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Intellectual property and Tech. law updates

S&A IP-Tech

January 2017

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IP Environment in India - Insight of Opportunities and Threats

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India is believed to have an incredible potential to become one of the world's leading markets and hub for the innovation, research and development. Intellectual property industry is assessed to have a huge growth potential in the current Indian and Global context. Intellectual Property Rights (IPRs) unarguably are emerging as a strategic business tool for any business organization to enhance its competitiveness. India has proven its endurance by not only withstanding the global economic slowdown but also emerged as one of the fastest growing economy across the globe. Over the last few years, with slogans like "Creative India: Innovative India"–"Make in India" the Government of India has been trying to position itself to be a pro-IP, knowledge-driven economy capable of competing with developed and developing countries in protecting and promoting innovation and other IPR in an array of industries. Lately, we have seen a paradigm shift towards high quality and value added ideas and innovations. Intellectual Property provides exclusive rights to the inventors or the manufacturer of the respective IP Property which in turns enables them to reap out the commercial benefits from the innovative idea or design. IPR provides some kind of granted monopoly and this is the main cause that inspires innovators to come up with innovations and new ideas. IPR also provides an added advantage of safety from the competitors.

Comprehending that invention is the engine for the growth of affluence and national competitiveness in the 21st century; The President of India has declared 2010 as the 'Decade of Innovation'. Declaration of 2010-2020 as the innovation decade can be seen as a desperate attempt towards making the Indian IP environment more healthy and supportive towards the indigenous as well as the international innovators. National Innovation Council (NInC) has been setup under the Chairmanship of Mr. Sam Pitroda, He will act as an adviser to the PM to discuss, to analyze and to help implement strategies for inclusive innovation in India and prepare a Roadmap for Innovation 2010-2020[1]. Government of India has recently approved the new IPR policy 2016 on May 13, 2016, which targets to encourage escalate awareness about and administer Intellectual Property in India. IP offices across the country are being transformed to increase the efficiency in processing the applications. Patent offices have been directed to ensure uniformity and consistency in the examination of applications. A Roadmap to increase the bilateral cooperation at global level and raising the public awareness level has been set up. Mass recruitment of Patent and trademark examiners are planned to take care of the ever increasing backlogs. Startups have a very inadequate possessions and manpower and can sustain in the cut throat competition only through continuous growth and development oriented innovations. For them the union Government of India has started a facility of faster allocation of patents under the "Tatkal" scheme. Startups are also facilitated with the reduced patent examination fee. These facilities are also available to the innovators who file their patents first in India. The new provisions introduced in the Patents Rules by way of 2016 amendments seek to grant patent within two and a half years and within one and a half year by March 2018 which otherwise used to take about five to seven years. To clear the backlogs the government of India has recruited large number of Examiners in each of the technological department at the Patent Office.. Further, by

[1] http://innovationcouncilarchive.nic.in

2016 amendment, the official fee for withdrawing an application for patent has been waived off and now the applicant can also claim a refund of 90% of examination fee in case the withdrawn application is not examined at the Patent Office. Accordingly, applicants are encouraged to withdraw application for which the applicant is "not interested" in acquiring a patent, thereby, automatically reducing the Examiner's load to some extent.

The Indian Government acknowledges that even after taking some major steps towards improving the overall IPR environment in the country, we still need to strike a balance in the IPR regime, its protection and effective promotion.. For instance, it will be obligatory for the administration to provide effect to the full essence and scope of the National IPR Policy, which endorses a host of methods including the periodic review and changes to the existing IPR legal and regulatory framework and creating a credible IPR enforcement system. Indian IP laws have many provisions for administrative, civil and criminal remedies for infringement of the IPR; however ineffective enforcement is one of the biggest problems that inhibit the growth of IP industry in the country

The Index which is created by the US Chamber of Commerce: Global Intellectual Property Center (GIPC) has around 30 principles critical to innovation including patent, copyright and trademark protections, enforcement, and engagement in international treaties. According to the report, the reason India scoring low rank was nonalignment with the international best practices in IPR. It also mentioned that India needs to provide ample protection from online piracy and shall strive to have proper law enforcement. The use of compulsory licensing, which is governments permission to allowing entities to manufacture, use, sell or import a patented invention without the permission of patentee, for the commercial and non-emergency situations has been a topic of discussion at various platforms.

