

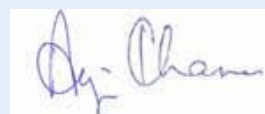
THE PATENTS NEWSLETTER

We at Lall & Sethi are pleased to share our Newsletter with recent highlights on the patent front in India. If you are following prosecution in India, you would be aware that there have been some major changes with the way Indian Patent Office is working currently. The changes are nothing short of revolutionary, with exponential increase in the issuance of examination reports and grants. The Indian Patent Office now aims towards reducing the prosecution time to 2-3 years; at the current rates, it looks like a realistic target.

Besides patents, this issue of Newsletter throws light on trade secret protection in India. Due to a lack of specific trade secret legislation in India, we have tried to provide details on various aspects, its protection and current jurisprudence. We also bring an update on start-ups in the healthcare sector in India and how they are using Artificial Intelligence tools to bring cheap and fast solutions in this area. Additionally, you can find updates on the working statement requirement in India.

The Newsletter further throws light on various contentious aspects such as working of the Intellectual Property Appellate Board (IPAB) and new and amended Delhi High Court rules. The new DHC rules provide for expedited adjudication and to increase the cooperative endeavour to settle dispute between parties with an ease to manage procedural aspects. We further provide an insight into the recent tests issued by the Courts in India to regulate the use of Section 107A i.e. Bolar exemption to avoid future misuse.

If you have any questions about the issues raised here or anything else related to your IP, please contact us at akhanna@indiaip.com



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Trade secret protection in India

Trade secrets in India have been recognized as, "information with commercial value which is not in the public domain and in relation to which the owner of the information has taken considerable steps to maintain confidentiality and secrecy." Even though trade secrets are not governed by any specific legislation in India, yet a protection regime exists whereby the rights of people owning the trade secrets may be safeguarded under appropriate circumstances. The trade secrets in India are therefore, protected through the Contract Law, Copyright Law, Information Technology Law, equitable doctrine of breach of confidentiality or unfair trade practices. Calcutta High Court in *Fairfest Media Ltd vs Ite Group Plc and Ors*¹ summarized the legal status of trade secret protection in India: "the essence of this branch of law whatever the origin it may be, is that a person who has obtained information in confidence is not allowed to use it as springboard for activities detrimental to the person who made the confidential communication."

The trade secrets' protection in India is approached on the basis of equity principle, breach of contractual obligations under common law, whereby if the owner has revealed the trade secret to another independent person for the purpose of running business in his absence, that person is not allowed to take advantage of it and involve in unfair trade practices. This necessitates that the employees who have access to trade secrets should be educated about the protection of trade secrets and be made to sign non-disclosure agreements (NDA). However, in *John Richard Brady v. Chemical Process Equipments P. Ltd. and Ors.*², the Delhi High Court invoked a wider equitable jurisdiction, awarding an injunction in the absence of a contract. The Court held that, "independent of an underlying contract or in the absence of one, he who has received information in confidence is not allowed to take unfair advantage of it."

This lays down that undue enrichment at the expense or detriment of another goes against the tenets of equity and fairness which need not be dependent on contractual obligations.

In order to protect a valuable trade secret, it is essential that a strong trade secret protection be in place. For this, first of all a trade secret must be identified. Any know-how cannot be a trade secret. The Delhi High Court in the case of *American Express Bank Ltd. v. Priya Puri*³, has provided a list of what can be said to be a trade secret. As per this judgment, a trade secret "can be a formula, technical know-how or a peculiar mode or method of business adopted by an employer which is unknown to others." However, routine affairs of the employer which are commonly in the knowledge of his employees and his competitors cannot be called trade secrets. Therefore, trade secrets must be well protected. Apart from maintaining secrecy, the employer must enter into a NDA with employees and any third party involved. Such restrictive covenants, aimed at protecting trade secrets are considered to be reasonable and non-conflicting with public policy during employment (*Niranjan vs Century*⁴). They are not considered to be in restraint of trade (Section 27, Indian Contracts Act, 1872⁵) and are hence, not void.

It must also be noted that agreements or contracts imposing restrictions on carrying on business by a former employee following termination of employment are generally considered to be in restraint of trade. However, in no case is a former employee allowed to take unfair advantage of the employer's trade secrets that are vital for its business. A former employee can also be restrained from "carrying (out) any activity which is competitive to that of company, and also from soliciting, interfering with, disturbing or attempting to disturb the relationship between the company or subsidiary and third party,

¹MANU/WB/0001/2015

²MANU/DE/05861987

³MANU/DE/2106/2006

⁴*Niranjan Shankar Golikari Vs Century Spinning and Mfg Co. Ltd (MANU/SC/0364/1967)*

⁵27. Agreement in restraint of trade, void.—Every agreement by which any one is restrained from exercising a lawful profession, trade or business of any kind, is to that extent void. —Every agreement by which any one is restrained from exercising a lawful profession, trade or business of any kind, is to that extent void." Exception 1.—Saving of agreement not to carry on business of which goodwill is sold.—One who sells the goodwill of a business may agree with the buyer to refrain from carrying on a similar business, within specified local limits, so long as the buyer, or any person deriving title to the goodwill from him, carries on a like business therein, provided that such limits appear to the Court reasonable, regard being had to the nature of the business.

including any customer or supplier of the company or subsidiary" (*Kumar Apurva v. Valuefirst*⁶).

As can be observed, formulation of NDA or confidentiality agreement or employment contract can go a long way in providing protection to trade secrets. However, it is very important that these documents be drafted carefully. The NDA should clearly mention what information an employee can pass, or cannot pass, provision of termination due to breach of this agreement, and a clear, definition of "third party" to whom disclosure of information is banned. The employment contract must have a termination clause and a general clause on breach of contract, non-solicitation clause, theft of information etc. The contract should also specify that the employee is mandated to take reasonable steps to keep all the confidential information in confidence except and to the extent when disclosure is mandatory under any law in force. Further to ensure enforceability of NDA/ confidentiality agreements, the definition of the confidential material ought to be well defined and the names of the contracting parties should be clearly written to avoid all ambiguities. It must also be ensured that only the authorized person is signing the contract. Scope of the agreement must not be very broad, onerous or too anti-

competition or else this may render the contract unenforceable. The context of the agreement, its terms and jurisdiction must be clearly defined. In case of an R & D unit, one should obtain a "document of ownership" signed by the scientist/engineer/technical person with a clause clearly stating that the ownership of IP generated by the person during his/her tenure of employment will rest with the company.

