protection over the same.	The matter was referred to mediation by an order dated 04.07.2014 after the Plaintiff filed an application for settlement. The matter as of now, is pending before the Delhi High Court Mediation and Conciliation Centre.



S.No	Case	Suit No.	Injunction	Status and comments
3.	Merck Sharp and Dohme & Anr vs. Shilpex Pharmysis & Ors	CS(OS) 1488/2013	<b>Ex parte injunction to the plaintiffs granted</b> since the defendants had launched ISTAGLIP-100 (Sitagliptin 100 mg), accordingly the prima facie case was made against the defendant.	The suit has been disposed of in terms of the settlement arrived at between the parties dated 01/11/2013 after a payment of Rs. 51,000 to plaintiff.
4.	Merck Sharp and Dohme & Anr vs NMC Biopharm & Ors	CS(OS) 1688/2013	<b>Ex-parte ad interim injunction granted</b> dated 02.09.2013	A decree of permanent injunction is passed in favour of the plaintiff and against the defendants dated 18/12/2013.
5.	Merck Sharp and Dohme & Anr vs Vetri Vadivelan and Ors	CS(OS) 2664/2013	<b>Ex-parte ad interim injunction granted</b>	Disposed of by the court after recording of settlement and application has been filed.

In yet another group of matters, lately a series of Quia timet injunctions have been granted to Novartis by the Delhi High Court for its Patent No. IN 212815 (herein after referred to as '815) that relates to Compound Vildagliptin its salts and formulation. Vildagliptin is sold under the trade name Glavus is an Antihyperglycemic used as Anti Diabetic Drug.

The whole saga started when Wockhardt Ltd in September, 2013 filed a revocation petition before the IPAB against '815. Novartis filed an RTI with the DCGI (Drug Controller General of India) seeking information regarding regulatory approvals issued for Vildagliptin. The RTI response provided them with a list of manufacturers to whom approval was issued. Soon after that Novartis filed plethora of suits against the companies that have obtained the regulatory approvals for manufacturing Vildagliptin presented in the Table 2 below. The Court granted injunctions since the prima facie case was made out and the Plaintiff would have incurred an irreparable loss if the injunction had not been granted.

In the case where Ranbaxy was the defendant, it argued on line with the Glenmark's argument in Sitagliptin that they intended to market Vildagliptin in crystalline (Form A). Plaintiff by their patent application no. IN4530/DELNP/2007 dated 13.06.2007 had applied for patent of crystalline form of Vildagliptin. However, the said application having been abandoned, the product under the said application had fallen into public domain. It was, therefore, open to a third party to deal with it in any manner whatsoever and thus, the Plaintiffs could not claim any rights qua crystalline form of Vildagliptin. However the Court was not convinced by the said argument and granted the injunction.

**Table: 2 Infringement suits relating to Vildagliptin for IN212815**

<b>Vildagliptin</b>				
<b>S.No</b>	<b>Case</b>	<b>Suit No.</b>	<b>Injunction</b>	<b>Status and comments</b>
1.	Novartis v. Wockhardt Ltd	CS(OS) 646/2014	<b>Ex- Parte Interim Injunction granted</b> on March 5, 2014	Before Joint Registrar on 10.11.2014 for Admission Denial. Before the Court on 08.12.2014.
2.	Novartis v. Biocon	CS(OS) 891/2014	<b>Ex- Parte Interim Injunction granted</b> on March 28, 2014	For admission/denial of the documents before the Joint Registrar on 10.11.2014
3.	Novartis v. Bajaj Healthcare	CS(OS) 1053/2014	<b>Ex- Parte Interim Injunction granted</b> on April 16, 2014. Permanent Injunction granted on July 28, 2014	<b>Disposed of</b> after an Affidavit was filed by the defendant that they shall not manufacture the drug.
4.	Novartis v. Alembic Pharmaceutical	CS(OS) 1051/2014	<b>Ex- Parte interim Injunction granted</b> on April 16, 2014	Before Joint Registrar on 10.11.2014 for Admission Denial.
5.	Novartis v. Glenmark Generics	CS(OS) 1054/2014	<b>Interim Injunction granted</b> on April 16, 2014 Defendant undertakes that, till the next date of hearing, shall not launch the drug in the Indian market The defendants are directed to place on record the documents evidencing the export of the drug Vildagliptin already made and in case any further export takes place, the documents evidencing export shall also be placed on record including approvals for export, if so required, along with the invoices evidencing the value of the export.	Before the Joint Registrar for admission/denial of the documents on 15th October, 2014. Before the Court for framing of issues and arguments on injunction application on 19th March, 2015