Key Areas of Strength as per GIPC[3]

- The government of India continued to make positive statements during 2015 on the need to introduce a strong IP environment.
- Ex officio powers introduced in 2007 for the Deputy and Assistant Commissioners of Customs.

Key Areas of Improvement suggested as per GIPC[3]

- Patentability requirements shall be made in line with that of the international standards.
- Regulatory data protection and patent term restoration should be made available.
- History of use of compulsory licensing for commercial and non-emergency situations shall be discouraged.
- Steps should be taken towards effective application and enforcement of civil remedies and criminal penalties against patent infringements.

Taking positive cues out of the various reports, the Union Government has implemented major steps in the direction of enabling the law enforcement agencies with recourses against infringement of Patents, Trademarks and Copyrights. Government of India has launched a new mission where the Indian Police personals will be equipped with special knowledge toolkit to identify and prosecute the IPR violations. The toolkit is jointly developed by Cell for IPR Promotion and Management (CIPAM) and the Federation of Indian Chambers of Commerce and Industry (FICCI). The CIPAM has taken all the essential actions to build up a healthy IP environment in the country by creating various awareness programmes and seminars. To further strengthen the law

enforcement and awareness of the state police CIPAM has already organized seven batches of training for the police officials in Andhra Pradesh. Also a three day training programme was arranged for the Police Officials in the state of Uttar Pradesh. CIPAM has also directed all the state police and judicial academies to introduce and take up training on enforcement of intellectual property rights. CIPAM is actively facilitating international engagements in the field of intellectual property rights protection. Two MoUs on IPR were recently signed with UK and Singapore. India-USA Workshop on Protection of Trade Secrets was successfully organized by CIPAM to discuss various aspects related to Trade Secrets and its impact on Industry. [2]

CONCLUSION

We now have to understand that creating innovation is of no use if we cannot assure the patent owner if the patent rights are protected by the State through adequate law enforcement. Today, India is on its way of adopting a balanced approach towards creating a stimulus for the betterment of the IPR industry as a whole. Recent developments in India, be it the New IPR policy or the initiatives taken by the National Innovation Council (NInC) or providing an effective toolkit in the form of checklist that will act as a reckoner for the police to deal with IP crimes or encouragement to innovators in terms of speedy patent examination in case they file first in India, all are a part of much needed attempt to improve the overall security of IPR and encouragement to create more IP in the country. While the latest Intellectual Property index results ranking India as one of the lagging end countries is a setback for us, however, the efforts undertaken by the Indian Government in recent past would definitely improve the IPR protection in the country. Further, the Courts and the Government are indeed acting cautiously over the recommendations and identifying areas that need improvements while also continuing with policies like compulsory licensing where it really matters for example in the cases of life saving drugs. India being a developing country with second largest population needs to carefully identify exact areas to act upon and strike an ever-evasive balance between commercial rights/recommendations on IPR protection while not succumbing to international pressure and give away the socialist approach towards the public at large.

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[2] http://pib.nic.in/newsite/PrintRelease.aspx?relid=156135

IPO Rejects Patent Application for Xtandi (Prostrate Cancer drug)

Saipriya Balasubramanian

Introduction:

The India Patent Office in its order issued on 18th November 2016[3], has denied a patent for the prostate cancer drug sold under the brand name Xtandi (generic name Enzalutamide). Xtandi was developed at the University of California, Los Angeles (UCLA) (***Applicant***) for fighting prostate cancer which is commercially sold in India by ASTELLAS PHARMA. The drug is currently sold at Rs 3.35 lakh[4] for a pack of 112 capsules normally to be taken by a patient in a month's time, accordingly, which amounts to Rs.11,000 approximately per day.