Apart from NDA and confidentiality agreements, it is important that the company take certain initiatives to ensure protection of their vital trade secrets. These include restricting access of trade secrets to only those employees who may have a legitimate need to know it, marking trade secret containing documents as confidential and maintaining electronics and computer secrecy. In order to keep computer secrecy, a Data Protection policy must be in place so that employees can be made aware of data theft, tampering with computers and its consequences. Under the Information Technology Act 2000, tampering with computer systems can invite a fine of up to approximately USD 1,40,000 under section 43⁷. These could also invite imprisonment of up to 3 years under section 66⁸. Breach of confidentiality and privacy is punishable under section 72⁹

⁶*Kumar Apurva v. Value first Digital Media Pvt. Ltd., MANU/DE/0945/2015*

⁷**43. Penalty for damage to computer, computer system, etc.-** If any person without permission of the owner or any other person who is in charge of a computer, computer system or computer network, - accesses or secures access to such computer, computer system or computer network downloads, copies or extracts any data, computer data base information from such computer, computer system or computer network including information or data held or stored in any removable storage medium. Introduces or causes to be introduced any computer contaminant or computer virus into any computer, computer system or computer network; damages or causes to be damaged and computer, computer system or computer network, data, computer database or any other programmes residing in such computer, computer system or computer network; disrupts or causes disruption of any computer, computer system or computer network; denies or causes the denial of access to any person authorized to access any computer, computer system or computer network by any means; provides any assistance to any person to facilitate access to a computer, computer system or computer network in contravention of the provisions of this Act, rules or regulations made thereunder; charges the services availed of by a person to the account of another person by tampering with or manipulating any computer, computer system or computer network he shall be liable to pay damages by way of compensation not exceeding one crore rupees to the person so affected. **Explanation.-** For the purposes of this section.- (i) "computer contaminant" means any set of computer instructions that are designed - (a) to modify, destroy, record, transmit data or programme residing within a computer, computer system or computer network; or (b) by any means to usurp the normal operation of the computer, computer system, or computer network; (ii) "computer database" means a representation of information, knowledge, facts, concepts or instructions in text, image, audio, video that are being prepared or have been prepared in a formalized manner or have been produced by a computer, computer system or computer network and are intended for use in a computer, computer system or computer network; (iii) "computer virus" means any computer instruction, information, data or programme that destroys, damages, degrades adversely affects the performance of a computer resources or attaches itself to another computer resources and operates when a programme, data or instruction is executed or some other even takes place in that computer resource; (iv) "damage" means to destroy, alter, delete, add, modify or re-arrange any computer resource by any means.

⁸**66. Hacking with Computer System. -** (1) Whoever with the intent of cause or knowing that is likely to cause wrongful loss or damage to the public or any person destroys or deletes or alters any information residing in a computer resource or diminishes its value or utility or affects it injuriously by any means, commits hacking. (2) Whoever commits hacking shall be punished with imprisonment up to three years, or with fine which may extend up to two lakh rupees, or with both.

⁹**72. Breach of confidentiality and privacy.-** Save as otherwise provided in this Act or any other law for the time being in force, if any person who, in pursuance of any of the powers conferred under this Act, rules or regulations made thereunder, has secured access to any electronic record, book, register, correspondence, information, document or other material without the consent of the person concerned discloses such electronic record, book, register, correspondence, information, document or other material to any other person shall be punished with imprisonment for a term which may extend to two years, or with fine which may extend to one lakh rupees, or with both.

of the IT Act with imprisonment up to 2 years or fine or both. Disclosure of information in breach of lawful contract is punishable with imprisonment up to 3 years or fine or both under section 72A¹⁰. Also, one should be careful with unsolicited submissions. Further, there should be sufficient legal support on whatever policies needs to be put in place by the employer. A non-compete clause must also be inserted into any contract. Caution must also be taken while hiring new employees. A proper pre-screening must be carried out to rule out any criminal record, any wrongful act including money laundering, fraud, corruption etc. Similar due diligence must also be carried out before entering into any third party agreement.

Even after taking due precautionary measures, one may face trade secret violation ending up in litigation. One of the major concerns then is that trade secrets may be made public during litigation in India. In an issue examined by a 9-judge bench of the Supreme Court of India¹¹; it has been held that for matters which lead to publication of secret processes, publication of which would destroy the very basis of the claim for relief etc., Courts may hold a trial in closed session and wholly exclude the public throughout the trial or a part thereof. The Delhi High Court has promulgated new Rules in November 2018 that allow formation of a 'Confidentiality Club' during litigation¹².

The various acts constituting breach of confidence that are commonly accepted by the Indian Courts are:

- the fact or the information must have quality of confidence in it;
- there must be an obligation of confidence relating to such fact or information;
- there must be an unauthorized use of that information to the detriment of the party

communicating it.

Further, in order to seek relief from courts, not only the specific trade secrets must be identified but it also needs to be proved as to how the plaintiff had ownership of them. The nature and quality of information that has been misused must also be shown to be confidential in the pleadings. In *Ritika. v Biba*¹³, a suit was filed for infringement of the plaintiff's fabric designs, the Delhi High Court took the view that if an injunction order were sought with respect to trade secrets, the specific trade secrets would have to be mentioned, as well as how the plaintiff had ownership of them; only then would the court consider granting an injunction order. A general order in respect of an unspecified trade secret could not be passed against the defendant.

Coming to the remedies, both civil and criminal remedies are available to the owner of the trade secrets in India. In case of a civil suit, an injunction against an unauthorized or illegal user can be obtained. However, the probability of obtaining an injunction from Indian courts is based on certain basic principles formulated in the Code of Civil Procedure 1908:

- a *prima facie* case in favor of an injunction exists;
- the balance of convenience is in favor of granting the injunction;
- there is a risk that, in the absence of an injunction, the owner will suffer irreparable loss and injury.

