Select Issues from India’s IP Law

Pre-grant Opposition

- Countries with a pre-grant opposition system:

Azerbaijan, Australia, Colombia, Costa Rica, Cote d'Ivoire, Ecuador, Egypt, Honduras, India, Israel, Mongolia, New Zealand, Pakistan, Peru, Portugal, Sri Lanka, Thailand, Zambia and Zimbabwe

- Section 25 of the Indian Patent Act
  - A pre-grant opposition can be initiated by *any person* after the application has been published and before the grant of the patent.
  - No fees
  - No prescribed form

Initial Procedure for Pre-grant Opposition:

- An opponent can file pre-grant opposition by way of representation (in writing) to the Controller, in the appropriate patent office, against grant of the patent.
- Controller gives a notice to the patent applicant
- Applicant to respond to the representation within 3 months
- The Controller may refuse the grant of the patent or may ask for amendment of the complete specification within one month after receiving the reply.
- If hearing is initiated, Controller may:
  - Grant patent, or
  - Refuse to grant patent

  Within one month from the completion of proceedings.

Advantages of pre-grant opposition:

- Controller can make a more informed decision on the patent application in the light of the information supplied by the opponent.
- Pre-emptive safeguard against evergreening of drug patents and grant of low-quality patents in general.
- If a considerable number of post-grant oppositions are successful, questions may be raised about the examination process of the Patent Office, a prospect not desired by the Patent Office.

Shortcomings of India's Pre-grant Opposition System

- Indian generic industry uses this process to purposefully delay the grant of foreign patents in order to justify the production of generic copies.
- The existence of both pre- and post-grant opposition proceeding creates problems as a potential patentee will survive a pre-grant opposition proceeding and have the patent granted only to face post-grant proceeding from the same opponent.
- The ability of third parties to submit references pre patent grant provides sufficient opportunity to weed out applications that do not meet novelty and inventive step requirements; and should be the preferred method of challenge pre-grant.
- Hurts patent applicants as it chips away at the term of any future patent available to the applicant.

India-EFTA FTA – Article 11(7)

Where a Party provides for a process that allows a third party to oppose a patent application prior to its grant, it shall ensure that this opposed patent application is processed and disposed of within a reasonable period of time and without undue delay including by swiftly rejecting prima facie unfounded oppositions, as determined by the competent authority.

Amendment to the Indian Patent Rules, 2003

Rule 55: Filing of opposition:

"(3) On consideration of the representation if the Controller is satisfied that, -

(a) no *prima facie* case is made out in the representation, he shall notify the opponent accordingly, and -

(i) unless the opponent requests to be heard in the matter, the Controller shall, within one month from the date of such notification, pass an order recording the grounds for refusal of the representation;

(ii) if opponent requests for a hearing, the Controller shall, after giving the opponent an opportunity of being heard, pass an order within one month from the date of hearing, recording his reasons for refusal or prima facie acceptance of the representation and the applicant shall be notified accordingly.

(b) a prima facie case is made out in the representation, the Controller shall, within one month of receiving the representation, pass an order recording his reasons and notify the applicant accordingly.

(4) The Opposition Board shall conduct the examination of the notice of opposition along with documents filed under rules 57 to 60 referred to under sub-section (3) of section 25, submit a report with reasons on each ground taken in the notice of opposition with its joint recommendation within two months from the date on which the documents were forwarded to them.

Local Working Requirement

Section 84 of the Indian Patent Act (Compulsory licences)

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

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

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

(c) that the patented invention is not worked in the territory of India.

(6) In considering the application field under this section, the Controller shall take into account,—

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;
(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

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

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—

(i) the patentee or persons claiming under him or

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

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

85. Revocation of patents by the Controller for non-working.

(1)Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

S86- where application is made for compulsory licence (s84) or revocation of patent (s85), then the controller can determine if sufficient time was available to patentee to work the invention on a commercial scale. If not, then the hearing of the application can be delayed by 12 months.