The provision of pre-grant opposition under Indian Patents Act enables any person to file notice of opposition on Form 7A at the Indian Patent Office (IPO) after the publication of an application for patent. Therefore, by way of pre-grant oppositions any person can assist the Controller of Patents in evaluating the application for patent. IPO has seen a surge of pre-grant opposition, especially in pharmaceutical applications and the said applications are scrutinized in detail because of the same. IPO is often regarded as being stringent on allowing grant of patent on drug compositions. The TRIPS agreement[5] contains flexibilities that were enhanced and clarified during the 2001 Doha Declaration on TRIPS and Public Health. The said agreement states, for instance, that for pharmaceutical patents, there is a flexibility to interpret and implement TRIPS provisions in a manner supportive of the government's right to protect public health.

Coming back to the instant case of Xtandi, the pre-grant oppositions was filed by a bunch of companies, including, Fresenius Kabi Oncology (***Opponent 1***), BDR Pharma (***Opponent 2***) and Indian Pharmaceutical Alliance (***Opponent 4***) as well as individuals: Mr.Umesh Shah (***Opponent 3***) and Ms. Sheela Pawar (***Opponent 5***). The main grounds of opposition were lack of novelty, lack of inventive step, and that the claimed compound did not constitute an invention under Section 3(d) *relating discovery of new form of known compound and with efficacy test* and Section 3(e) *relating to mere admixture resulting in aggregation of properties of compounds* of the Patents Act, 1970.

The Application:

The present application relates to diarylhydantoin compounds including diarylthiohydantoins and methods for synthesizing them. The claimed compounds of the said application are used for the treatment of hormone refractory prostrate cancer. The application was initially filed as PCT national phase with 46 claims. In the reply to first examination repot (FER) issued by the Patent Office, the Applicant reduced the number of claims to 15 and further only 3 claims were retained pursuant to an official hearing with the Controller of Patents.

Grounds of Opposition and Prior Art relied on:

The following are the grounds and the documents relied on by the opponents:

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[3] http://ipindiaservices.gov.in/decision/9668-DELNP-2007-24746/9668delnp2007.pdf

[4] http://keionline.org/node/2662

[5] http://www.firstpost.com/world/india-at-wto-takes-strong-stand-to-save-generic-drugs-industry-calls-for-transparent-health-assessment-of-trade-deals-3102716.html

S. No.	Sections	Documents Cited	Comments
1	Section 25(1)(b)- Lack of Novelty	US5411981 (US'981) US6087509(US'509) 2440/DEL/1996 US 5434176(US'176) US 5750553(US'553)	=> US'981 already disclosed Enzalutamide; US'509 disclosed a family of compounds phenyl, phenylimidazolidines represented by a Markush structure including the compound claimed in the present invention. US'509 also disclosed the use of compounds for anti-androgenic activity useful against tumors.
2	Section 25(1)(e)-Lack of Inventive step	US5411981(US'981) US6518257(US'257) US46366505(US'505) US4097578(US'578) US5705654(US'654) US6087509(US'509)	=> Obvious selection of cyano group, CF3(Trifluoromethyl), fluoro-N-Methylbenzamide (or aryl substituted with fluoro and methylcarbamoyl) groups from the generic disclosure of US'981, US'257 and US'505 => Formation of imidazolidine ring already a known process in view of US'578 =>US'509 disclosed compounds which are similar to enzalutamide maintain the same hydantonin moiety attached to a phenyl ring further substituted by a cyano and a trifluoromethyl group.
3	Section 25(1)(f) Not an invention u/s 3(d) Not an invention u/s 3(e)	US4511981(US'981)	=> US'981 disclosed compounds which are structurally similar to Enzalutamide. Therefore, enzalutamide is a derivative of the known compounds of US'981. => The compounds claimed in claims 3-12 of the present application is a mere admixture of the compounds Enzalutamide as claimed in claim 1 and there is no demonstrated synergy in the present application.
4	Section 25(1)(g)- Lack of clarity and Sufficiency		=> Best mode of performing the invention is not mentioned. => Markush structure mentioned in the specification of present application encompasses several diaryl hydantonin compounds => Superiority of compound RD162' is not demonstrated in the specification.
5	Section 25(1)(h)- Section 8 requirement not completed		The details with respect to all the foreign applications in respect of the same/substantially same invention were not disclosed completely in accordance with the requirement of Section 8(1) and (2) of the Act.