The owner of the trade secret can also claim damages. Similarly, a criminal complaint may also be lodged alleging theft under section 378 of the Indian Penal Code (IPC) 1860. In order to satisfy the requirements of Section 378, the trade secret must have a physical form (e.g. client lists,

¹⁰72A Punishment for disclosure of information in breach of lawful contract. -Save as otherwise provided in this Act or any other law for the time being in force, any person including an intermediary who, while providing services under the terms of lawful contract, has secured access to any material containing personal information about another person, with the intent to cause or knowing that he is likely to cause wrongful loss or wrongful gain discloses, without the consent of the person concerned, or in breach of a lawful contract, such material to any other person, shall be punished with imprisonment for a term which may extend to three years, or with fine which may extend to five lakh rupees, or with both.

¹¹*Naresh Shridhar Mirajkar and Ors Vs State of Maharashtra and Anrs*, MANU/SC/0044/1966

¹²http://delhihighcourt.nic.in/writereaddata/upload/Notification/NotificationFile_OXY08957.PDF

¹³*Ritika Apparel Pvt. Ltd. v Biba Apparels Pvt Ltd.* (MANU/DE/0784/2016)

formulae or blueprints) and must be proven to have actually been stolen. A complaint alleging criminal breach of trust under Section 408 of the IPC, read with section 420 alleging cheating, may also be initiated. However, the same would apply only in situations where an agreement (express or implied) of trust exists and has been

contravened. Therefore, it can be seen that a myriad of options are available to the owner of a trade secret in India to be able to safeguard his trade secrets. India's position, thus, should not be mistaken to connote that insufficient protection is accorded to trade secrets and confidential information.

Contributed by Dr. Anju Khanna

BOLAR DOCTRINE- REGULATION AND SAFEGUARDS

Section 107A¹ of the Patent Act, 1970, popularly known as India's "Bolar Exemption", is a defence for patent infringement, when the invention is used or sold by a third party for purposes related to research and development. The provision allows generic pharmaceutical companies to conduct research on a patented product while it is still valid.

India is the global leader in generics drug supply. It supplies 50 to 60 percent of global demand for many vaccines (including ARVs), 40 percent of generics consumed in the US and 25 percent of all the medicines dispensed in the UK². Branded generics dominate the market in India, making up for 70 to 80 per cent of the retail market³. Hence this provision has always been in the limelight and also been a point of contention between proprietary and generic drug manufacturers. In a recent matter, the Delhi High Court pondered upon the provision and issues pertaining to permissibility of export under Bolar provision.

Bayer filed a suit to injunct Alembic and Natco Pharma⁴ from making, selling, distributing, advertising, exporting, offering for sale and in any manner directly or indirectly dealing in RIVAROXABAN and any product that infringed Bayer's patent IN 211300. An appeal was filed by Bayer

against judgment of a single bench which had permitted Alembic to export the patented products for clinical trials for approval of drug from foreign regulatory authorities. The Division Bench (DB) upheld the order of the Ld. Single Judge allowing Alembic Pharmaceuticals Ltd. to export small quantities of Rivaroxaban. The DB held the sale of patented article within India or outside for research or experimental purposes under Bolar exemption constitutionally valid. However, the Court recognised that said provision is unregulated and prone to misuse. The Court laid down tests necessary to regulate the use of the Section 107A exemption to avoid future misuse and the inquiry and adjudication in such cases would be in regard to the following:

- (1) The patent granted;
- (2) The nature of the product or elements sought to be exported;
- (3) The details of the party or party importing the product;
- (4) The quantity sought to be exported;
- (5) Other particulars with respect to the end use of the product, to establish that it is solely for research and development of information to regulatory authorities in the other country;
- (6) All particulars regarding the relevant regulations,

¹107A. Certain acts not to be considered as infringement.—For the purposes of this Act,— (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product; (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights.

²Trends & Opportunities for Indian Pharma, FICCI, accessed on September 8, 2019.

³India Pharma 2020 Propelling access and acceptance, realising true potential; Report by McKinsey & Company, Inc. , accessed on September 8, 2019.

⁴ Bayer Intellectual Property GmbH v. Alembic Pharmaceuticals Limited, DHC order dated 22nd April, 2019

covering the kind and scope of inquiry, including the quantities of the product (i.e. the patented product or compound, API or fine chemical needed). These details must be supplied by the exporter/seller of the product to the overseas buyer. In case the defendant is not the seller, it should disclose who had purchased the product in the relevant quantities, to facilitate its impleadment in the proceedings. In the event it cannot do so, the consequences of such results ought to be considered by the court.;

(7) If the regulations are in the language of that country, an authentic English translation to facilitate a speedy resolution;

(8) Appropriate interim order, including undertaking by way of affidavit to compensate the plaintiff, in the event the suit was to be decreed and the extent of such monetary compensation. The affidavit should be of authorized personnel, and kept alive during the pendency of litigation, duly authenticated by the board of director or other controlling body of the defendant- and whenever the

company or entity undergoes amalgamation or transfer, suitable undertaking from the successor organization;

(9) If necessary, verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/or its facilities abroad;

(10) If it is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article, unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the defendants in monetary terms, to preclude litigation that prevents trade or competition;

Thus, the Courts have recognised that due to the unregulated nature of the provisions related to the exemption, further specific measures have be placed to monitor the misuse of the provision and to ensure that exports are genuinely made for research purposes only.

Contributed by Ms. Manika Arora

Overlap of IP rights: design and passing off rights

The overlapping of various IP's is an unresolved issue when it comes to the grant of remedies for their infringement. The overlap between design and trademark rights is one such issue that was waiting to be resolved. A design, which is obtained in early part of the life cycle of a product may acquire secondary meaning of a badge of origin, quality and repute of the product over a period of time. The design is then said to have acquired distinctiveness which is a pre-requisite of trade mark and hence starts to serve the purpose of a trademark. In this judgement, the Court clarified the position when the other party makes a similar or deceptively similar imitation of a design, this act not only amounts to design piracy under section 22 of the Design Act but is also liable for passing off action under the common law as it deceives the public into believing that the imitated product is associated with the original one and hence cutting on the former's revenue. The "Carlsberg" bottle had a registered design and due to its extensive use and marketing, the consumers started associating the bottle's appearance with the product origin, making it an indicator of the source and quality of the product. A suit was filed against the defendant for the Design piracy as well as Passing Off action.