S.No	Case	Suit No.	Injunction	Status and comments
6.	Novartis v. Cadila Healthcare	CS(OS) 1052/2014	<b>Interim injunction granted</b> on April 16, 2014	Before the Joint Registrar for admission/denial of the documents on 15th October, 2014. Before the Court for framing of issues and arguments on injunction application on 15th December, 2014.
7.	Novartis AG and Ors. versus Ranbaxy Laboratories Ltd	CS (OS) No. 2703/2014	<b>Interim Injunction granted</b> on September 8, 2014	Before the court for hearing of Order XXXIX Rules 1 & 2 CPC application on 2.12.2014.

As mentioned above, Novartis has successfully obtained injunction against seven Indian companies out of which the matter has been settled with Bajaj Healthcare, after the defendant submitted an affidavit to the effect that they shall not manufacture the impugned drug.

It can be safely said that it is totally at the discretion of the Court to grant injunctions and the same varies on case to case basis. The orders till now were directed to life saving drugs, wherein public interest and cost of the drug played an imperative role, however it would be interesting to see the outcome of both the classes of suits mentioned above wherein these factors are not so applicable.

### Electronic Patent Register

The Indian Patent Office released the new version of electronic Patent Register in the IPAIRS on 30th September 2014. The electronic Patent Register can be accessed through the following link: <http://ipindiaonline.gov.in/patentsearch/search/index.aspx> (please copy paste the URL if the link does not work).

The electronic Patent Register includes the legal status and bibliographic details of the granted Patents along with other details like due dates, annuity details, information u/s 146 i.e. working of Patents in the territory of India, linked applications etc. The electronic Patent Register strives towards collating all the information after a patent is granted.

The said initiative is in line with the practices of the Patent Offices in major jurisdictions like the US and EP. However the prosecution history i.e. file wrapper is not linked to the said register and has to be still accessed using the application status tab. Further patent family i.e. corresponding applications /patents in various jurisdictions is not included in the said Register.

This is a part of recent initiatives that have been taken up by the Indian Patent Office towards making the system accessible, transparent, user-friendly and efficient. While there may be much left to desire, the steps are in the right direction.

## Amendment After the Grant of Patent

In India it is possible to amend the patent after grant, subject to the provisions of the Indian Patent Act in this regard. Sections 57<sup>1</sup>, 58<sup>2</sup> and 59<sup>3</sup> of the Indian Patents Act provide for amendment of patent or patent application or any document thereof.

On filing a request in the prescribed manner accompanied with the prescribed fees the patentee may apply for an amendment of the application for patent, complete specification or any document relating thereto to be amended subject to such conditions, if any, and as the Controller thinks fit. Such request may also be made for amendment of priority date.

The request must state the nature of the proposed amendment, highlighted in an annexed copy along with the reasons. The amendments are allowable only by way of disclaimer, correction or explanation. Such amendments are allowed only for the purpose of incorporation of actual fact. Further, no amendment of a complete specification is allowed the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or the amended claim(s) do not fall wholly within the scope of claim(s) of the specification before the amendment.

<sup>1</sup> 57. Amendment of application and specification or any document relating thereto before Controller.—(1) Subject to the provisions of section 59, the Controller may, upon application made under this section in the prescribed manner by an applicant for a patent or by a patentee, allow the application for the patent or the complete specification or any document relating thereto to be amended subject to such conditions, if any, as the Controller thinks fit:

Provided that the Controller shall not pass any order allowing or refusing an application to amend an application for a patent or a specification or any document relating thereto under this section while any suit before a court for the infringement of the patent or any proceeding before the High Court for the revocation of the patent is pending, whether the suit or proceeding commenced before or after the filing of the application to amend.

(2) Every application for leave to amend an application for a patent or a complete specification any document relating thereto under this section shall state the nature of the proposed amendment, and shall give full particulars of the reasons for which the application is made.