Applicant's Arguments:

- With regards to lack of novelty, the applicant submitted that the cited prior art documents do not disclose any diaryl compound or any other compound that is even closer to the structure of Enzalutamide.
- With regards to lack of inventive step, the applicant submitted that citation US'981 does not talk about methylcarbamyl group and that US'981 suggests acetamido group which is different than the methylcarbamoyl group. The Applicant further submitted that the compounds disclosed or taught under the cited documents are structurally dissimilar and have dissimilar modes of action and therefore the said documents fail to guide the person skilled in the art to perform the present invention as envisaged in the present patent application.
- With regard to Section 3(d), the Applicant submitted that Enzalutamide the claimed compound is a New Chemical Entity (NCE) and the same is not a salt, ester, ether, polymorph, derivative, etc. of a known substance. Therefore, Enzalutamide cannot be regarded as the known substance under Section 3(d).
- With regard to Section 3(e), the Applicant submitted that the revised claims disclose a novel diaryl thiohydathoin compound, Enzalutamide, a new chemical entity and therefore the combinations of Enzalutamide would be new and inventive which cannot be considered as an aggregation of the known properties of the components.
- In response to ground of lack of clarity and sufficiency as per Section 25(1)(g), the Applicant submitted that the present invention is sufficiently disclosed to the fullest extent with sufficient working examples, synthetic schemes and test procedures to determine the biological activity of the disclosed compounds. RD162 is specifically disclosed as Example 56 in the complete specification. In response to ground of non-compliance with Section 8, the Applicant submitted that, the information related to the corresponding foreign patent applications has been submitted to the Learned Controller at regular intervals, therefore the Applicant pleaded to dismiss the aforesaid ground of opposition.

Section 25(1)(b)

The Controller observed that none of the documents cited by the Opponents specifically disclosed the structure of the compound as claimed in the present application either by the way of claim or as an example. The claimed compound can only be arrived by suitable substitutions of different R group and X,Y,A,B etc. The Controller further pointed that to arrive at the structure of Enzalutamide, a person has to pick some suitable substituents from the definition given in markush structure as given in prior art and hence picking and putting is not allowable in ascertaining the novelty of the claimed invention. Therefore, the Controller dismissed the ground, reasoning that the claimed compound is novel and not anticipated in view of the cited prior art documents.

Section 25(1)(e)

The Controller observed that US'981 clearly mentioned that even moderately sized groups are not favored at ortho and meta position of the aryl ring. That leads to the only option is halogens out of the disclosure given in US'981 at this position. The Controller further mentioned that the applicant has failed to show in their application that fluoro substitution has any effect on the activity and there is no difference in activity of RD153 and compound that doesn't have fluoro substitution at this position and Enzalutamide. Also, the fluoro-N-Methylbenzamide moiety is clearly in the prior art US'257. Further, the formation of imidazolidine ring was already known in the art in view of US'578. Hence, the Controller

stated that the claimed invention lacked inventive step in vide of US'981 in combination with US'257 and US'578.

Section 25(1)(f)

As the claimed compound Enzalutamide lacks novelty and inventive step due to the aforementioned reasons, the applicant's claim that the compound is a new chemical entity was denied by the Controller. Further the applicant failed to demonstrate an improvement in efficacy thereby making the claim unpatentable under section 3(d) of the Act.

The Controller further stated that the applicant in the present invention failed to show any synergistic effect when the compound Enzalutamide is used as a composition. Hence, the Controller accepted the opponent's objection to the application under to Section 3(e) of the Act.