In the present matter the bench adjudicated on important the issue of maintainability of composite suit in respect of piracy of registered design and passing off action for the Trade dress. Multiplicity of suits in respect of the same subject matter has also been one of concerns of the court. Resolving the matter, a five Judge Bench of the Delhi High Court held that design piracy as well as passing off action constitute two separate cause of actions in the fact that one infringes the right of the proprietor as guaranteed under the Design Act while the other causes injury by riding upon his reputation in the market and deceiving the customers by presenting an association with the same. It was held that separate suits are required to be filed for separate causes of action claiming different reliefs. The court held that a composite suit in relation to infringement of a registered design and a passing off should be maintainable as on the same cause of action against the same Defendants, territorial jurisdiction made by the Plaintiff on one cause of action would be sufficient for the other. The bench addressed that composite suit has the advantage of a bird's eye view by the Court with respect to a common set of facts. By reason of existence of common questions of law and/or fact between the causes of action of infringement of a registered design and passing off, to a large extent, the evidence of the two cause of action will also be common. In such scenarios, joinder of causes of action must be done in order to avoid multiplicity of proceedings.

THE INTELLECTUAL PROPERTY APPELLATE BOARD: BACK ON THE TRACK

The Intellectual Property Appellate Board (IPAB) is a tribunal constituted for adjudication of technical issues regarding IP rights. IPAB has jurisdiction to deal with matters pertaining to the Patents Act, 1970; the Trademarks Act, 1999; the Copyright Act, 1957; the Geographical Indications of Goods (Registration and Protection) Act, 1999 and the Protection of Plant Variety and Farmers Right Act, 2001. According to rules as defined in various acts, the IPAB Bench must comprise of a Judicial Member and a Technical Member.

The IPAB has been non-functional since several months due to absence of technical members for patent, trademarks and copyright cases; pendency of cases, hence, had become a cause of concern. The post of technical member for patents was lying vacant since 4th May 2016 and that for trademarks was lying vacant since 5th December 2018. For copyright, no technical member has ever been appointed and only one technical member was appointed for Plant Varieties Protection. As a consequence, no hearing could take place in the matters related to patents, copyright and trademarks.

In *Mylan Laboratories Limited vs Union of India and others*, the petitioner (Mylan Laboratories Limited) filed an appeal along with a stay application before the IPAB on 17th May 2019 against an order dated 14th March, 2019 passed by the Deputy Controller of Patents and Designs. The impugned order had dismissed a pre-grant opposition filed by the petitioner. The petitioner approached the Court for urgent hearing of the stay application as the IPAB was not functioning. On Courts' direction, the Deputy Registrar, IPAB filed a status report with respect to the vacancy of the

position of technical members. This further revealed that there was a huge backlog of cases before the IPAB. As on 23rd May 2019, 3935 cases were found to be pending before

the IPAB (Figure 1). This was deemed to be a complete failure of the objectives with which the IPAB was established. In the last five years (January 2014-June 2019), the number of cases disposed of by IPAB is significantly lower when compared to the filings made during the same time period (Figure 2).

Even the number of hearings conducted in relation to patents in past years is very low. From 2014-2016, in all 93 hearings were conducted (2014 – 46; 2015 – 30; 2016 – 17).

The Delhi High Court in its order dated July 8th, 2019, directed that the IPAB Chairman and the technical member (Plant Varieties Protection) are to hear all urgent matters pertaining to patent, trademark and copyright till the vacancies of other technical members are filled up. Further, the Court said that the orders that shall be passed by the Chairman and the technical member, Plant Varieties Act will not be held invalid on the ground of lack of quorum. Also, if the technical member

(Plant Varieties Protection) is not available for any reason or is recused, the Chairman of the IPAB can proceed to hear the urgent matters. The Court further held that, in patent matters, the IPAB Chairman can take expert opinion from the members of the panel of scientific advisors under section 115 of the Patent Act, 1970.

This is certainly a welcome direction given by the Delhi High Court. In the coming months it is hoped the Delhi High Court's orders are implemented with appointment of technical members and smooth adjudication in the matters of the IPAB.

Contributed by Ms. Manika Arora & Ms. Rashmi Tandon

Figure 1:

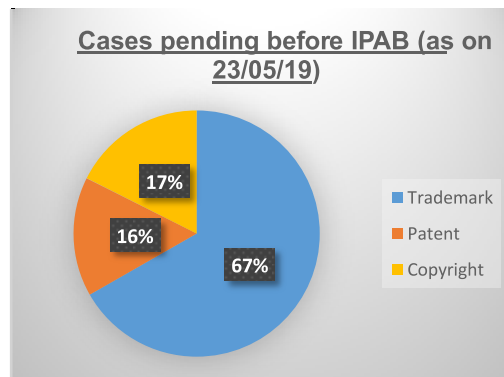
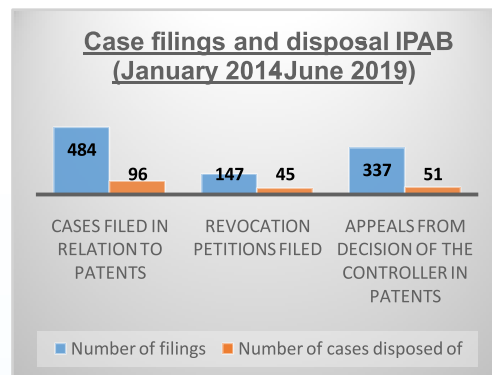


Figure 2:



WORKING STATEMENT REQUIREMENT - AN UPDATE

After a patent is granted in India, the patentee is required to file a statement of working (Form 27) of the patented invention on a commercial scale as per section 146(2) of the Indian Patent Act. The working statement should have information about whether the patent has been worked or not worked in India. If not, then the statement ought to provide reasons for not working and the steps being taken for the working of the invention. If the invention has been worked, then the statement ought to provide the quantum and value of sale of the patented product along with details of manufacturing and/or import from other countries. The patentee is also required to disclose whether public requirement has been met or not at a reasonable price and if met, then whether partly/adequately or to the fullest extent.

