# Patents

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## India

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### Patent enforcement proceedings

### 1 Lawsuits and courts

What legal or administrative proceedings are available for enforcing patent rights against an infringer? Are there specialised courts in which a patent infringement lawsuit can or must be brought?

### Legal proceedings

At present, the civil courts have exclusive jurisdiction to entertain and decide issues concerning patent infringement. Under the Patents Act 1970 (the Act), the court of first instance for a patent infringement action is the District Court. Where in an infringement action, the defendant opts to challenge the validity of the suit patent, the Act requires the suit to be transferred to a High Court. Further, the High Courts of Delhi, Bombay, Calcutta and Madras exercise original jurisdiction for patent infringement actions subject to the pecuniary jurisdiction as prescribed under the respective Rules. This implies that an infringement action may be directly brought before these specific High Courts provided the pecuniary limits are satisfied.

Further, the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 has been introduced with effect from 23 October 2015. It creates commercial divisions in High Courts and commercial courts at the district level for ensuring that commercial disputes arising out of transactions between merchants, bankers, financier, traders, etc are disposed of expeditiously. Such transactions include intellectual property rights. The commercial divisions in High Courts and commercial courts at district level will deal with all matters relating to commercial disputes involving an amount of one crore or more rupees.

All suits of a value of one crore or more rupees that are pending in the High Court shall be transferred to the commercial division. Likewise, all suits pending in the district courts, with a value of one crore or more rupees, would be transferred to the commercial court.

Any appeal filed in a High Court against the orders of tribunals such as the Intellectual Property Appellate Board would be heard by the Commercial Appellate Division of the High Court if it relates to a commercial dispute.

At present, India does not have specialised courts to hear and decide patent infringement actions even though the requirement of the same has been recognised in the recent draft national IPR policy. The majority of patent infringement actions have been instituted before the High Court of Delhi in the recent past and, as a result, the court has seen a marked transition in judges becoming more conversant and gaining expertise in the realm of patent law. On a general note, patent enforcement actions come within the scope of regular litigation before civil courts.

### Administrative proceedings

The Patent Office and the Intellectual Property Appellate Board (IPAB), a specialised statutory body established to deal with IP issues, has jurisdiction to decide on issues of patent invalidity, in addition to a High Court.

### 2 Trial format and timing

### What is the format of a patent infringement trial?

Proceedings against infringement of a patent are initiated by filing a civil suit either in the district court, or in some jurisdictions, directly before the High Court.

Once such a suit is listed before court, summons will be issued to the defendant. If the defendant fails to appear despite having been served through various means, he or she will be proceeded ex parte.

### Interim stage

In every suit, the plaintiff can file a petition seeking interim relief. The court may grant an interim injunction against the defendant, if the plaintiff satisfies the following criteria: it is a prima facie case; there has been irreparable harm; the patent is valid and infringed; and the balance of convenience is in favour of injunction.

Ex parte injunctions (where no notice is served on the defendants) will be granted where it appears that the object of granting the injunction would be defeated by the delay of giving notice to the defendants. However, in patent infringement cases, ex parte injunctions are usually declined as the complex issues involved in these cases often require a consideration of the defence raised by the defendant.

The High Court of Delhi has granted ex parte and interim injunctions in cases where the defendant's product was yet to be launched in the market (quia timet actions). For instance, such ex parte orders have been passed in *Bristol-Myers Squibb and Anr v JD Joshi and Anr, Bristol-Myers Squibb and Anr v Dr BPS Reddy, Ors Yuhan Corporation v Ajanta Pharma Ltd, Vifor (International) Ltd v Symed Laboratories Pvt Ltd, Novartis v Ranbaxy and Dong-A Pharmtech Ltd v Emcure Pharmaceuticals Ltd.* 

### Trial in patent infringement suits

If the defendant wishes to contest the suit, it will be obliged to file a written statement to the plaint.

The defendant may also file a counterclaim seeking revocation of the patent at any stage, either with the written statement or later. Where the suit is instituted before the district court and a counterclaim of revocation is filed, the suit and the counterclaim will be transferred for adjudication to the High Court under section 104 of the Patents

The plaintiff may then seek leave to file a replication to the written statement. The plaintiff is entitled to file a written statement where a counterclaim for revocation of the patent sought to be enforced has been filed by the defendant.

In a patent infringement case, it is open to the parties to file affidavits of technical experts to substantiate their case, at any stage up to the stage of trial.

When the pleadings are complete, the parties will be required to admit or deny each other's documents filed in the proceedings. Ordinarily, all documents sought to be relied upon by the parties must be filed prior to admission and denial of documents. Documents admitted by a party may be read as part of the evidence led by the opposite party.

After admission and denial, issues are framed in the suit by the court. Issues are framed to list the matters of controversy between the parties. The evidence led by the parties will have to cover and be

confined to the issues that are framed. Under section 115 of the Act, in any suit for infringement or any proceeding before a court, scientific advisers may be appointed by the court to advise in its inquiry or report upon any question of fact. More recently the courts have started accepting the importance of a scientific adviser or expert evidence in patent cases. The two significant decisions of the Delhi High Court in 2015, Merck v Glenmark and Roche v Cipla, have relied heavily on the expert evidence. In fact, in Aventis v Binish Hasmukh Chudghar (an infringement suit filed by Aventis Pharma SA against Intas for the drug cabazitaxel) the court appointed Dr HM Chawla and Dr SV Eswaran as independent scientific advisers with the consent of both parties. The scientific advisers have to assist the court in deciding on a specific technical aspect, ie, whether the compound cabazitaxel, as claimed in Aventis's patent IN225928, is not new as regards what was known as per the prior arts Markush formula. This is being considered as a progressive step by courts in India and as a step towards 'hot-tubbing' in patent disputes in India.

The suit then proceeds to the stage of trial. The parties will file a list of witnesses.

The parties were, in the past, required to examine their own witnesses before an officer of the court. However, this process of examination-in-chief has been substituted by filing an affidavit of examination-in-chief, by amendments to the Code of Civil Procedure 1908.

Upon filing the affidavit of examination-in-chief, witnesses will be cross-examined by counsel for the opposite party.

The trial process outlined above can take place before the court that is hearing the suit, or in the presence of the joint registrar of the court, or before a court-appointed local commissioner.

After examination and cross-examination, final arguments in the suit take place before court, after which the judgment will be delivered.

The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 has also introduced strict timelines to ensure prompt resolution of disputes; however, as the disputes covered are large the effectiveness will only be tested with time. The projected timeline of litigation under the new act is given below. According to calculations the lifespan of a commercial dispute action could be as short as 12 months:

Stage	Timelines			
Issuance of summons	1 to 10 days			
Completion of pleadings	30 to 120 days (plus time taken for completion of service)			
Inspection of documents	30 to 60 days (from date of filing written statement)			
Admission-denial (though affidavit)	15 days (from date of inspection - can be extended by court)			
First case management hearing	4 weeks (from date of filing affidavit of admission-denial)			
Conclusion of trial and final arguments	6 months (from date of first case management hearing)			
Pronouncement of judgment	90 days (from conclusion of arguments)			

### 3 Proof requirements

What are the burdens of proof for establishing infringement, invalidity and unenforceability of a patent?

### Burden of proof (infringement)

The burden of proof of establishing infringement rests on the plaintiff. However, where the subject matter of infringement is a process patent relating to a new product and there is a substantial likelihood that an identical product has been made by the same process by the defendant and the plaintiff has been unable to discover, the burden of proving that the process by which the defendant prepared the substance rests on the defendant (section 104A of the Act).

The standard of proof in a patent infringement action as well in an invalidity action is based on a balance of probabilities. This means that the plaintiff must present evidence that shows that infringement is more probable than not. It is pertinent to note that Indian patent law does not recognise the concept of presumption of validity of a granted patent as has been held by the Supreme Court in *Bishwanath Prasad* 

v Hindustan Metal Industries (1979 2 SCC 511). However recently, in Telefonaktiebolaget LM Ericsson (Publ) v Mercury Electronics & Anr, it was clarified that, section 13(4) as interpreted in Bishwanath Prasad v Hindustan Metal Industries talks about presumption of validity of a patent only to the extent that no liability shall be incurred by the Central Government or any other officer in connection with the grant of patent.

Also, division bench (DB) comprising of Justice BD Ahmed and Justice Sanjeev Sachdeva of Delhi High Court passed an order granting an injunction in a patent matter involving 3M Innovative Properties Ltd (plaintiff) and Venus Safety & Health Pvt Ltd (defendant). The Court in the order hinted at a presumption of validity of the patents holding that the grant of the patent by the Indian Patent Office and the US Patent Office heightens the burden for establishing a credible challenge.