Disclosure of Local Working

Commitments under India-EFTA FTA

- No Party shall require patent owners to provide annual disclosures of information concerning the working of a patent.
- Where a Party does provide for periodic disclosure of information concerning the working of a patent, the periodicity shall not be less than 3 years and
- Confidential information , including information of commercial value, contained in such disclosure may not be published.
- A Party may require a patent owner to provide information concerning the working of a patent, in a given case, in accordance with its domestic laws and regulations.
- With respect to the working of a patent, a patented invention may not be considered as 'not worked' within the territory of a Party merely because the product resulting from the invention was imported.

Disclosure of Local Working

Rule 131(1) – disclosure is done according to Rule 146(1) and procedure in set out in Form 27

Old Rule 131: *(2)The statements referred to in sub-rule (1) shall be furnished in respect of every calendar year within three months of the end of each year.*

Amended Rule 131: *"(2) The statements referred to in sub-rule (1) shall be furnished once in respect of every period of three financial year, starting from the financial year commencing immediately after the financial year in which the patent was granted, and shall be furnished within six months from the expiry of each such period.*

Provided that the Controller may condone the delay or extend the time in filing of such statement for a period up to three months upon a request made in Form 4.".

Failure to file Form 27 or submission of incomplete form leads to the presumption of non-working for the purposes of a compulsory licence.

Data Exclusivity

- Difference between data exclusivity, marketing exclusivity, patent linkage
- Pharmaceutical products – Central Drugs Standard Control Organization Rules, 2019
- Agro-chemicals – Insecticides Act, 1968

75. Application for permission to import new drug for sale or distribution.—

(7) The local clinical trial may not be required to be submitted along with the application referred to in sub-rule (1) if,—

i. the new drug is approved and marketed in countries specified by the Central Licencing Authority under rule 101 and if no major unexpected serious adverse events have been reported; or
ii. the application is for import of a new drug for which the Central Licencing Authority had already granted permission to conduct a global clinical trial which is ongoing in India and in the meantime such new drug has been approved for marketing in a country specified under rule 101; and
iii. there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and
iv. the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the Central Licencing Authority:

80. Application for permission to manufacture new drug for sale or distribution.—

(7) The local clinical trial may not be required to be submitted along with the application referred to in sub-rule (1) if,-

i. the new drug is approved and marketed in countries specified by the Central Licencing Authority under rule101 and if no major unexpected serious adverse events have been reported; or
ii. there is no probability or evidence, on the basis of existing knowledge, of difference in Indian population of the enzymes or gene involved in the metabolism of the new drug or any factor affecting pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug; and
iii. the applicant has given an undertaking in writing to conduct Phase IV clinical trial to establish safety and effectiveness of such new drug as per design approved by the Central Licencing Authority:

Article 39(3) of the TRIPS Agreement

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against **unfair commercial use**. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Plant Varieties Protection

- PPVFR v UPOV 1978 and UPOV 1991

PPVFR Features:

- Plant breeder rights and registration of new plant varieties that fulfill the conditions of novelty, distinctiveness, uniformity and stability (NDUS)
- The PPVFR Act recognises the rights of the farmers to save, use, sow, resow, exchange, share or sell their farm produce including seeds of a protected variety
- Benefit-sharing
  - breeder under an obligation to disclose the information regarding the use of any genetic material conserved by any tribal or rural families that the breeder may be using in developing the new variety
  - commercial breeder has to share the benefits that will accrue upon the registration of the variety with the farmers or the traditional rural communities who have contributed towards developing the variety.
- Allows farmers to register their varieties under the category of extant varieties, which is another novel feature of the PPVFR Act that allows registration of already existing varieties.
- Issuance of CL against a registered variety after three years of registration if the breeder fails to satisfy the reasonable requirements of the public for seed or other propagating material or that the seed or propagating material has not been made available to public at reasonable price

UPOV 1991

- UPOV 91 restricts the rights of farmers to freely use their seeds or other propagation material for further cultivation. This right is limited to those countries which make special provision for it.
- Article 15.2 of UPOV 91 provides for an **optional exception** "to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety", which member countries could implement, if they wish.
- But this exception is very limited. It excludes propagation material which is not the product of the harvest (eg. fruits or berries) and it prohibits all exchange and selling of protected material - as farmers are only allowed to reuse their seed on their own holding.
- And in addition this exception has to be implemented "safeguarding of the legitimate interests of the breeder," which means that even where seed saving is allowed, at least bigger farmers have to pay royalties to the breeders.