(3) Any application for leave to amend an application for a patent or a complete specification or a document related thereto under this section made after the grant of patent and the nature of the proposed amendment may be published.

(4) Where an application is published under sub-section (3), any person interested may, within the prescribed period after the publication thereof, give notice to the Controller of opposition thereto; and where such a notice is given within the period aforesaid, the Controller shall notify the person by whom the application under this section is made and shall give to that person and to the opponent an opportunity to be heard before he decides the case.

(5) An amendment under this section of a complete specification may be, or include, an amendment of the priority date of a claim.

(6) The provisions of this section shall be without prejudice to the right of an applicant for a patent to amend his specification or any other document related thereto to comply with the directions of the Controller issued before the grant of a patent.

<sup>2</sup> 58. Amendment of specification before Appellate Board or High Court.— (1) In any proceeding before the Appellate Board or the High Court for the revocation of a patent, the Appellate Board or the High Court, as the case may be, may, subject to the provisions contained in section 59, allow the patentee to amend his complete specification in such manner and subject to such terms as to costs, advertisement or otherwise, as the Appellate Board or the High Court may think fit, and if, in any proceedings for revocation the Appellate Board or the High Court decides that the patent is invalid, it may allow the specification to be amended under this section instead of revoking the patent.

(2) Where an application for an order under this section is made to the Appellate Board or the High Court, the applicant shall give notice of the application to the Controller, and the Controller shall be entitled to appear and be heard, and shall appear if so directed by the

Appellate Board or the High Court.

(3) Copies of all orders of the Appellate Board or the High Court allowing the patentee to amend the specification shall be transmitted by the Appellate Board or the High Court to the Controller who shall, on receipt thereof, cause an entry thereof and reference thereto to be made in the register.

<sup>3</sup> 59. Supplementary provisions as to amendment of application or specification.— (1) No amendment of an application for a patent or a complete specification or any document relating thereto shall be made except by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed, except for the purpose of incorporation of actual fact, and no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.

(2) Where after the date of grant of patent any amendment of the specification or any other documents related thereto is allowed by the Controller or by the Appellate Board or the High Court, as the case may be,—

(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;

(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and

(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.

(3) In construing the specification as amended, reference may be made to the specification as originally accepted

An application for amendment may be published along with the nature of proposed amendment.. Any person interested may file a notice of opposition in the prescribed within three months from the date of publication of the application for amendment. Where such a notice of opposition is filed, the Controller notifies the applicant for amendment. Controller follows the procedure as prescribed for a normal Opposition and gives both the applicant and the opponent an opportunity to be heard. Amendments allowed after the grant of patent are published.

A leave to amend the complete specification obtained by fraud is a ground for revocation of patent under Section 64<sup>4</sup>. If any suit for infringement is pending before a Court or any proceeding for revocation of the Patent is pending before the High Court, the Controller will not pass any order allowing or refusing the application for amendment.

In Solvay Fluor GmbH. v. E.I. Du Pont de Nemours and Company (M.P. No.36/2009 in TRA/7/2007/PT/KOL) the Intellectual Property Appellate Board (IPAB) accepted amendments to the specification as made by the patentee. To give a brief background of this patent, application for patent was filed on 12.11.1996 by the petitioner (DuPont) for a patent for an invention relating to a “fire extinguishing composition.” The application was granted patent No. 175594 on 9th February, 1996. Solvay had filed revocation proceedings against the impugned Patent.

Du Pont filed a petition to amend the specification to include data for overcoming the objections made under sections 3(d) & 3(e)<sup>5</sup> of the Act. In the application for amendment, it was clarified that the invention was a synergistic composition, comprising a fire extinguishing agent and a propellant, which are two separate elements and distinct. The Petition added the following Paragraph to be added in the Patent:

“More particularly, a person of ordinary skills in the art would understand composition of present invention as comprising at least one Fluoro Substituted Propane (HFG227ea) and a propellant being two separate and distinct components each of / which have a synergistic action on the other in the composition so as to achieve the objective of the present invention.”

Further, evidence was also advanced in line that the combination had an unexpected advantage resulting from synergy between its components.