In the case of invalidity, the standard of proof required might be higher.

Also, in *F Hoffmann-La Roche v Cipla* the single judge of the Delhi High Court held that the onus of proof in the revocation proceedings is akin to the principle of onus of proof involved in the civil cases, which is on the balance of probabilities.

#### Burden of proof (invalidity and unenforceability)

A patent may be invalidated on any of the grounds mentioned in sections 25(2) or 64 of the Act. Under section 25(2), a notice for post-grant opposition can be filed before the controller within one year from the date of publication of the grant of patent. A petition for revocation under section 64 may be filed with the appellate board or on a counterclaim in a patent infringement suit with the High Court by any interested person or the central government. In an invalidity action, the burden of proof to establish invalidity lies with the petitioner.

An interested person is one who has a direct, present and tangible commercial interest that is injured or affected by the continuance of the patent on the register (see section 2(1)(t) of the Act and Ajay Industrial Corporation v Shiro Kanao of Ibaraki City, AIR 1983 Del 496).

In Sankalp Rehabilitation Trust v F Hoffmann-La Roche, which was an appeal against the post-grant opposition order for the medication Pegasys, filed by Sankalp, a non-governmental organisation, the IPAB held that a wider interpretation should be given to the words 'person interested' in view of public interest. The IPAB further held that as the Indian Patent Act includes 'a person doing research' in the definition of 'person interested', an interest that is an academic one and not necessarily commercial, and when the Act only uses the word 'includes', which is a word that is not restrictive, the Ajay Industrial case and the Thailand Court case may be applied. The IPAB further held that public interest 'is a persistent presence in intellectual property law and will not melt into thin air, nor dissolve'.

### 4 Standing to sue

Who may sue for patent infringement? Under what conditions can an accused infringer bring a lawsuit to obtain a judicial ruling or declaration on the accusation?

An action for infringement of a patent may be instituted by the patentee him or herself. If the patent is licensed exclusively, the rights of the exclusive licensee to sue for infringement are equivalent to that of the patentee. The exclusive licensee must make the patentee a party to the proceedings either as a plaintiff or defendant.

The Patents Act 1970 further provides scope to a licensee who has been granted a compulsory licence to put the patentee on notice of the infringement and call upon him or her to take proceedings to prevent infringement. If the patentee neglects to do so within two months of being called upon to do so, such a licensee may institute proceedings as though he or she were the patent holder, making the patent holder a defendant in the proceeding.

Any person, not being the patentee or exclusive licensee, may institute an action for declaration of non-infringement upon satisfying both of the following conditions: that such a person has written to the patentee or exclusive licensee for a written acknowledgment of the declaration sought, along with all particulars of such communication; and that the patentee or exclusive licensee has refused or neglected to give such an acknowledgment.

### 5 Inducement, and contributory and multiple party infringement

To what extent can someone be liable for inducing or contributing to patent infringement? Can multiple parties be jointly liable for infringement if each practises only some of the elements of a patent claim, but together they practise all the elements?

The concept of contributory infringement has not been incorporated within the statute and, hence, each person or entity taking part in the act of infringement shall be individually liable. However, the concepts of vicarious liability, abetment and contributory infringement are common law principles, which a court, if it deems fit, may import into patent infringement disputes for imputing liability on such 'indirect infringers'.

### 6 Joinder of multiple defendants

Can multiple parties be joined as defendants in the same lawsuit? If so, what are the requirements? Must all of the defendants be accused of infringing all of the same patents?

All such persons or entities who are considered necessary and proper parties in order for the proper and final adjudication of the suit may be added as parties thereto.

Addition and deletion of parties during the course of litigation is permitted under Indian law. However, such addition and deletion can only be made after obtaining permission from the court.

### 7 Infringement by foreign activities

### To what extent can activities that take place outside the jurisdiction support a charge of patent infringement?

Being a territorial right, a patent is infringed only if the rights of the patentee, as defined in section 48 of the Act, are infringed. Section 49 of the Act clarifies that the use of a patented invention in foreign aircraft or vessels or land vehicles registered in a foreign country, which temporarily or accidentally happen to be within India or its territorial waters, is not deemed to be an infringement.

This exemption does not extend to vessels, aircraft or land vehicles of persons ordinarily resident in a foreign country, the laws of which do not confer corresponding rights with respect to the use of inventions in vessels, aircraft or land vehicles owned by persons ordinarily resident in India while in the ports or territorial waters of that foreign country.

### 8 Infringement by equivalents

### To what extent can 'equivalents' of the claimed subject matter be shown to infringe?

Indian courts have tacitly recognised the doctrine of equivalents. In *Raj Prakash v Mangat Ram Chowdhury* [1978] AIR Delhi 1, the Delhi High Court held that the pith and marrow of the invention claimed has to be looked into and courts were not to be weighed down in the detailed specifications and claims made by parties. The court also held that the title of the specifications of an invention does not control the actual claim. Under Indian law, one cannot avoid infringement by substituting an obvious equivalent for an inessential integer, or by some trifling or inessential variation or addition, while, on the other hand, one cannot be held to have taken the substance of a patented invention if one omits or substitutes something else for an essential integer.

Further, in *Ravi Kamal Bali v Kala Tech and Ors* (38) PTC 435 (Bombay), the doctrine of equivalents was discussed to settle a dispute relating to the infringement of a patent relating to tamper-proof locks or seals.

### 9 Discovery of evidence

What mechanisms are available for obtaining evidence from an opponent, from third parties or from outside the country for proving infringement, damages or invalidity?

Discovery is permitted after the institution of the suit and may be conducted by the plaintiff or the defendant in a suit. For this purpose, the party seeking discovery may file an application requesting the court to direct the other party to provide the requisite information or materials to the applicant. In addition, a party can also seek inspection and discovery

of any document relied upon by the opposite side by sending a notice under the Civil Procedure Code 1908.

Further, a party may also make an application to court seeking leave to deliver interrogatories in writing to the opposite party. These interrogatories are answered by the opposite party, by an affidavit within 10 days or within such time that the court may allow.

#### Anton Piller orders

The Anton Piller process in India has been fine-tuned over the years and, on account of the judicial enthusiasm to protect intellectual property, now includes additional safeguards like lock-breaking powers and the freedom to have police assistance if violence is anticipated. Anton Piller orders may also include Norwich Pharmacal-type provisions where the court directs not only the defendant, but also third parties such as customs and excise departments, to disclose relevant details (for example, details of sources or customers) to the court-appointed commissioner.

Recently, the Delhi High Court has even granted John Doe orders that allow court-appointed commissioners to enter the premises of any suspected party who may not even be named in the suit and collect evidence of infringement. Although previous practice was to specify a defendant and location to a particular local commissioner, courts have recently made provision in *Anton Piller* orders for roving commissioners, permitting the court commissioner to visit any location where the commission of infringing acts is suspected. This ensures optimisation of the ex parte injunction.

The John Doe process has been supplemented by orders granting additional powers to court commissioners. These range from the power to witness a trap purchase, as in *IBM v Kamal Dev*, to lock-breaking powers in several cases involving clothing manufacturer Levi Strauss. Additionally, courts have also issued directions to local police to assist in the enforcement of a civil court order.

When it was suspected that a counterfeiter was monitoring the High Court for a possible lawsuit, in one instance the applications for injunction and the grant of *Anton Pille*r orders were heard in camera by the Delhi High Court.

Discovery from the defendants or inspection of records or the defendant's machinery (*Graf* + *Cie AG v Perfect Equipment Pvt Ltd & Anor*, a Delhi High Court decision (unreported)) is also available.

### 10 Litigation timetable

### What is the typical timetable for a patent infringement lawsuit in the trial and appellate courts?

A patent infringement suit typically used to last for two to three years. With the enactment of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 this average timeline is expected to be reduced further to one to two years. The courts in India, especially the High Court of Delhi, have warmed to the idea of fast-track litigation in intellectual property matters. This trend of fast-track litigation is becoming increasingly common in patent litigation in view of the relatively lower chances of obtaining an interim injunction as well as the limited term of exclusivity available under the patent regime.