A comparison with other countries reveals that there is no country in the world that demands a working statement of patents from a patentee in the way that India does. In a few countries, where there is a provision for a compulsory license, such information may be demanded after an application for a compulsory license has been filed. For instance, in China, even on filing of a compulsory license application, the patentee may provide legitimate reasons for non-working¹. In Brazil, there is no requirement of reporting the working of a patent, but on filing of a compulsory license, the patentee has to prove that he has exploited the patent². In Greece, non-working is a ground for compulsory license, however if the patentee justifies lack of exploitation or insufficient exploitation in the country, compulsory license will not be granted³. In Mexico, there is no express obligation or requirement to file evidence of working the patent; however, on filing of an application for compulsory license, the patentee has 1 year to show working either through export or directly⁴. In

Thailand, non-working of a patent is a ground for compulsory license, however, patentee is not required to submit any evidence for "working". The responsibility to prove the "non-working" of a patent is with the third party who intends to apply for the compulsory license⁵. The Indian scenario, on the other hand, is completely different. Indian practice necessitate that the patentee furnishes information pertaining to working/non-working of the invention on a commercial scale. The requirement is both onerous and obsolete.

Non-compliance with the requirement of filing of a working statement has always been an issue. Time and again, people have asserted that Form 27, is vague and therefore, inapplicable. In 2015, a Public Interest Litigation (PIL) was filed in the Delhi High Court (DHC) by Shamnad Basheer, calling for strict compliance to this requirement of the Indian Patent Act⁶. In the said case, the DHC disposed of the matter and directed the Government to bring about all necessary amendments in the relevant provisions of the working statement, within strictly imposed deadlines. As around 45 years had elapsed since the old Form 27 is being used, the Court held, "Be that as it may, expeditious steps regarding the working of the statutory provisions as well as the changes, if any, are required in the statute, rules and prescribed forms deserve to be taken". The Court recognized that the current Form 27 failed to take into consideration "*the several scientific and technological requirements as well as the confidentiality issues relating to some of the patents*". (emphasis ours). The Court also recognized that the current format of Form 27 is difficult to comply with due to the way it is worded. Further recognizing the difficulties faced by patentees in furnishing information in Form 27, the Court observed "*In case, any party has reservation of any kind in furnishing details, it*

¹Article 48 of the Patents Law of 12/03/1984 as last amended on 27/12/2008

²Article 68-74 of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001

³Articles 13 and 14 of Law No. 1733/1987 on Technology Transfer, Inventions and Technological innovation (2011)

⁴Article 70 of Law on Industrial Property (consolidated text published in the official journal of Federation on January 25, 2006)

⁵Section 46 of the Patent act B.E. 2522 of 11/03/1979 last amended by the Patent Act (No. 3) B.E. 2542 (1999)

⁶*Shamnad Basheer vs. Union of India*.W.P.(C) 5590/2015

would have to disclose the reasons for such reservation and the patent office would be required to take a view in the matter so far as its satisfaction regarding compliance with the requirements of Section 146 is concerned".

Following this, a set of Draft (amended) rules were notified by the Indian Patent Office on May 31, 2019. Besides other things, it contained a new draft Form 27 for filing statement of working/non-working of an invention. The new draft Form 27 is not very different from the previous Form 27, but is presented in a more structured way. The major difference is that it does not contain the requirement of providing "quantum" of a product sold. Further, the new Form 27 requires the patentee to give the approximate value accrued in India to the patentee/licensee from that product and from the product obtained directly by the process separately. Further, a note has been added that states, "where the value accrued from a particular patented invention cannot be derived separately from the value accrued from related patents, and all such patents are granted to the same patentee, the details of all such patents need to be provided." Further, a note has been added that says that every patentee and every licensee is required to file the Form 27. If a patent is granted to two or more persons, all the patentees may file the form jointly, however, each licensee is required to file this form individually. Further, the patentee is also supposed to acknowledge that the information as disclosed in Form 27 to the Indian patent Office will be made public.

On comparing the draft of new Form 27 with the existing one, the new form is found to be even more tedious to comply with. Not only this, but there are still various issues and concerns that need to be addressed. First, the draft Form 27 fails to take into consideration the confidentiality issue as raised by the Hon'ble Delhi High Court. The new form still asks for commercial/financial information that is

the confidential for the patentee. Second, there is no option available to the patentee in the form to give reasons, if the patentee chooses not to share the details required. Third, disclosure of the said confidential information may weaken the negotiating position of the patentee in any future licensing negotiations and can jeopardize on going infringement litigations. Fourth, this provision of the Patent Act clearly defeats the very idea of competition by demanding and putting such information in public domain. Fifth, the entire exercise of collecting confidential data from the patentees is futile as patent examiners are anyways not equipped to analyze the correctness or completeness of the data submitted by the patentees. Sixth, no country has penal consequences attached to any requirement related to grant of a compulsory license. However, in India, penalty is levied if correct information required in the Form 27 is not furnished. Last but not the least, the requirement of filing Form 27 and providing confidential business information puts an unnecessary burden on the patentee and is also in contravention of basic legal principles. Further, when patentees own patent portfolios comprising thousands of patents, it is practically not feasible to accurately track the value generated from working of each and every patent.

Keeping in mind the various facts as stated above, an ideal scenario will be where a patentee will not be required to furnish the information as required in Form 27. However, as of now, that still remains farfetched. We hope that the Government of India takes cognizance of the various concerns of patentees and revisits their rules and policies so that the compliance of their requirements does not become a hindrance to the path of innovation.

Contributed by Dr. Anju Khanna

DELHI HIGH COURT (ORIGINAL SIDE) RULES, 2018

The Delhi High Court issued new rules after Supreme Court's guidelines in *Az Tech India v. Intex Technologies (SLP 18892/2017)*. In a passing off case, in *AZ Tech v. Intex Technologies*, an SLP was filed against the interim order passed by the Delhi High Court (DHC). The Supreme Court directed the DHC to dispose of the matter expeditiously and did not interfere with the interim order. The Apex Court however noted that the interim order was almost a decision on merits of the suit. The Apex Court also noted that writing an exhaustive judgment at interim stage is a disturbing trend which would govern the parties for a long duration of time while disposal of the main suit can take years. The Supreme Court took cognizance of the pendency of IPR cases at the DHC and directed the Registrar General to submit reports on steps being taken to address the issue of pendency. The Supreme Court directed DHC to come up with effective ways or means to dispose of IPR cases. DHC issued new Rules i.e. Delhi High Court (Original Side) Rules, 2018 with effect from March 1, 2018, to streamline the processes. The new rules provide for cutting short time line, streamlining the procedure for completion of pleadings, interrogatories, discovery, appointment of local commissioner, checking random adjournments and imposing cost for causing delay etc. As per the rules, adjournment will be granted only in exceptional cases and must be recorded in writing. Consent of the parties will not be a good cause for seeking adjournments and exemplary cost may also be applied. Further, DHC came with the amended rules to increase the cooperative endeavour to settle dispute between parties with an ease, and these amended rules came into force on 1st November, 2018. A new Rule 17 has been added which speaks of 'Confidentiality Club', which is a procedure followed in patent litigation in many jurisdictions. Following has been established under confidentiality club:

- Quorum of Confidentiality club
 - Max three advocates from each party (not in-house lawyers)
 - Not more than two external experts.
- As a protocol for confidentiality club, the rules provide that the court may allow constitution of a confidentiality club by permitting filing of all confidential information in a sealed cover to be kept in the safe custody of the Registrar General.
- Members are not allowed to make copies of any confidential information.
- Copies of confidential document given to opposite party only at the discretion of the court
- Confidential document shall not be available for inspection after disposal of the matter.

Further Chapter XA has been added regarding case management which gives procedural aspects of the direction and orders from the court. According to the rules, the court may, either on its own motion, or on any application of any party, permit an expert witness to testify. In such a case, the court may pass appropriate orders for recording of his testimony (including by **hot tubbing** technique, etc), manner of recording, document relied upon by the expert and the fee payable to him. Hot tubbing procedure encourages representatives, experts and the judge to focus on the issues prior to the trial and to clearly identify areas of disagreement. Time at the trial is saved by this degree of focus and the job of the judge in evaluating disagreements is made easier by dealing with each area of disagreement before moving on to the next. The amended rules also place provisions for summary judgement without recording oral evidence, to expedite disposal. These new rules will go a long way in improving the process, reducing pendency and streamlining and ensuring effective disposal of IPR matters.

Contributed by Ms. Manika Arora

Updates from the Indian Patent Office

The last five years have witnessed a major overhaul in the working of the Indian Patent Office (IPO). After the introduction of numerous initiatives by the government, Indian Patent Office and introduction of National Intellectual property rights (IPR) Policy in the year 2016, there has been a distinct change. It is a well-established fact that IPR is the driving fuel of any knowledge driven economy. With increasing cognizance of IPR in society, a vision to strengthen IPR regime in the country is taking shape. The policy makers and the stakeholders are all striving hard to encourage innovation and empower the innovators. The Indian Patent Office (IPO) has been playing a key role in accomplishing this objective by simplifying and easing the patent procedures. During the past few years, several steps have been taken by the IPO for enhancing efficiency, uniformity and consistency in processing of patent applications and providing a transparent intellectual property rights (IPR) framework.

Some initiatives taken in this direction are: upgradation of the IT systems and online website (InPASS), providing an online payment gateway, mandatory e-filing of applications by patent agents, additional 10% fee on filing through physical mode, digitization of documents etc. The procedural improvements carried out by the IPO further include conducting of hearings through video-conferencing/ audio-visual communication devices, launching of an official mobile app for IPR and SMS alert facilities to help the applicants get information and updates related to their filed applications. As a consequence, there has been a considerable increase in filing of patent applications and their disposal in last 5 years.

Other welcoming procedural changes introduced by the IPO include allowing withdrawal of applications before issuance of the First Examination report (FER) and refund of fees paid for filing the request of examination, limited adjournments of hearing in opposition proceedings and a provision for deleting claims during national phase entry in India. All this will go a long way in making the IPR regime robust. Further, hiring of new patent examiners and auto-allocation of requests for examination of patent irrespective of the location within India has further resulted in a 407% surge in issuance of examination report from FY 2015-16 to FY 2018-19. This is evident from the comparative table 1 and the graph shown in Figure 1 below:

Table 1:

CUMULATIVE STATISTICS: Yearwise Comparison (FY 2015-16 - FY 2018-19)																				
IP	Applications Filed					Applications Examined					Grants/ Registrations					Disposal				
	FY 2015-16	FY 2016-17	FY 2017-18	FY 2018-19	% Change FY 2018-19 vs. FY 2015-16	FY 2015-16	FY 2016-17	FY 2017-18	FY 2018-19	% Change FY 2018-19 vs. FY 2015-16	FY 2015-16	FY 2016-17	FY 2017-18	FY 2018-19	% Change FY 2018-19 vs. FY 2015-16	FY 2015-16	FY 2016-17	FY 2017-18	FY 2018-19	% Change FY 2018-19 vs. FY 2015-16
Patents	46904	45444	47854	50688	8%	16853	28967	60330	85436	407%	6326	9847	13045	15284	142%	21987	30271	47695	51781	136%
Trademarks	283060	278170	272974	338542	20%	267861	532230	306259	337541	26%	65045	250070	300913	316798	387%	116167	290444	555777	519185	347%
Designs	11108	10213	11837	12583	13%	7545	11940	11850	12661	68%	7904	8276	10020	9512	20%	8273	8332	10788	11414	38%
Copyrights	14812	16617	23217	18099	22%	9325	16584	26195	16443	76%	4505	3596	19997	14687	226%	4505	3596	32008	21546	378%

(Source: <http://cipam.gov.in/iprends/>)

Table 2

COMPARITIVE STATISTICS CUMULATIVE UPTO April 2017-18 Vs. April 2018-19												
IP	Applications Filed			Applications Examined			Grants/ Registrations			Disposal		
	April, 2018	April, 2019	% Change	April, 2018	April, 2019	% Change	April, 2018	April, 2019	% Change	April, 2018	April, 2019	% Change
Patents	3958	4278	8%	5733	5393	-6%	1001	1455	45%	2906	3062	5%
Trademarks	26550	28638	8%	17474	12892	-26%	25351	8133	-68%	33128	26848	-19%
Designs	992	1256	27%	932	1076	15%	479	1050	119%	476	1175	147%
Copyrights	1896	1731	-9%	1170	287	-75%	1606	790	-51%	2006	1043	-48%

(Source: <http://cipam.gov.in/iprends/>)

Further, it can be seen that there is an increase in both patent grant and disposals in the FY 2018-2019 as compared to the previous years. Also, the comparative statistics cumulative up to April 2017-18 vs April 2018-19 show that there is a 45% increase in patent grants and around 5% increase in disposal of patent applications (Table 2). A comparative study related to patenting trends in India in various technological fields (from April 2014-August 2019) reveals that maximum patents are granted in the field of chemical sciences followed by engineering and pharmaceuticals (Figure 2). The fields where the number of patents granted is very low include traditional knowledge, microbiology, food technology and metallurgy. The area of biotechnology also has very low number of granted patents indicating that it is also an area where India is lacking as far as innovation is concerned.