Section 3: Inventions not patentable

- Frivolous inventions
- *Public ordre* or morality or which causes serious prejudice to human, animal or plant life, to health and environment
- Discovery of scientific principles
- New forms of a known substance but lacking efficacy
- Admixtures, mere rearrangement
- Method of agriculture or horticulture
- Any process for the medicinal, surgical, curative ---procedures
- Plants and animals, in whole or parts
- Computer programme per se, algorithms
- An invention which is in effect traditional knowledge or aggregation or a duplication of known properties

Section 3(d) of the Patent Act

- Section-3 of the Patent Act as amended in 2005 while defining the inventions not patentable provides under sub-section (d) the following:-

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

- *Explanation to the provision*

Interpretation of Section 3 (d)- Novartis Judgment

- M/s. Novartis obtained patent for ‘Imatinib and its salts’ in 1993 in other countries, before the international obligations under TRIPS took effect in India.

- Novartis applied for a patent for ‘Beta Crystalline form of Imatinib Mesylate’ in India in 1998 claiming that it could be stored better and was easier to process. The Indian Patent Office found that there was no significant medicinal benefits and therapeutic efficiency in the Beta Cyrstalline form of Imatinib Mesylate over the Imatinib Mesylate.

- The Hon’ble Supreme Court of India upheld the finding of the Indian Patent Office that the claimed invention did not satisfy novelty and the higher threshold of inventive step as prescribed in Section 3(d) of our Patents Act.

- The judgement has dealt with the term ‘efficacy’ in Section 3(d). It mandates that in case of medicine that claims a cure for a disease, the test of efficacy can only be “therapeutic efficacy” and therapeutic efficacy of a medicine must be judged strictly and narrowly.

Exceptions and Compulsory License

TRIPS: Exceptions to Rights

- Article 30 – limited exceptions to the exclusive rights, do not unreasonably conflict with normal exploitation, without prejudice to the legitimate interest of the patent owner.
- Article 31 – other use without authorization of the right holder.
  - on individual merits.
  - Case of National Emergency, other circumstances of extreme urgency or public non-commercial use.

Compulsory License

- Compulsory licensing is enabled under four sections of the Patents Act
  - Section 84 (general CLs to be issued by the Controller on application) ,
  - Section 91 (issue of CL by the Controller for a related patent on application) ,
  - Section 92 (issue of CL by the Controller based upon a notification by the Central Government) and
  - Section 92 A (issue of CL by the Controller on application for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems).
- In addition, Section 100 provides for use of inventions for the purpose of government and acquisition of inventions by Central Government.

Compulsory License

- Section 84 allows grant on application by an interested person provided
  - Reasonable requirement of Public has not been met
  - Patented invention is not available to the public at reasonable prices
  - Patented invention is not worked in the territory of India

Bayer vs NATCO Pharma : The case on Compulsory Licensing

- The voluntary licence application by M/s Natco Pharma was not accepted by M/s Bayer Ltd.
- The application for Compulsory licence was filed under Section 84(1) of the Patents Act.
- found that the submissions of the applicant was justified and that M/s Bayer Ltd. did not meet the requirements of the public and that the drug was excessively priced. With respect to the issue of "working of the patent in the territory of India", CGPTDM concluded that section 84(1) (c) (regarding working of patents) is also attracted in this particular case.

Bayer Vs NATCO

- M/s Bayer filed an appeal against the said order of CGPDTM dated 9.3.2012 before IPAB.
- IPAB disposed of the appeal while maintaining the compulsory license and increasing the royalty to be paid to M/s Bayer Corporation by 1%.
- M/s Bayer Corporation filed an appeal against the IPAB order in the High Court of Bombay. The Court in its judgment upheld the decision of the IPAB and that of the Controller General.
- It also accepted the view of IPAB on 'working of a patent'
- The Supreme Court did not accept the SLP

Section 92A: CL for Export of Pharmaceutical Products

- In 2007, Nepal had reportedly sought CL for ‘Tarceva’ (a Roche Product) and Sutinib (a Pfizer product).

- The demand was taken back under pressure