The Controller accepted the said amendments and did not object to the amendments thereof. It was stated that:

*“As regards the proposed amendment which is by way of disclaimer, as far as the composition, of the invention is concerned the proposed disclaimer is within the limits of the principal claim, i.e. Claim (1) as accepted. Therefore the proposed amendment is acceptable to the extent that the present invention comprises at least one fluoro substituted propane and a propellant being two separate and distinct components and further the amendment to that aforesaid extent is explanatory in nature and is therefore allowable.”*

The IPAB held that “we are convinced that the amendments proposed are allowable and we hereby order that the amendments shall be carried out in the patent specification and the Controller shall take the necessary steps and procedures in this respect in the prescribed manner”.

Analyzing the provisions under the Patents Act with regard to amendments the IPAB held that “permissible amendments are as follows: (i) the amendment can only add an actual fact; (ii) the applicant is not allowed to introduce new matter into the specification; and (iii) amendments must be of the nature of a disclaimer, correction or an explanation.”

<sup>4</sup> 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—

(o) that leave to amend the complete specification under section 57 or section 58 was obtained by fraud.

<sup>5</sup> 3. What are not inventions.

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;



IPAB further held that the Section 58 gave power to the Court to allow patentee to amend patent in proceedings in which the validity of patent was put in question and held that it was a wide discretion. It summarized that such discretion should be exercised as per guidelines given in *SmithKline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 561. These guidelines include:

- the onus to establish that amendment should be allowed is upon the patentee and full disclosure must be made of all relevant matters. If there is a failure to disclose all the relevant matters, amendment will be refused;
- the amendment will be allowed provided the amendments are permitted under the Act;
- the amendment needs to be sought promptly-patentee to show reasonable grounds for delay;
- a patentee who seeks to obtain an unfair advantage from should have known of the need to amend the patent, which he knows or should have known should be amended, will not be allowed to amend; and
- the court is concerned with the conduct of the patentee and not with the merit of the invention.

In *AGC Flat Glass Europe SA Vs Anand Mahajan and Ors* (2009 Indlaw DEL 2227) the Court opined that the patentee could amend his specification or claim during the pendency of infringement proceedings subject to the conditions of Section 59 of the Indian Patents Act.

In the particular case the patentee (plaintiff) filed an

application for amendment (under section 58) for claim 1 during pendency of patent infringement suit. The patentee had added words “a sensitizing material, typically tin” in claim 1 on a mirror without copper layer in its coating.

The question was whether this amendment was allowable or not. The defendant contented that this amendment changed the scope of the original invention. On this, the court referred to UK decisions and divided such amendments into two categories: *“the first one is a situation where the patentee has been apprised of prior art by an opponent and amendment is undertaken to overcome the prior art; the second is a situation where the patentee himself has been aware of the prior art but has never taken steps to amend the patent on his own. UK Courts have held the second situation as being inexcusable, where the patentee must not be allowed to amend his patent”*. The Court opined that second category did not apply to this case. Hence the amendment was held to be allowable in this case.

The Court pointed that the amendment was within the scope of the invention as the description clearly mentioned the presence of a sensitizing process as one of the three stages in manufacture of mirrors and patentee’s amendment was by way of explanation.

Though there are not too many judicial precedents with respect to amendment of patents, but if the amendments fall within the scope of the disclosure, only adds an actual fact and is of the nature of a disclaimer, correction or an explanation, it will be allowed.

## MEDICAL TECHNOLOGY IN INDIA – THE WAY FORWARD...

India is today one of the top emerging markets in the highly knowledge based global pharmaceutical sector. To ensure a robust and thriving manufacturing sector with continued foreign investment the government is providing impetus through a plurality of initiatives. Amongst other sectors, such initiatives could certainly bolster the Indian medical technology sector that requires urgent intervention.

Globally, the objective of healthcare system is fostering innovation to improve accessibility and provide effective therapies facilitating early diagnosis, shorter hospitalization and convalescence. Given that the disease profile in India is different from the western world, especially in the in-vitro diagnostics sub-segment like rapid diagnostics for malaria, dengue and other Communicable diseases, the situation calls for local innovation in addition to importation.

In India the import, manufacture, sale and distribution of medical devices are regulated under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945. It includes certain devices as under:

S. 3(b) “drug” includes— (iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.”

The Regulatory Authority that governs the regulations of import and manufacture of medical devices in India is Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare. The regulatory requirements for import, manufacture and labeling of Veterinary medical devices is same as devices meant for human beings.