When looking at the data of FER disposal, the trend, however, differs slightly. From April 2014- August 2019, maximum FERs that have been disposed of relate to patent applications in the field of electrical/electronics followed by mechanical engineering and chemical sciences. Biotechnology is again the field with lowest FER disposal (Figure 3).

Further the request for India as International Search Authority has also increased in the last year. Steps have been taken by the IPO to provide high quality International Search Reports (ISRs) and International Preliminary Examination Reports (IPERs) while adhering to strict time lines. The IPO has now reportedly achieved 99% timeliness in issuing ISRs under PCT.

Many new developments are anticipated in near future that include development of a Japan-India Patent Prosecution Highway (PPH). On October 29th 2018, the leaders of the two countries concurred to start the PPH. Further, Draft Patents (Amendments) Rules dated December 4, 2018 were amended with respect to international applications, patent opposition and procedural formalities. One of the important changes proposed to be introduced is extension of eligibility to file a request for expedited examination to female applicants, applicants eligible for PPH program participation, small entities and government undertakings acting as applicants. Further no transmittal fee and no fees is proposed to be levied for the preparation of certified copies of priority documents for international applications filed through e-PCT. Also, pre grant opposition to be decided by a bench comprising of two members. In case of different opinions on the

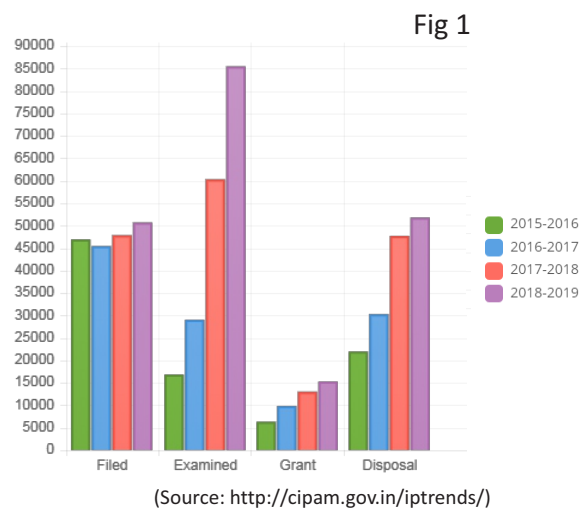
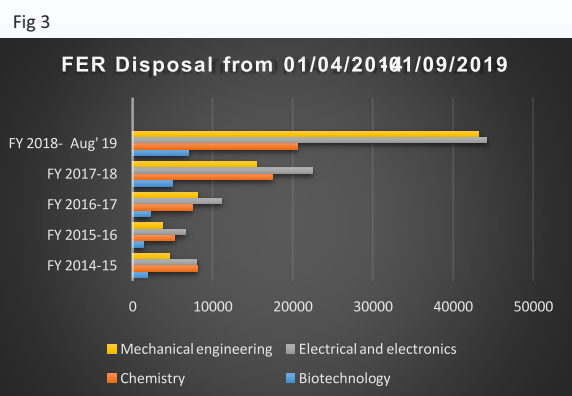
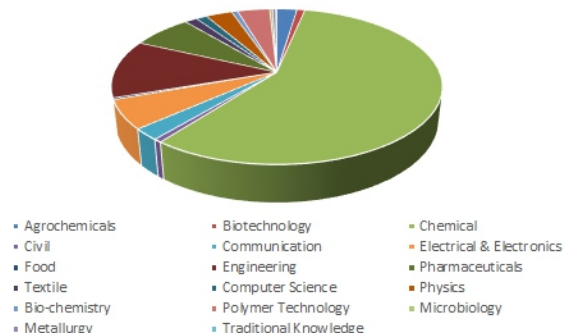


Fig 2
FIELD WISE PATENTS GRANTED: 01/04/2014-01/09/2019



issue, a third member will be assigned to the bench to arrive to a final decision of the majority.

The main objective ahead of the IPO now is to reduce the pendency and bring down the time from filing of application till grant to 2-3 years. Hopefully, this will be achieved soon in the years to come. Once achieved, this will give a new impetus to the entire innovation industry.

Given the initiatives taken by the Indian Government through the IP reforms, we believe the IP ecosystem is marching towards positive and efficient changes. For ensuring high quality examination of IP titles, specialized technical group have also been established to ensure access to relevant expertise for examination. In consultation with stake holders, guidelines have been established to address complex examination questions arising in specific technology fields, including traditional knowledge and biological material, biotechnology, pharmaceuticals and computer-related inventions. The Government is thus, leaving no stone unturned to ensure that India's IP services are at par with the best in the world.

Contributed by Ms. Manika Arora & Ms. Rashmi Tandon

AI & Healthcare Startups in India

India is a large country, ranking seventh by geographical area and second only to China in population, at about 1.33 billion inhabitants. India is also a low middle-income country with a GNI per capita of 2020 USD¹. Adding to the above, India faces a shortage of healthcare providers². These conditions have led to several healthcare gaps that need to be filled in India. These gaps can be seen as opportunities to solve by both business and technical innovations.

One technology area that seems like the promised elixir for solving India's health problems is the catchphrase technology of "Artificial Intelligence" or "AI" for short. The term encapsulates all software and allied technologies that have capability of machine learning and analysis of big data to find solutions and results that earlier seemed impossible to achieve. The Indian Government is also exploring the AI route and has in fact published a national strategy for artificial intelligence, with the hash tag: #AI FOR ALL in June 2018³. The document highlights that AI can provide increased access and affordability of quality healthcare to the citizenry of India. Alongside the government, the healthcare industry is also adopting AI technologies. AI is being widely adopted amongst several modern healthcare industry in order to make routine medical procedures more

cost and time efficient. There are several startups that have originated in India that are working towards developing and providing AI solutions to the healthcare problems prevalent in India. We bring the focus on some of these startups below to showcase the development of AI technologies in India.