Section 25(1)(g)

The Controller refused the ground of opposition for lack of sufficiency as the specification fully and sufficiently describes the claimed invention. Enzalutamide (RD 162') is specifically disclosed as Example 56 in the complete specification and its process for preparation is also disclosed.

Section 25(1)(h)

The Controller stated that the requirement of Section 8(1) and 8(2) was complied on different dates by filing the information regarding corresponding applications in other jurisdictions. Therefore, in view of the aforestated, the Controller dismissed the ground stated under section 8.

Conclusion

The Controller in his decision, refused to grant patent over Xtandi, as the claimed invention lacked inventive step under Section 2(1)(ja) and is not patentable as the claims falls under Section 3(d) and 3(e) of the Act.

Entitlement to Apply For and Be Granted A Patent

Suchi Rai

Who under the Indian Patents Law is entitled to apply for a Patent?

In India, a person to be eligible to file an application for a patent should either be the "true and first inventor" of the invention or an assignee or legal representative / heir(s) of the "true and first inventor". An eligibility criterion for persons filing Patent Application in India is provided under [6]Section 6 of Patents Act, 1970 (the Act).

Proof of Right to apply for a patent in India:

An assignee of the true and first inventor is eligible to file a patent application for patent in India, provided that the requirement under [7]Section 7 of Act to submit the "Proof of Right" document is duly met. Additionally, where an application for patent is made by an assignee, there is a requirement to submit a declaration mentioning the name of the inventor(s) claiming to be the true and first inventor(s).

Both Sections 6 and 7 of Patents Act, 1970 mention that the person entitled to apply for a patent shall be the true and first inventor of the invention.

First filing:

Considering a hypothetical situation wherein, two genuine inventors working independently and unaware of each other's work, invent on the same concept and involving the same technical advancements on an invention and proceed with filing a patent applications respectively in India. One of the inventors chooses to file a provision application in India immediately when the scope of the invention was ascertainable, whereas, the other inventor chooses to wait for some detailed results and drafting of the specification and files an application for patent at a later date with complete specification and claims. In such a scenario, both the inventors are true and first inventor, however, one of them is the "first filer". This "first filer" in the given facts of the case gets an earlier priority over the subsequent filer, and as per [8]Section 13 of the Act, the patent application filed first on an same inventive concept gets the priority over the application filed thereafter. Accordingly, the subsequently filed application, although filed along with the complete specification, is anticipated by the "first filed" application in India. In other words, when two inventors file their respective patent applications on the same inventive concept, as per Section 13 of the Act, the application filed first will get the priority and the subsequently filed application

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[6] Section 6 in The Patents Act, 1970:
Persons entitled to apply for patents. -
(1) Subject to the provisions contained in section 134, an application for a patent for an invention may be made by any of the following persons, that is to say,-
(a) by any person claiming to be the true and first inventor of the invention;
(b) by any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application;
(c) by the legal representative of any deceased person who immediately before his death was entitled to make such an application.
(2) An application under sub-section (1) may be made by any of the persons referred to therein either alone or jointly with any other person.

[7] Section 7 in The Patents Act, 1970
Form of application. -
(2) Where the application is made by virtue of an assignment of the right to apply for a patent for the invention, there shall be furnished with the application, or within such period as may be prescribed after the filing of the application, proof of the right to make the application.
(3) Every application under this section shall state that the applicant is in possession of the invention and shall name the person claiming to be the true and first inventor; and where the person so claiming is not the applicant or one of the applicants, the application shall contain a declaration that the applicant believes the person so named to be the true and first inventor.

[8] Section 13 in The Patents Act, 1970:
Search for anticipation by previous publication and by prior claim.-
(1) The examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification-
(b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

will be considered as anticipated even if the first filed application is not published by the Patent Office at the time of filing of the subsequent application.

In addition to Section 13, [9]Section 25 of the Act also has the provision to oppose the application for patent on the ground that the invention was already claimed in a specification which was filed earlier then the patent application which claims the same subject matter and filed later on.

Accordingly, both Section 13 and Section 25 support the concept that the first filer gets the priority and hence a grant of patent over the invention.