In fact, there have been several cases, such as the following, in which direct IP cases were disposed of within a few months:

- Bajaj Auto Limited v TVS Motor Company Limited (2009), where the Supreme Court directed the lower court to dispose of the suit within two and a half months from the date of the order;
- F Hoffmann-La Roche Ltd & Anr v Cipla Limited (2009), where the direction was to conclude the trial as expeditiously as possible;
- B Braun v Rishi Baid (2010), where the direction was to dispose of the suit within four months and a schedule was laid down; and
- Bristol-Myers Squibb v Ramesh Adige (2011), where parties were directed to complete recording of evidence within a maximum period of four months from the first date fixed before the Local Commissioner.

Recently, in 2016, Pfizer Inc's suit against SP Accure Labs Pvt Ltd and Accure Labs Pvt Ltd and an online pharmacy, Modern Times Helpline Pharma, to restrain from infringing the patent that covers their anticancer drug Sunitinib, was decreed against the defendants and a decree of permanent injunction was passed. In the instant case, the defendants submitted their written statement 229 days after service of summons. The Delhi High Court held that the delay of 229 days in filing the

written statement is contrary to the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act of 2015. Consequently, the Court refused to take on record the written statement of the defendants.

It is possible to agree on a timeline for deciding a lawsuit through a court regulated process.

Appeal proceedings generally last between six months and two years.

### 11 Litigation costs

What is the typical range of costs of a patent infringement lawsuit before trial, during trial and for an appeal? Are contingency fees permitted?

The typical range of costs in a suit for patent infringement would be:

- for the filing of a suit, approximately US\$50,000 to US\$60,000 not including stamp duty and court fees, which will be based on the amount of damages sought by the plaintiff;
- during the trial, the fee may range between US\$150,000 and US\$300,000 depending on the complexity of the case and the fee of the senior advocate engaged; and
- for an appeal to the Supreme Court, the fee may range between U\$\$350,000 and U\$\$650,000.

The fees mentioned above may vary depending on the complexity of the case and the number of court appearances.

The Bar Council of India prohibits advocates from charging fees to their client's contingent on the results of litigation or paying a percentage or share of the claims awarded by the court.

### 12 Court appeals

What avenues of appeal are available following an adverse decision in a patent infringement lawsuit? Is new evidence allowed at the appellate stage?

An appeal may be referred to a single judge of the High Court from an order of the District Court. An appeal against an order of the single judge of the High Court may be referred to a larger bench of the High Court. An appeal may be referred on the following illustrative grounds: incorrect appreciation of fact or law; or violation of principles of natural justice.

Further, an appeal from the division bench (consisting of two judges) of the High Court lies with the Supreme Court.

The aggrieved party can refer the first appeal to final adjudication in a suit as a matter of right. The second appeal from a decision is admissible at the discretion of the court.

The courts have, in a number of civil cases (the Supreme Court in *A Andisamy Chettiar v A Subburaj Chettiar*), held that additional evidence can be produced at the appellate stage of any proceedings, under three cases as has been mentioned under Rule 27 of Order XLI of the Code of Civil Procedure 1908:

- the court from whose decree the appeal is preferred has refused to admit evidence that ought to have been admitted; or
- the party seeking to produce additional evidence establishes that
  notwithstanding the exercise of due diligence, such evidence was
  not within his or her knowledge or could not, after the exercise
  of due diligence, be produced by him or her at the time when the
  decree appealed against was passed; or
- the appellate court requires any document to be produced or any witness to be examined to enable it to pronounce judgment, or for any other substantial cause, the appellate court may allow such evidence or document to be produced, or witness to be examined.

Whenever additional evidence is allowed to the produced, by an appellate court, the court shall record the reason for its admission.

### 13 Competition considerations

To what extent can enforcement of a patent expose the patent owner to liability for a competition violation, unfair competition, or a business-related tort?

Recently, a judgment has dealt with the highly complex issue of *Competition Act v Patent Act*. The judgment, in the case of *Ericsson v Micromax* and *Ericsson v Intex*, has clearly demarcated the boundaries between the Competition Act 2002, and the Patents Act 1970.

Ericsson had filed a patent infringement suit against Micromax and Intex alleging that eight of the SEPs held by it in 2G and 3G devices (also covered by various patents) were being infringed by Micromax. In November 2013, Micromax and Intex filed a complaint with the Competition Commission of India (CCI) alleging that Ericsson was abusing its dominant position in the market by not adhering to FRAND terms and extracting exorbitant amount of royalties' inspite of being bound by ETSI Property Rights Policy and. A writ petition was filed by Ericsson in the Delhi High Court against an order of the CCI under section 26(1) directing the Director General to investigate the allegations of anti-competitive practices levied on Ericsson by Micromax and Intex. Ericsson alleged that the CCI has no jurisdiction over the allegations on royalty as the matter falls under the Patents Act 1970. Ericsson argued that there are adequate mechanisms available to prevent any abuse of patent rights under the Patent Act itself. Therefore, the CCI, which gets its powers from the Competition Act 2002, is outside its jurisdiction when it is investigating Ericsson on the charge of abuse of dominant position in the market of technology patents. The Delhi High Court judgment dated 30 March 2016, in Ericsson v Micromax, held that the CCI can carry out its investigation into Ericsson's apparent anti-competitive practices. The Court reasoned that Patent Law and Anti-trust law are not mutually exclusive as both may offer redressals, albeit fundamentally different, for the same grievance.

The order clearly lays down the fact the CCI (general statute) cannot be ousted of its jurisdiction just because the case also comes into the domain of special statute, the Patents Act. However, in the event of any irreconcilable inconsistency between the two legislation, the special statute would override the general statute, even though the earlier general statute contains a non-obstante clause.

### 14 Alternative dispute resolution

### To what extent are alternative dispute resolution techniques available to resolve patent disputes?

Alternate dispute resolution mechanisms have become an integral part of resolving disputes. The Delhi High Court, in particular, has an effective mediation and conciliation centre through which mediation mechanisms are explored. The court quite frequently refers matters for resolution through mediation, even though very few patent matters have been so referred. Courts also take into consideration arbitration agreements.

However, arbitration is not available to assess invalidity, as the Patent Office does not recognise arbitral awards in this respect.

### Scope and ownership of patents

### 15 Types of protectable inventions

Can a patent be obtained to cover any type of invention, including software, business methods and medical procedures?

Although section 2(1)(j) of the Act states that any new product or process involving an inventive step and capable of industrial application is patentable, sections 3 and 4 (under chapter 2) of the Act define inventions that are not patentable. Section 3 includes:

- an invention that is frivolous or that is contrary to wellestablished laws;
- an invention of which the primary or intended use or commercial exploitation would be contrary to public policy or morality or that would cause serious prejudice to human, animal or plant life or health, or to the environment;
- the mere discovery of a scientific principle or the formulation of an abstract theory or the discovery of any living or non-living substance occurring in nature;
- the mere discovery of a new form of a known substance that 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 (according to the explanation to this clause, 'salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the

same substance, unless they differ significantly in properties with regard to efficacy');

- 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;
- the mere arrangement or rearrangement or duplication of known devices, each functioning independently of one another in a known way;
- · a method of agriculture or horticulture;
- any process for medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to keep them free of disease or to increase their economic value or that of their product;
- plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for the production or propagation of plants and animals;
- a mathematical or business method or a computer program per se or algorithms;
- a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
- a mere scheme or rule or method of performing mental acts or method of playing games;
- · a presentation of information;
- · topography of integrated circuits; and
- an invention that, in effect, is traditional knowledge or that is an aggregation or duplication of known properties of a traditionally known component or components.

Section 4 includes inventions relating to atomic energy. In 2016, in a decision given by the Kolkata Patent Office, a patent application by Merck Eprova AG was refused for falling within the ambit of section 4 (relating to the field of atomic energy as prescribed by section 20 of the Atomic Energy Act) of the Patents Act. The Controller of Patents refused the application based on a letter from the Department of Atomic Energy, which stated that the invention relates to atomic energy and should be refused.

### 16 Patent ownership

Who owns the patent on an invention made by a company employee, an independent contractor, multiple inventors or a joint venture? How is patent ownership officially recorded and transferred?

A company employee or an independent contractor's right to apply for and own a patent is governed by the terms of the agreement between employee and employer or contractor and contracting party.

A patent may be owned by an individual, a group of individuals or a legal entity (eg, a company). A firm may also apply for a patent as an assignee (Shinning Industries v Shri Krishna Industries, AIR 1975 ALL 231).

A patent may be jointly filed and owned by two or more parties. An application may be filed by the inventor or assignee, or a legal representative of deceased persons who were entitled to make such an application, immediately before their death. A patent applicant may be a legal entity and need not necessarily be a natural person.