Right off the bat, this Karnataka based startup called **Cardiac Design Labs** designs, develops and sells intelligent wearable devices. Their devices help in prompt detection of diseases for diagnosis and results are readily available for printing as well⁴. They have filed two patent applications for seeking patent protection relating a technology for cardiac monitoring & real time detection of episodes. One of the two applications has been granted with Patent Number 311295 and the second was abandoned.

Another startup making notable contribution is **Spectral Insights** which offers 24x7 access to high quality digital slide images anywhere (biopsies, blood smear, TB) and analytical tools which helps in improving accuracy. One of their products, *Vulcan Digital Pathology*, enables image acquisition, databases, user management, analysis and reporting tools. The company has also built automated microscope that makes digital images which are available

¹[https://en.wikipedia.org/wiki/List_of_countries_by_GNI_\(PPP\)_per_capita](https://en.wikipedia.org/wiki/List_of_countries_by_GNI_(PPP)_per_capita)

²<https://www.thehindu.com/sci-tech/health/india-facing-critical-shortage-of-healthcare-providers-who/article27096738.ece>

³https://www.niti.gov.in/writereaddata/files/document_publication/NationalStrategy-for-AI-Discussion-Paper.pdf4

⁴Home page - Cardiac Design Labs impacting Lives; "http://www.cardiacdesignlabs.com"; accessed on September 10, 2019

locally as well as over the cloud⁵. They filed for patent applications to secure patent rights for their spectrometer & optics imaging systems. They currently have two pending patent applications; one is awaiting examination while the second has been published.

On the same lines is **Artelus**, a company using deep learning algorithms in order to detect diabetic retinopathy instantly, at a rate faster than humans. Their products can detect lung and breast cancer; analyse X-rays and IVF medical images by way of artificial intelligence⁶. **Orbuculum** is another startup that uses a learning AI algorithm that uses genomic data, for predicting diseases such as diabetes, neurological disorders, cancer, cardiovascular diseases⁷.

There are several healthcare start-ups focused on cancer diagnosis and care; one of them is **OncoStem Diagnostics**, a Bangalore-based startup, which provides personalized cancer treatment with the help of machine learning algorithms. They are developing innovative prognostics and solutions for various types of cancers⁸. They have secured patent protection for their invention related to prognosing & predicting breast cancer recurrence in patients vide Patent no. 300707. **Niramai (Non-Invasive Risk Assessment with Machine-learning and Artificial Intelligence)** is another startup, that use low-cost devices to take high-resolution thermal images with no radiation using AI. Their solution, *Thermalytix* uses thermal imaging and cloud based AI analytics for pain-free early stage breast cancer detection⁹. This startup is very active in securing patent rights and has filed seven patent applications related to screening of breast cancer under its name.

Tissue culture is an ever-evolving field of science, providing

breakthrough in treatment of chronic diseases, and **Advancells** is another committed organization, focusing on therapeutic applications of Regenerative Medicine. They work towards replacing and regenerating human cells, tissues or organs to restore or establish normal function. This provides a safe and effective treatment to patients all over the world.

Startups such as **Vector Doc** and **Onli Doc** provide cogent solutions by using AI to provide quick access to medical prescription and history, providing a whole new meaning to on-call doctor. **VectorDoc** was formulated in 2012 by Yantra Mind based on some unique features for cases, referrals and diagnostic decision making through artificial intelligence-based solutions¹⁰. **OnliDoc** uses an AI-driven platform for end-to-end medical diagnosis. Their database can search for doctors, manage appointments, and store medical records and prescriptions. On the diagnosis and treatment side, AI is also used to help in treatment selection, to recommend first actions and prognostic prediction.¹¹

Various applications of AI are not only efficient in the diagnosis of diseases but are also helpful in improving the mental health of people nowadays. This can be observed by the initiatives taken by a company named **Touchkin**, a Bengaluru based startup, which designed an AI-based conversation coach called **Wysa** for helping in detecting and subduing depression symptoms in its users¹².

Thus, innovations that amalgamate AI in healthcare by several startups is playing a pivotal role in transforming the healthcare industry of India and it can be said that a healthcare revolution is brewing in India.

Contributed by Mr. Aditya Kochhar

⁵ Home page- Spectral insights; "<https://spectralinsights.com/>"; accessed on September 10, 2019

⁶ Products- Artificial Learning System; "<https://artelus.com/>"; accessed on September 10, 2019

⁷ About; "<https://www.f6s.com/orbuculum>"; accessed on September 10, 2019

⁸ CanAssitBreast; "<https://oncostem.com/canassistbreast.php>"; accessed on September 10, 2019

⁹ Home – "<https://www.niramai.com/>"; accessed on September 10, 2019

¹⁰ Homepage – "<https://www.vectordoc.com/>"; accessed on September 10, 2019

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ANJU KHANNA – MANAGING PARTNER & DIRECTOR - PATENTS



Dr. Khanna heads the Patent Department and is in-charge of both patent prosecution and litigation at the firm. She has more than 18 years of work experience with 15 years in the field of patents. Dr. Khanna oversees and handles work in different technology domains including chemistry, pharmaceutical, medical devices, electrical and mechanical inventions, telecommunication to name a few. She is actively involved with the Patent Office and the DIPP and organizations like the CII and Invest India etc. in policy decisions and regularly engages with them in this regard. A few examples of such engagements are CRI guidelines, pharmaceutical inventions' guidelines, working statement requirements, SEP paper etc. Dr Khanna is a member of the Patent Committee of APPA and is a member of INTA, AIPPI and IPO association.



THE TEAM

RAGHAV MALIK PARTNER



Raghav Malik, Partner at the firm, is an advocate registered with the Bar Council of India since 2006. With an experience of around 11 years, his practice focuses on overall IP prosecution and enforcement for both domestic and international clients. He specializes in strategy building, enforcement strategies, anti-counterfeiting actions and other legal issues arising thereto. He represents clients in the field of pharmaceuticals, apparel, banking & financial services and FMCGs. He also heads the Nepal branch office. He is a member of International Trade Marks Association (INTA) and is actively involved in INTA Committees. He is also a member of Intellectual Property Attorneys Association (IPAA).