Here it is worth noting that only notified medical devices are regulated in India and there is no clear direction for the

medical devices which are not notified as a Drug under Section 3(b)(iv) of the Act. This may lead to custom clearance hurdles during the import of a non-notified medical device as the custom officials may extensively quiz on the regulatory status of the device.

Pricing of the medical devices is yet another worrying factor. Several news reports suggest overpricing by local distributors and hospitals. Experts are therefore mooting on a price regulatory authority similar to National Pharmaceutical Pricing Authority (NPPA) for medicines.

The proposed Amendment Bill 2013 to the Drugs and Cosmetics Act seeks to partially address this by creating a separate chapter for devices, thereby distinguishing them from drugs and pharmaceuticals. However, sooner than later there is required a separate medical device regulatory act based on globally harmonized regulations which would help in fostering transparency and streamlining the regulatory process.

After the adoption of TRIPS agreement India has a well-established statutory, administrative, and judicial frameworks to safeguard IPRs. Medical technology includes software programs which can be protected under copyright and hardware components which can be patented. Further, software providing technical effect in combination with hardware can be patented subject to other patentability requirements.

Indian Patents Act, 1970 specifically excludes any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products<sup>1</sup>. However, Medical devices including method/process are patentable in India.

Patent filing trend<sup>2</sup> in the field of medical technology in India shows 5071 published application under the category of diagnosis, surgery, identification (IPC:A61B); 3235 under the category of devices for introducing media into, or onto,

<sup>1</sup> THE PATENTS ACT, 1970 (Section 3(i)) 3. **What are not inventions.** (i) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

<sup>2</sup> <http://ipindiaonline.gov.in/patentsearch/search/index.aspx>

the body(IPC:A61M); 2853 under the category of filters or implantable devices (IPC:A61F); 745 under the category of Electrotherapy; magnetotherapy; radiation therapy; ultrasound therapy (IPC:A61N); 265 under the category of physical therapy apparatus (IPC:A61H); 174 under the category of devices using stimulated emission (IPC:H01S); 49 under the category of Veterinary instruments, implements, tools, or methods (IPC:A61D). The filing trend in India is in sync with the global filing trend in this field of medical technology.

While patent litigation between local players and large multinationals is fairly common in the pharmaceutical sector, in a rare show in the medical device sector recently Poly Medicure, an Indian medical devices firm with annual sales of just over Rs 320 crore, has won a five-year long patent battle with crore German medical devices and pharma giant B Braun as the European Patent Office (EPO) revoked two of the latter's patents covering features of intravenous (IV) safety catheters<sup>3</sup>. Small Indian medical devices companies asserting their rights and foraying in patent litigation on a global space is an indicator that the local innovators and companies of this sector are here to stay.

As per the PwC – CII report titled “India Pharma Inc: Gearing up for the next level of growth (October 2012)”<sup>4</sup>, the Indian pharma industry has been growing at a compounded annual growth rate (CAGR) of more than 15% over the last five years and has significant growth opportunities. PwC's medical technology innovation scorecard suggests that the medical technology innovation ecosystem, long centered in the United States, is moving offshore. The nature of innovation is changing as developing nations become the leading markets for smaller, faster, more affordable devices that enable delivery of care anywhere at lower cost thus giving a wakeup call to the local innovators.

Additive manufacturing, also known as 3-D printing is one

area which Indian Innovators can make use of in fostering affordable and customized devices. It opens limitless opportunities for India being an IT hub which can help create electronic design blueprint for the production of devices like prosthetics. Nevertheless, it would bring with it a number of regulatory issues which would be required to be resolved through consultation with all the stakeholders.

This is an era of intelligent systems wherein the boundaries of what a machine can do is continuously shifting. Providing an impetus to the power electronics sector along with the control and embedded technologies would help create products with overwhelming features. There is therefore a need to identify the potential of different players and a need to mutually create opportunities benefitting this sector as a whole.