In the case of jointly owned rights in a patent, unless there is an agreement to the contrary, each of the co-owners shall exercise his or her rights to his or her own benefit without accounting to the other owners. A licence under the patent shall not be granted and a share in the patent shall not be assigned by a co-owner without the consent of the other co-owners (section 50 of the Act).

The rights in the invention can be assigned to any person or legal entity either during the pendency of the application or after the patent is granted. Section 68 of the Act states that assignment, mortgage, licence or a creation of any other interest in the patent shall not be valid unless it is in writing, outlining the terms and conditions governing the rights and obligations of each party.

Where persons become entitled by assignment, transmission or operation of law to a patent or to a share in a patent, they have to apply to the controller for the registration of their title in the register of patents (section 69 of the Act).

The Patent Office maintains a register wherein all information pertaining to a patent, including names and addresses of the grantees, their assignees, notifications of such assignments and of transmissions of patents, licences under patents and amendments, extension and revocation of patents, is recorded (section 67 of the Act).

In the Order No. 252 of 2013 in *NTT DoCoMo Inc v Controller of Patents*, the IPAB clearly held that the applicant for a patent has to substantiate or establish the proof of right to make an application irrespective of the nature of the application, namely, convention, non-convention, national phase or a divisional application.

#### Defences

### 17 Patent invalidity

How and on what grounds can the validity of a patent be challenged? Is there a special court or administrative tribunal in which to do this?

The following defences are available to an alleged infringer:

- challenges to the title of the plaintiff defendants may argue that the
  plaintiff is not entitled to sue, due to reasons such as defective title;
- grounds for revocation all the grounds available to challenge the suit patent's validity are available as grounds for defending an infringement action;
- Gillette defence the defendant may prove that the act complained
  of was merely what was disclosed in a publication that could be
  relied on against the validity of the patent, without any substantial or
  patentable variation having been made. (See Hindusthan Lever Ltd v
  Godrej Soaps Ltd [1996] AIR Cal 367 and Raviraj Gupta v Acme Glass
  Mosaic Industries (1994) 56 DLT 673);
- Bolar provision under Indian law, the act of making, constructing, using, selling or importing a patented invention solely for uses related to the development and submission of information required under any law in force in India will not amount to infringement;
- parallel import the import of patented products, by any person from a person who is duly authorised under the law to produce and sell or distribute the product, is not considered to be an infringement;
- innocent infringement though the fact that the defendant was an innocent infringer would not be a factor in determining liability, it would play a role in determining whether an account of profits and damages should be granted in favour of the plaintiff: the Act expressly states that damages or accounts of profits will not be granted against a defendant who proves that he or she was not aware and did not have reasonable grounds to believe that the patent existed, on the date of infringement; and
- experimental use any use of the patented invention merely for the purposes of experimentation or for carrying on research, including imparting education, is not considered an act of infringement.

### 18 Absolute novelty requirement

### Is there an 'absolute novelty' requirement for patentability, and if so, are there any exceptions?

New invention or novelty has now been defined in the Patent (Amendment) Act 2005 and has been restricted in scope from relative to absolute novelty. Thus, for any invention to be considered novel, it should not have been anticipated by publication in any document used in the country or elsewhere in the world before the date of filing of the patent application.

The absolute novelty test has been defined by section 2(1)(l) of the amended Act. For the grant of a patent, the relative novelty test is applied for determining anticipation under section 13.

The courts will therefore need to harmonise these provisions of the Act

Exceptions to anticipation have been provided by sections 29 to 33 of the Act.

### 19 Obviousness or inventiveness test

### What is the legal standard for determining whether a patent is 'obvious' or 'inventive' in view of the prior art?

Under section 2(1)(j), inventive step is now defined by the amended Act to mean a feature of an invention that involves a technical advancement as compared to the existing knowledge or that has economic

significance, or both, and the invention must not be obvious to a person skilled in the art.

Such a definition is more or less well accepted internationally and in all probability the term economic significance might be interpreted as being synonymous with industrial application.

On the question of obviousness, the division bench in the recent *Roche v Cipla* appeal held that 'to test obviousness' the first test required to be applied is to see who is an ordinary person skilled in art and its characteristics. The features of a person skilled in the art are:

- · that of a person who practises in the field of endeavour;
- belongs to the same industry as the invention;
- · possesses average knowledge and ability; and
- is aware of what was common general knowledge at the relevant date.

The Division Bench crafted the steps to determine obviousness or lack of inventive step in the nature of following queries:

- to identify an ordinary person skilled in the art;
- to identify the inventive concept embodied in the patent;
- to impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date:
- to identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications; and
- to decide whether those differences, viewed in the knowledge of alleged invention, constituted steps that would have been obvious to the ordinary person skilled in the art and rule out a hindsight approach.

#### 20 Patent unenforceability

Are there any grounds on which an otherwise valid patent can be deemed unenforceable owing to misconduct by the inventors or the patent owner, or for some other reason?

A valid patent must be worked in the country. There are no provisions in the Act for post-grant opposition or revocation of a patent due to misconduct by the patent owner, but certainly a patent can be revoked on the ground of misrepresentation and fraud. The main mechanism for invalidating a valid patent is by revocation as laid out in sections 25(2) and 64 to 66 of the Act.

### 21 Prior user defence

Is it a defence if an accused infringer has been privately using the accused method or device prior to the filing date or publication date of the patent? If so, does the defence cover all types of inventions? Is the defence limited to commercial uses?

Enterprises that have made significant investments and were producing and marketing the concerned product covered by a patent application under the old Act (before 1 January 2005) will continue to manufacture the product even after the grant of a patent and no infringement proceeding will be instituted against such enterprises. A patent holder shall only be entitled to receive a reasonable royalty from the enterprises. This provision is applicable until the patent applications that were made prior to 1 January 2005 are disposed of by the Patent Office. There is, however, no prior user defence available.

### Remedies

### 22 Monetary remedies for infringement

What monetary remedies are available against a patent infringer? When do damages start to accrue? Do damage awards tend to be nominal, provide fair compensation or be punitive in nature? How are royalties calculated?

A patentee may claim damages as well as litigation costs from the patent infringer. Costs were awarded to the patentee from the infringer by the Delhi High Court in the recent *Roche v Cipla* case (appeal decided in 2015) and *Merck v Glenmark*.

Further, no damages have been awarded in Merck v Glenmark. However, in Roche v Cipla, Cipla would be liable to render accounts concerning the manufacture and sale of its infringing product, Erlocip; the matter would be then listed before the joint registrar, who would record evidence pertaining to the profits made by Cipla concerning the offending product. Thereafter the report of the joint registrar would be placed before the single judge for appropriate orders.

Persuant to the Commercial Courts Act, the court has wide powers to impose costs in favour of the successful party and may take into account the frivolity of the case, refusal to mediate, raising frivolous counterclaim or claim for damages or otherwise wasting the court's time. The costs may include attorney fees and the fees and expenses of the witnesses in the case.

Although there is no precedent for ascertaining the basis likely to be used for determining liability, it is likely that it will be calculated by considering the reasonable royalty, lost profits and the account of profits.

Damages, both punitive and exemplary, have been granted by courts in India in cases of infringement of intellectual property rights. The basic method followed to calculate damages takes into account:

- the time period of business of the defendant;
- · sales made during the said period by the defendant;
- the percentage of royalty in the concerned industry;
- the profit earned by the defendant on the aforesaid sale at the said royalty;
- · the actual or prospective loss caused to the plaintiff; and
- factors to enhance the aforesaid damages, namely, punitive and exemplary damages and loss of reputation.

In the case of patent infringement actions, there is no precedent. However, it is most likely that this trend will also be followed in actions for patent infringement.

Though contested patent infringement cases have not yet been finally decided by Indian courts, punitive damages have been granted in intellectual property cases. Accordingly, it is likely that the trend will also be followed in patent litigation.

There are no laws specifically meant for or guiding royalty determination or FRAND terms in India.

In 2012, the Controller General of Patents granted a compulsory licence to NATCO Pharma to manufacture sorafenib tosylate (patented by Bayer). On observing that reasonable requirements of the public were not satisfied (the drug was accessible only to a little above 2 per cent of eligible patients), the drug was not 'reasonably affordable' to the public (priced at 2.8 lakh rupees for a month's treatment) and non-working of the patent (working of patent was construed as local working, namely, manufactured to a reasonable extent within the territory of India), a compulsory licence was issued under section 84 of the Indian Patent Act. The case was appealed at the IPAB, which broadly confirmed the impugned order. However, the IPAB increased the royalty rate by 1 per cent, making the royalty 7 per cent in comparison with the royalty fixed by the Controller at 6 per cent.

Bayer's contention was that terms and conditions of the compulsory licence were fixed arbitrarily, violating the mandatory requirements of section 90. In particular, it raised objections against the 6 per cent royalty rates fixed in accordance with recommendations of the United Nations Development Programme. It submitted that the retailers and stockists get a margin of 30 per cent, which is substantially higher than the 6 per cent margin that the inventor gets as royalties. The board concurred with the Controller in holding that 'royalty shall be paid on the net sale of the drug and not from the margin'. However, in view of the pleadings and evidence before it, it increased the royalty fixed by the Controller by 1 per cent to 'meet the ends of justice'.

In different patent litigations, involving FRAND issues before various courts in India, different interim royalty rates arrangement have been set by the court depending on the facts of the case:

Suit	Interim Arrangement Rates			
Ericsson v Micromax	0.8 to 1.3% of the net selling price			
Ericsson v Gionee	1.25 to 2% of the net selling price			
Ericsson v Intex	0.8 to 1.3% of sale price			
Ericsson v Xiaomi	0.8 to 1.3% of the net selling price			
Dolby v Oppo+ Vivo	34 rupees/ unit sold / manufactured / imported			

### 23 Injunctions against infringement

To what extent is it possible to obtain a temporary injunction or a final injunction against future infringement? Is an injunction effective against the infringer's suppliers or customers?

The following reliefs are available under the Act against a patent infringer:

- · permanent injunction;
- damages or an account of profits;
- seizure, forfeiture or destruction of infringing goods, or materials and tools predominantly used to create the infringing goods; and
- · litigation costs.

On 7 October 2015 Mr Justice AK Pathak granted the first-ever permanent injunction in a patent infringement suit under the Patents Act 1970. The detailed judgment of 133 pages is in relation to the patent infringement action by Merck against Glenmark with respect to patent number IN209816, which covers the type-II diabetes drug sitagliptin.

The judgment restrains the defendant by permanent injunction from making, using, selling, distributing, advertising, exporting, offering for sale or deadline in sitagliptin phosphate monohydrate or any other salt of sitagliptin in any form, alone or in combination with one or more other drugs. The plaintiff was also entitled to actual costs of the proceedings under the order.

In another landmark judgment by the Delhi High Court towards expounding and interpreting patent law in India, *F Hoffmann-La Roche v Cipla* (2015), the court not only upheld the validity of the suit patent but also ascertained that the patent was being infringed. However, keeping in view the fact that Roche's IN196774 patent would expire in March 2016, the Division Bench of the Delhi High Court did not grant an injunction against Cipla. Importantly, the Division Bench directed Cipla to render accounts concerning manufacture and sale of Erlocip for the calculation of damages.

Therefore the grant of a permanent injunction does not necessarily follow a finding of patent infringement and a court does have judicial discretion to deny the grant of a permanent injunction notwithstanding a finding of patent infringement. However, there are no specific rules for a particular subject matter in this regard.

The grant of a permanent injunction may be broader and the order granting injunction need not necessarily be limited in scope to particular items alleged to be infringing the patent. The effect of the injunction is limited to the patent infringer and will be effective against a third party only if it is made party to the action.

### 24 Banning importation of infringing products

To what extent is it possible to block the importation of infringing products into the country? Is there a specific tribunal or proceeding available to accomplish this?

Effective border enforcement mechanisms are available in India. The government of India formulated the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007 under the Indian Customs Act 1962. These rules were formulated with a view to strengthening the statutory and executive guidelines thereby aiding patent holders to enforce their rights at the borders of the Indian territory.

India has a unique system wherein the border measures have also been extended to the domain of patent law.

When the Intellectual Property (Imported Goods) Rules 2007 were initially implemented, the customs authorities were quite active in detaining goods on the basis of registered patent rights. However, one of the cases of detention resulted in prolonged litigation in numerous forums where the detention was challenged and, ultimately, the goods were released. Subsequent to this experience, customs have been circumspect in detaining goods on the basis of registered patent rights and tend to examine and scrutinise the validity of the patent and the rightholder's case on infringement in detail before detaining the goods. However, in appropriate cases, it is possible to convince customs to detain goods by satisfying them on a prima facie case on validity and infringement.

In February 2011 the government of India issued Circular No. 10/2011 relating to implementation of the above mentioned rules. Through this Circular, an on-line, system driven, centralised bond

management module has been created as part of the existing automated recordation and targeting system. Through this system a right-holder is allowed to furnish a one-time bond along with security at the time of registration and all the ports have access to this centralised account. In the case of interdiction of allegedly infringing goods, if the amount of centralised bond and the security are not sufficient to cover the value of the goods interdicted, then within three days of interdiction, the rightholders would be required to execute a supplementary bond and furnish security for the corresponding amount.

A leading patent case is the *Dual SIM Card* case, wherein the patent holder, RamKumar, filed an infringement action against Micromax and Spice and also made representation to the chief commissioner of customs, Chennai, and the chairperson of the Central Board of Excise and Customs to seize dual SIM phones that infringed his patent under the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007. The proceedings against multiple defendants have still not concluded and are pending before the Madras High Court.

In 2015, Ericsson sued Lava for allegedly infringing various patents in the field of telecommunications pertaining, inter alia to 2G, EDGE and 3G devices. Lava challenged the validity and essentiality of Ericsson's patents. The Delhi High Court granted interim injunction on 10 June 2016. The defendant was also barred from exporting the impugned goods. The Custom Authorities were directed not to release consignments of mobile phones imported by Lava into India and using the technology of the suit patents.

### 25 Attorneys' fees

### Under what conditions can a successful litigant recover costs and attorneys' fees?

It is possible to recover costs from the losing party. In *Austin Nichols and Co and Seagram India Pvt Ltd v Arvind Behl CS* (OS) No. 177/ 2005, decided on 29 November 2005, the Delhi High Court awarded costs of 1,885,000 rupees in favour of the plaintiff.

Further, in the matter of *F Hoffmann-La Roche Ltd*  $\mathcal{O}$  *Another v Cipla Ltd*, the Delhi High Court, while dismissing the plaintiff's appeal against an order refusing the grant of interim injunction, imposed costs of 500,000 rupees on the plaintiff.

### **26** Wilful infringement

Are additional remedies available against a deliberate or wilful infringer? If so, what is the test or standard to determine whether the infringement is deliberate? Are opinions of counsel used as a defence to a charge of wilful infringement?

Punitive damages would be an additional remedy available against a wilful infringer.

There is no case in India where opinions of counsel have been used as a defence to a charge of wilful infringement. However, it should be possible to use the same as defence. The onus in this case would be on the plaintiff to prove wilful infringement, which requires him or her to show 'objective recklessness' on the part of the respondent. Under this higher standard, the plaintiff must show:

- that 'the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent'; and
- that the objectively defined risk was known or should have been known to the infringer.

### 27 Time limits for lawsuits

### What is the time limit for seeking a remedy for patent infringement?

Section 40 of the Limitation Act 1963 provides that the limitation period for intellectual property matters is 'for compensation for infringing copyright or any exclusive privilege: three years from the date of the infringement'.

In the case of *M/s Bengal Waterproof v M/s Bombay Waterproof Manufacturing Co & Another*, AIR 1997 SC 1398, the Supreme Court of India stated that a fresh cause of action would accrue with every subsequent act of infringement. It was a case of passing off as well as infringement of a registered trademark. The court also cited section 22 of the Limitation Act as an indicator of its thought process. The section states 'in the case of a continuing breach of contract or in the case

of a continuing tort, a fresh period of limitation begins to run at every moment of the time during which the breach, or the tort as the case may be, continues'.

Clearly, since every instance of infringement would give rise to a fresh cause of action, the limitation clock would not start if the infringement was continuing.

### 28 Patent marking

Must a patent holder mark its patented products? If so, how must the marking be made? What are the consequences of failure to mark? What are the consequences of false patent marking?

It is not mandatory to mark the patented invention with the patent number. In view of section 111(1) of the Act, which states that a person shall not be deemed to have been given notice that a patent exists merely by the presence of the words 'patented' or 'patent granted' on the patented products, it is desirable to also mention the patent number.