“Medical Technology: Vision 2025”<sup>5</sup>, a whitepaper released by BCG-CII (August 2014) highlights following potential medical technology roadmap for India:

- Medical technology relevant regulation
- Reward local and market relevant innovation
- Build manufacturing infrastructure
- Collaborative partnerships
- Capability development and training
- Integrated stakeholder forum for meaningful engagement

Medical technology sector in India provides pockets of big opportunity right now for the investors. In a positive environment created by the new government, it would be worth watching how India would balance between innovation and affordability in this sector.

<sup>3</sup><http://www.indiaoppi.com/sites/default/files/PDF%20files/OPPI%20News%20Updates%20September%206-8,%202014.pdf>

<sup>4</sup>[http://www.pwc.in/en\\_IN/in/assets/pdfs/pharma/pharma-summit-report-31-10-12.pdf](http://www.pwc.in/en_IN/in/assets/pdfs/pharma/pharma-summit-report-31-10-12.pdf)

<sup>5</sup><http://www.cii.in/PublicationDetail.aspx?enc=W6AWRXARJdt/qhxA0hv1Fcmyb142xGTC6vlpYOQ5XQ>

### Directions to expedite examination

The Patent Office was again challenged yet again for inordinate delay in the examination process. Nitto Denko Corporation filed a writ at the Delhi High Court in 2013 (*Nitto Denko Corporation vs Union of India & Ors, W.P.(C) 3742/2013 and CM 4197/2014*) regarding this delay being caused by the respondents in the examination of their patent applications and non-adherence to the time schedule provided under Patents Rules, 2003. The time for putting an application in order for grant is one year from the date of issuance of the First Examination Report (FER) and as per the Rules it should take 11 months in total to service the FER to the applicant. However in practice there is a delay of many years, first in the issuance of FER and after issuance to grant also there is an inordinate delay.

After the Writ was filed the Controller of Patents was directed to file an affidavit disclosing the steps which the respondents are taking to ensure to stick the time prescribed for processing the applications, to disclose year-wise pendency of the applications as on 31.10.2013 as also the time which the Patent Office expects to take to clear the backlog of such applications. Thereafter, the government appointed a committee on 26.12.2013 to come up with a program for time-bound disposal of the pending patent applications and to suggest ways and means to ensure that fresh applications can be decided within the statutory time limit fixed in this regard. The committee after several deliberations came up that the pendency can be reduced by increasing the required number of manpower.

After considering the report of the committee dated and the suggestions made by the parties, Court issued following directions to the respondents:-

*"1. The Ministry of Commerce and Industry and other concerned Ministries to take urgent steps so that posts proposed in the plan scheme of Modernisation and Strengthening of Intellectual Property Offices (MSIPO) could be created within a period of 9 months to enable issue of first examination reports within reasonable time.*

*2. The Government to consider additional outlay apart from Rs.309.6 crores already approved by the Cabinet Committee under the 12th Plan for creation of further posts of Examiners and Recruitment/Training of the newly recruited examiners.*

*3. The Government will further expedite the creation of posts sought under the 12th Plan in consultation with Department of Expenditure and Department of Personnel and Training within a period of 9 months.*

*4. The DIPP/Government may explore alternative methods of recruitment of examiners through UPSC, IITs or by using the second obtained through GATE/NET examination.*

*5. It is also directed that efforts should be made to ensure that the Flexible Complementing Scheme as approved by the committee is implemented at the earliest in consultation with other concerned departments specially Department of Personnel and Training and the Department of Science and Technology for immediate implementation in the Indian Patent Office in order to resolve the issue of attrition.*

*6. The Government is directed to constitute a committee."*

Earlier also in *Dr. Vinitha Ponnukutty v Controller of Patents & Designs & anr. (2011 (46) PTC 869 (Mad.))*, Madras High Court had observed that the time limit prescribed under the Indian Patents Act and Patent Rules for the disposal of the Application is to be followed in the letter and spirit, however no substantial changes were actually implemented after the said ruling.

It is a welcoming initiative by the Delhi High Court and will go a long way in the working of the whole patent system in India. Increasing the manpower in the Patent Office by implementing the scheme of Modernisation and Strengthening of Intellectual Property Offices (MSIPO) within the next 9 months and investing more money in the training and recruitment of the examiner will definitely help clearing the backlog. It would be interesting to witness the changes to be actually implemented by the authorities.



THE LEAP OF FAITH.....





### 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's technical 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 records. 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.



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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.