This would prevent cases of innocent infringement where, if the defendant proves that at the date of infringement he or she was not aware and had no reasonable grounds for believing that the patent existed, the court will not grant damages or accounts of profits for infringement.

Patent marking for patented articles in India may be done by indicating the term 'patent' or 'patented' or 'patent applied for' or 'patent pending'. When applied, these terms are deemed to refer to a patent in force in India or to a pending application for a patent in India, as the case may be, unless there is a clear indication that the patent has been obtained or applied for in any country outside India. Marking of a patented article with respect to the patent is not compulsory to take an action in the event of infringement. In order to obtain damages or an account of profit for infringement, the infringer is supposed to be aware of the existence of the patent. It is to be noted that marking of the patented article, unless accompanied by the patent number, does not make the infringer deemed to be aware of the existence of the patent.

In cases of unauthorised claim of patent rights, namely, false representation, the penalty for such false marking can extend up to 100,000 rupees. In cases where the marking is made along with the patent number, and the patent is expired, abandoned or revoked, it is advisable that the said marking is removed. However, if such marking is not removed, unintentionally or by mistake, it is likely that the penal provision would not apply. For unmarked patented articles, the awareness of the existence of the patent may be provided to a third party by way of advertisement, publication, websites and even notices. Wilful infringement does increase the chances of higher damages being awarded. However, as mentioned earlier, patent marking itself, unless accompanied by the patent number, is not considered to bring awareness of the patent to the infringer.

### Licensing

### 29 Voluntary licensing

Are there any restrictions on the contractual terms by which a patent owner may license a patent?

A voluntary licence is a contract between two or more parties and, therefore, respects the principles of privity of contract. The licence granted may be sole, exclusive or non-exclusive.

Section 140(1) of the Act makes it unlawful to insert certain restrictive covenants in any contract relating to a patented article or process. Such covenants will be void.

### 30 Compulsory licences

Are any mechanisms available to obtain a compulsory licence to a patent? How are the terms of such a licence determined?

Chapter XVI of the Patents Act 1970 governs the procedure for the grant of compulsory licences for patents in India; section 84 of the Patents Act broadly deals with the conditions under which a compulsory licence may be granted. Under this section, any time after the expiry of three years from the date of grant of a patent, any person interested may make an application for the grant of a compulsory licence on any one of the following grounds:

- that the reasonable requirements of the public with respect to the patented invention have not been satisfied;
- that the patented invention is not available to the public at a reasonably affordable price; or
- that the patented invention is not worked in the territory of India.

Further, under section 92 of the Act, the government may, by notification in the Official Gazette, declare that compulsory licences should be granted in respect of any patent in circumstances of national emergency; extreme urgency; or public non-commercial use.

A revision has been effected to section 90 by the amended Act. While settling the terms and conditions under which a licence is to be granted, the controller, among other things, permits a licence to be granted with the predominant purpose of supply of the product to the Indian market and also the export of the patented product.

Also, under section 90(1)(viii) of the amended Act, if a licence is granted to remedy an anticompetitive practice, as determined by judicial or administrative process, the licensee is permitted to export the patented product.

A compulsory licence may also be obtained for the manufacture and export of patented pharmaceutical products to any country that have insufficient or no manufacturing capacity in the pharmaceutical sector, for the concerned product to address public health problems in such a country, provided that a compulsory licence has, for such country, by notification or otherwise, permitted the import of the patented pharmaceutical product from India under section 92A. In 2008, two compulsory licence applications made under section 92A by NATCO on patents of Roche and Pfizer relating to Tarceva and Sutent were disposed of. The Patent Office in these two compulsory licence applications for the first time applied the principles of constitutional law and provided the patentee a right to be heard even though the Patents Act was silent on this aspect. Section 90 of the Patents Act provides indicators for settling the terms and conditions for the grant of a licence under section 84.

To date, very few compulsory licences have been granted. In 2012, the controller general of patents granted a compulsory licence to NATCO Pharma to manufacture sorafenib tosylate (patented by Bayer). On observing that reasonable requirements of the public were not satisfied (the drug was accessible only to a little above 2 per cent of eligible patients), the drug was not 'reasonably affordable' to the public (priced at 2.8 lakh for a month's treatment) and non-working of the patent (working of patent was construed as local working, namely, manufactured to a reasonable extent within the territory of India), a compulsory licence was issued under section 84 of the Indian Patent Act. The case was appealed at the IPAB, which broadly confirmed the impugned order. However, the IPAB increased the royalty rate by 1 per cent, making the royalty 7 per cent in comparison with the royalty fixed by the Controller at 6 per cent.

A compulsory licence application was filed by Lee Pharma with respect to AstraZeneca's patent covering the anti-diabetes drug saxagliptin. The Controller General of Patents issued a notice stating the applicant's failure to establish a prima facie case. The Controller General, after hearing the applicant on establishment of a prima facie case, rejected the compulsory licence application for failure to establish the grounds for obtaining a compulsory licence under section 84 of the Patents Act. On the issue of reasonable requirements of the public being met, the Controller held that currently there are four key gliptins available in the market to treat type 2 diabetes, namely, linagliptin, sitagliptin, saxagliptin and vidalagliptin. In absence of data, there is no way to understand the requirement of saxagliptin in the market or to decide whether its reasonable requirement is being met. Regarding availability to the public at a reasonably affordable price, the Controller held that the applicant failed to establish the number of people being denied access due to pricing of the patented drug. Further, since the information regarding number and type of patients in the market is not available, availability and affordability cannot be predicted. On the issue of working of the patented invention in the territory of India the Controller held that manufacturing in India is not a prerequisite to establish the working of the patent in India. The need for manufacture in India has to be determined on a case-by-case basis. Since the applicant failed to show the exact requirement of saxagliptin or whether it is in short supply, it is very difficult to conclude whether manufacturing in India is necessary.

### Patent office proceedings

### 31 Patenting timetable and costs

How long does it typically take, and how much does it typically cost, to obtain a patent?

A basic overview of the timeline of the patenting process in India is as follows:

Timeline of patenting process in India								
	Filing <b>↓</b>							
	Publication <b>↓</b>	18 mont publicatio						
	Req	48 months from priority date						
	Issuance of fi	12 months						
	Re <b>↓</b>							
Pre-grant opposition		Fur examinat	6 months extendible by 3 months					
after publication of grant	<b>V</b>	Hea <b>↓</b>						
		¥	Refused <b>↓</b>					
	<b>→</b>	<b>V</b>	Appeal <b>↓</b>					
Post-grant opposition within one year of notification								

The period for the grant of a patent in India is about five to seven years.

The approximate government fee for filing an application and maintaining a patent in US\$ is set out in the following table.

### 32 Expedited patent prosecution

#### Are there any procedures to expedite patent prosecution?

The Indian Patent Office is in the process of modernising and expanding and has recruited a large number of examiners. This is expected to reduce the period for the grant of a patent from about five to seven years to an average of two to five years.

The application is published after the expiry of 18 months from the date of filing or priority date, whichever is earlier. The publication of the application can be accelerated by filing a request to the controller with the requisite fee.

The Patents Rules, 2003 were amended in the year 2016 and have been effective from 16 May 2016. The new Rules brought major procedural changes in patent prosecution, for expediting the prosecution of patent applications, some of which, are as follows:

Examination of applications: the reply to the Examination Report has to be filed within six months (instead of 12 months) from the date of issuance of the first statement of objections. This period can be extended by three months provided the request for extension is filed before the expiry of the six-month period.

Expedited examination of applications provision for filing an expedited request for examination are available under two circumstances: India is designated as the international searching authority or elected as the international preliminary examining authority in the corresponding international application; or the applicant is a start-up (definition in rule 2(fa).

Hearings: hearing submissions have to be filed within 15 days from the date of hearing. A hearing adjournment request should be made at least three days before the date of hearing. No party will be given more than two adjournments and each adjournment shall not be for more than 30 days.

### 33 Patent application contents

What must be disclosed or described about the invention in a patent application? Are there any particular guidelines that should be followed or pitfalls to avoid in deciding what to include in the application?

Under section 10 of the Indian Patents Act, every complete specification should fully and particularly describe the invention and its operation or use and the method by which it is to be performed. It should also disclose the best method of performing the invention that is known to the applicant and for which he or she is entitled to claim protection.

Finally, the specification should end with a claim or claims defining the scope of the invention for which protection is claimed and be accompanied with an abstract to provide technical information on the invention.

Filing of patent applications in India									
	For e-filing			For physical filing					
	For natural persons other than natural persons either alone or jointly with natural persons		For natural persons with 10% additional fee	For persons other than natural persons either alone or jointly with natural persons with 10% additional fee					
	-	For small entity	For others except small entity	-	For small entity	For others except small entity			
Filing application with provisional/complete specification (with one priority date) National phase/Convention/Ordinary application	29	73	145	32	80	60			
For every additional priority date	9	73	145	32	80	160			
For each sheet of specification in excess of 30	3	7	15	3	8	16			
For each claim in excess of 10	6	15	29	6	16	32			
Under section 11(B) and rule 24(1)	73	182	364	80	200	400			
Renewals of patent (per year)									
3rd to 6th year	15	36	73	16	40	80			
7th to 10th year	44	109	218	48	120	240			
11th to 15th year	87	218	436	96	240	480			
16th to 20th year	145	364	727	160	400	800			

### **Update and trends**

### India gets its first National IPR policy

On 12 May 2016, the Indian government approved its first National Intellectual Property Rights (IPR) Policy. The scope of the policy encompasses all legislation related to IP protection in the country. The objectives of the policy are creating or improving: IPR awareness, outreach and promotion, generation of IPRs, A strong and balanced legal and legislative framework, administration and management, commercialisation of IPRs, enforcement and adjudication, and human capital development.

### Patents (Amendment) Rules 2016 enforce major changes in patent procedure

The Patents Rules 2003 were amended in 2016 and have been effective from 16 May 2016. The new Rules brought major procedural changes in patent prosecution, some of which are as follows:

- leaving and serving documents: It is compulsory for Patent Agents to file documents through electronic filing. Original documents have to be submitted within 15 days from e-filing.
- fee refund: Fee refund (90 per cent refund) is provided for applications that an applicant wants to withdraw, and those for which a request for examination has been filed but the first examination report has not been issued.
- amendments: the applicant may now delete claims while entering the national phase.
- examination of applications: The reply to the examination report
  has to be filed within six months from the date of issuance of the
  first statement of objections. This period can be extended by three
  months, provided the request for extension is filed before the
  expiry of the six-month period.
- expedited examination of applications: provision for filing an expedited request for examination is available under two circumstances: India is designated as the international searching authority or elected as the international preliminary examining authority in the corresponding international application; or the applicant is a start-up (definition in rule 2(fa).
- hearings: hearing submissions have to be filed within 15 days of the
  date of hearing. A hearing adjournment request should be made at
  least three days before the date of hearing. No party will be given
  more than two adjournments and each adjournment shall not be
  for more than 30 days.
- power to extend time prescribed: the following deadlines may not be extended: 31 months' timeline for entering national phase in India; filing priority document/ English translation of priority document; filing review against the order of the Controller.
- fees for sequence listing: Fees apply for every page of sequence listing capped at the amount of 120,000 rupees (for other than natural persons).

### Application for Sofosbuvir Sees the Sun

The application for patent for Sovaldi (Sofosbuvir) was finally granted on 9 May 2016. The Controller found the application for patent to be novel, inventive and outside the prohibitory ambit of section 3(d). The Controller noted that the substitution in the entity claimed is unique and there is neither exemplification nor enabling disclosure in any of the cited prior art documents, of the claimed entity. The Controller also held that the compound is inventive as the analysis of the opponent is based on hypothetical compounds, and a person skilled in the art would not be motivated to select a compound for further research from prior art unless the same is enabled or listed as a promising compound. The Controller also held that the compounds claimed are outside the prohibitory ambit of section 3(d) as it is a new chemical entity.

### Patent Application for Cancer Drug (Enzalutamide) Refused by the Indian Patent Office

Five pre-grant oppositions against Indian patent application No. 9668/DELNP/2007, which covers the anti-cancer drug Enzalutamide, were decided by the Controller of Patents in relation to the order on 8 November 2016. The application was rejected for lack of inventive step and patentability under section 3(d) and 3(e) of the Patents Act. As per the Controller, the claimed compound Enzalutamide is obvious in view of a combination of prior arts and, as the compound claimed is lacking novelty and inventive step, the argument of the applicant that section 3(d) is not applicable as the claimed compound is a new chemical entity, is not acceptable.

### Cipla's Patent Application for HIV drug rejected

The Indian Patent Office rejected Cipla's patent application for its HIV drug composition comprising a combination of the drugs ritonavir and darunavir. The application was rejected on the grounds of lack of inventive step in view of the prior area documents. In addition to this, the Controller held that the claimed subject matter does not clearly show an advantage or surprising effect over the prior art composition to establish an inventive step. The Controller also rejected the application under section 3(d) of the Patents Act as he considered the new layered form of a known combination, as being statutorily barred from patentability u/s 3 (d).

### Interim Relief to Dolby in suit against Oppo and Vivo

Dolby International AB took Chinese companies Oppo and Vivo to dourt on 26 October 2016 for patent infringement by using audio noise reduction, encoding and compression techniques. As an interim relief, the Delhi High Court has directed Oppo and Vivo to deposit in an escrow account a royalty of 34 rupees per smartphone imported or sold. In the meantime, Oppo and Vivo have been allowed to continue their operations in the country as long as they agree to enter into a licensing agreement in accordance with FRAND terms.

Patent Act. In the order, the IPAB held the following with respect to voluntary filing of divisional applications:

- the applicant can file one or more divisional applications if the invention disclosed in the parent application does not relate to a single invention or to a group of inventions forming a single inventive concept; and
- the divisional application should not include any claim already claimed in the parent application (to avoid double patenting).

Further, in a decision dated 17 July 2013, in the matter of Indian Patent Application No. 3273/KOLNP/2008 of Genentech Inc, the Controller held that a divisional application of a divisional would be considered as a divisional of the original parent application provided the same is filed during the pendency of the original application.

### 36 Patent office appeals

### Is it possible to appeal an adverse decision by the patent office in a court of law?

It is possible to appeal an adverse decision by the Patent Office. Under the Act, an appeal against an order or directions of the controller lies before the IPAB. The board, under section 116 of the Act, was constituted on 2 April 2007. Thus, at this time, all such appeals lie to the High Court, as was the case before the Patents Act 1970 was amended by the 2002 amendment.

In a recent decision of the IPAB, it held that the decision of the Controller in a review petition is not appealable and that the appeal is restricted to certain provisions and not available against an order in a review petition passed under section 77(1)(f).

However, although the Indian Patents Act does not provide for an appeal against the order of the Controller in a pre-grant opposition proceeding, a recent decision of the Delhi High Court held that an applicant is entitled to file an appeal against the order of a controller in a pre-grant opposition proceeding, as an order under section 25(1) it is to be treated as being an order under section 15 of the Indian Patents Act, which order is appealable.

In two landmark cases, the IPAB treated orders issued under non-appealable provisions of section 11(B)(4) and 77(f) as appealable.

The first such order was issued under section 11(B)(4) treating an application for patent as 'deemed withdrawn' for failure to file the request for examination within the prescribed time period of 48 months from the date of priority of the application. Statutorily, orders passed under section 11(B)(4) are not appealable but the appellant's attorneys argued that since the applicant had filed the request for examination in a timely fashion, the said order should be taken as an order under section 15 of the Indian Patents Act, which bestows upon the applicant a right to appeal. The IPAB agreed with the submissions of the appellant and allowed the appeal. In the second case, an order issued in a pregrant opposition, which was treated as a review petition under orders of the Delhi High Court to correct a procedural irregularity that had

### Update and trends (continued)

#### Ericsson v Lava

In 2015, Ericsson sued Lava for allegedly infringing various patents in the field of telecommunications pertaining, inter alia, to 2G, EDGE and 3G devices. Lava challenged the validity and essentiality of Ericsson's patents. The Delhi High Court granted interim injunction on 10th June 2016. The defendant was also barred from exporting the impugned goods. The custom authorities were directed to not release consignments of mobile phones imported by Lava into India and using the technology of the suit patents. The Court ruled that Ericsson was undisputedly the owner of the suit patents and had taken steps for execution of a FRAND licence agreement. The Court noted a wilful delay on the part of Lava to conclude the licence agreement on FRAND terms. The Court also ruled in favour of the plaintiff on prima facie validity of the impugned patents and held that product patents cannot be labelled as an algorithm because they are not a set of instructions, and are not theoretical in nature. The Court concluded that the patents are not hit by section 3(k) and that the defendant has failed to raise any credible challenge to the suit patents.

### Etanercept applications granted by the IPO

In a significant victory for Pfizer, Inc the Delhi Patent Office allowed two of its applications (2315/DELNP/2007 and 2317/DELNP/2007), covering their commercial method for production of Etanercept. Each of the applications were opposed in pre-grant oppositions filed by Biocon Ltd, and Mylan Laboratories Ltd. A ground of double patenting was raised in respect of the two applications. This ground was, however, dismissed and the Controller held that the inventions claimed are patentably distinct and do not involve any issue of evergreening or double patenting. In 2315/DELNP/2007, three specific media conditions are needed in the method of production of polypeptides whereas in 2317/DELNP/2007 specific media characteristics and their combinations, along with certain culture conditions for the production of TNFR-Ig, have been claimed.

### Merck Sharp & Dohme ex-parte ad-interim injunction for Sitagliptin maintained

Merck Sharp & Dohme Co sued Teva API India Pvt Ltd for infringement of its patent IN 209816 covering the anti-diabetes drug Sitagliptin and obtained an ex-parte ad-interim injunction. A review was filed, however the same was not heard by the single judge and therefore Teva filed an appeal before a Division Bench (DB) at the Delhi High Court. The Division Bench maintained the injunctions and opined that the continuation of the injunction was not causing any injuries to Teva. The

DB opined that marketing authorisation for the drug would require two to three years while the interim application could be decided by the end of 2016 and hence, the DB declined to interfere with the injunction order of the single judge.

### uziveedu restrained from selling Bt Cotton

Monsanto Technology LLC sued Nuziveedu seeds for infringement of its Trademarks Bollguard/BG and Bollguard-II/BG-II and its Patent IN 214436, in respect of genetically modified hybrid cotton seeds. The defendant was earlier appointed the plaintiff's sub-licensee to manufacture and sell the seeds using the plaintiff's trademarks and patent. The Court-granted injunction, however, allowed that all seeds manufactured by the defendant up to 30 November 2015 could be sold by the defendant with the plaintiff's trademarks. However, the defendant was restrained from selling all seeds manufactured by them after such date. The defendant must pay royalties to the plaintiff for the seeds that were sold.

### Patent revoked by the IPAB while its surrender application was pending

Mylan Laboratories Ltd filed an application for revocation of patent No. 224314, assigned to ICOS Corporation. ICOS Corporation, instead of filing a counter statement to the revocation application, sent a communication to the IPAB stating that they no longer have a business interest in maintaining the patent, owing to the presence of many generic products in the market. They also applied for the surrender of their patent under section 63 of the Patents Act before the Indian Patent Office. The IPAB held that, in the absence of filing any counter statement by the patentee, the applicant has established their case and, as a result, the impugned patent would become invalid.

### Vipro Lifesciences prohibited from commencing marketing of Vardenafil or Vardenafil hydrochloride

Bayer Intellectual Property Gmbh sued Vipro Lifesciences for infringement of its patent covering the drug Vardenafil. At the time of the suit the defendant had not started marketing the product in India, however, the infringing product had been exported. The defendant gave an undertaking to the effect that they had not commenced marketing the infringing goods. The suit was decreed in favour of the plaintiff with further directions that, subject to the furnishing of information regarding exports by the defendant to the plaintiff, the plaintiff shall not press for damages or for accounts against the defendant.

With regard to the disclosure of prior art under section 10(4) of the Indian Patents Act in the patent specification, the IPAB in the *Novartis* case did recognise that under the law (section 10(4)) disclosure of prior art is not mandatory, but held that, despite there not being any specific provision under Indian law, the relevant prior art including the closest one ought to be disclosed in the patent specification, and the applicant cannot be considered to have discharged his or her duty or obligation unless the prior art is disclosed so that the invention can be sufficiently distinguished over the prior art.

### 34 Prior art disclosure obligations

### Must an inventor disclose prior art to the patent office examiner?

The Act contains no provision that makes it mandatory for an inventor to disclose prior art, although to meet the requirement of sufficiency of description, it is important to distinguish the invention over prior art as was also held by the IPAB in *Novartis v Ranbaxy and Others*. It is, however, mandatory to provide information of the corresponding applications filed in other countries under section 8 of the Act within six months of their filing; and to provide search and examination reports in the corresponding application to the Patent Office examiner. Failure to do so is a ground for pre-grant opposition, post-grant opposition and revocation of the patent. Patents recently have been revoked by the IPAB on grounds of non-compliance with obligations under section 8 (*Uniroyal v VRC Limited, Hindustan Unilever v Tata Chemicals*, etc).

A recent order by the Division Bench of the Delhi High Court has helped elucidate the legislative intent behind section 8 of the Indian Patents Act. The Division Bench held that:

- the power to revoke a patent under section 64(1) is discretionary and not automatic;
- the court is to first examine whether omission to furnish information is deliberate, intentional, accidental, clerical or on account of bona fide error;
- the court will have to examine the evidence for wilful suppression
  of information and cannot revoke a patent immediately on the
  grounds of non-compliance with section 8; and
- it will also have to be determined if the omission of the information
  or part of the information was material to the grant of the patent,
  which can be answered only at the conclusion of the trial.

### 35 Pursuit of additional claims

May a patent applicant file one or more later applications to pursue additional claims to an invention disclosed in its earlier filed application? If so, what are the applicable requirements or limitations?

A patent applicant can file either a divisional application under section 16 of the Patents Act or a patent of addition under section 54 to pursue additional claims. There is no limitation on the number of claims. However, as mentioned in question 31, the fee for each claim in excess of 10 is US\$20 or US\$5 per claim.

The divisional application has to be filed any time prior to the grant of a patent on the ground of unity of invention, and a patent of addition can be filed any time during the life of the main patent.

The Intellectual Property Appellant Board has recently, in its judgment in *LG Electronics Inc v Controller of Patents*, adjudicated on the maintainability of divisional application under section 16 of the Indian

ensued due to a patent being granted without processing of a pre-grant opposition, was treated as appealable by the IPAB. The IPAB held that the order issued in the review petition under section 77(f) was in effect an order in a pre-grant opposition that was being treated as a review petition under directions of the High Court, and since orders in pregrant oppositions are appealable, the order in this case was also held to be appealable.

### 37 Oppositions or protests to patents

### Does the patent office provide any mechanism for opposing the grant of a patent?

The Act provides for pre-grant opposition and post-grant opposition.

After the patent application has been published in the official journal, and at any time before the grant of a patent, any person may submit a written opposition to the controller on the grounds listed in section 25(1) of the Act.

Also, post-grant opposition can be filed by any interested person before the expiry of one year from the date of publication of grant of the patent.

The grounds of pre-grant opposition, post-grant opposition and that of revocation are quite similar.

### 38 Priority of invention

Does the patent office provide any mechanism for resolving priority disputes between different applicants for the same invention? What factors determine who has priority?

Section 11 of the Act contains the rules for fixing the priority dates. Different priority dates may be allotted to separate claims to settle the disputes between different applicants for the same invention.

### 39 Modification and re-examination of patents

Does the patent office provide procedures for modifying, re-examining or revoking a patent? May a court amend the patent claims during a lawsuit?

A patent application may be amended by filing an application for amendment to the controller, before or after the grant of the application, insofar as the amendment is within the scope of the disclosure by way of disclaimer, explanation or correction. An amendment may also be effected for change of name, address, nationality or address for service (section 58 of the Act, subject to section 59).

The High Court, in any proceedings before it for revocation of a patent, allows patentees to amend their complete specification, subject to the terms as to costs and so on. Also, instead of revoking a patent, the High Court can allow the specification to be amended.

The nature of amendments that are permissible to the complete specification:

- · are those by way of disclaimer, correction or explanation;
- · must be for the purpose of correcting an obvious mistake;
- should not claim or describe matter not disclosed in substance in the specification before amendments; and
- should fall wholly within the scope of the specification before the amendment.

There is no provision under the Indian Patents Act for re-examining a patent once granted, except that any person interested may approach the Patent Office in a post-grant opposition or the IPAB in a revocation petition to invalidate the patent.

### 40 Patent duration

### How is the duration of patent protection determined?

The duration of patent protection is 20 years and it is determined from the date of filing the application. If a provisional application has been filed followed by a complete specification, the term of the patent is counted from the date of filing the provisional application.

In the case of national phase applications under the Patent Cooperation Treaty, the term is calculated from the international filing date. On being granted a patent, the patentee shall have privileges and rights from the date of publication of the application except in the case of postal applications, where the rights and privileges will accrue from the date of grant of a patent.



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