"Wrongful obtaining" of the invention:

Considering a hypothetical situation wherein an inventor (the true and first inventor) is deprived of his right to file the application for patent by some other party who learnt about the invention from the actual inventor. This other party, upon learning about the invention from the first inventor under confidentiality restraints, immediately files an application for patent in India in his own name. As per Section 13, this person by being a first-filer would get priority and may get the rights over the patent wrongly appropriated in his own name. In such a scenario, the true and first inventor has the remedy under the law to oppose the application for patent under [10]Section 25 of the Act on the ground that the invention was "wrongfully obtained" from the true and first inventor. In such a situation, complete data of research for the invention and other relevant evidences can be submitted to protect the rights in the invention of the true and first inventor. Further, a similar ground is also available for revocation of patent under [11]Section 64 of the Act.

Concluding the above discussion, it is established that by filing an application for patent first (as soon as possible), the true and first inventor or his assignee can secure its patent. However, in case any person "wrongfully obtains" an invention from the true and first inventor and manages to file first to wrongly register a patent in his name, such persons (wrongful obtainers) can be checked under the relevant Opposition and Revocation provisions of the Act.

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[9] Section 25 in The Patents Act, 1970
Opposition to the patent. -
(c) that the invention so far as claimed in any claim of the complete specification is claimed in a claim of a complete specification published on or after priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

[10] Section 25(1)(a) in The Patents Act, 1970
Opposition to the patent. -
(a) that the applicant for the patent or the person under or through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;

[11] Section 64(1)(c) in The Patents Act, 1970
Revocation of patents. -
(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds that is to say-
(c) that the patent was obtained wrongfully in contravention of the rights of the petitioner or any person under or through whom he claims;

Contesting grant of a patents at the Patent Office by the way of Oppositions

- *Shrimant Singh*

A patent being an exclusive monopolistic right over a technology given to an individual, care of a high degree is warranted towards the examination and grant of such monopolistic right. The Patents Act, 1970 ("the Act") clearly prescribes what is an "invention" under Section 2(1)(j) and what are not inventions hence not patentable as per Sections 3 and 4 of the Act. While the Examiners and Controllers examine an application for patent as per the qualifications or tests provided under the Act, the other parties are also enabled under the law to represent and oppose to grant of an application for patent.

Under the Patents Act, there are two instances at which the grant of a patent can be opposed, namely, pre-grant opposition and post-grant opposition.

Pre-Grant Opposition: Section 25(1) of the Act stipulates that where an application for a patent has been published but a patent has not been granted, any person may, in writing represent by way of opposition to the Controller against the grant of patent on the grounds—

(a) that the applicant has wrongfully obtained the invention;

(b) that the invention as claimed has been published before the priority date of the claim;

(c) that the invention as claimed is already claimed in an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim;

(d) that the invention as claimed was publicly known or publicly used in India before the priority date of the claim;

(e) that the invention as claimed is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim;

(f) that the claim cannot be regarded as an invention within the meaning of this Act, or is not patentable under this Act;

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;

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

(i) that in the case of a convention application, the application was not made within twelve months from the date of the first application in a convention country;

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

(k) that the claimed invention is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.

Rule 55 of the Patents Rules, 2003, ("the Rules") prescribes the process involved in the pre-grant opposition proceedings. The main provisions relating to initiating or defending the pre-grant opposition are:

(1) A "representation" for opposition shall be filed on Form 7(A) provided in Schedule II of the Rules, at the appropriate office with a copy to the applicant. The same shall include a statement and evidence in support of the representation and a request for hearing, if so desired by the opponent.

(2) Such representation shall be considered by the Controller only when a request for examination of the application has been filed.

(3) On consideration of the representation if the Controller is of the opinion that application for patent shall be refused or the complete specification requires

amendment(s), he shall give a notice to the applicant to that effect.

(4) On receiving the notice under sub-rule (3), the applicant shall, if he so desires, file his statement and evidence, if any, in support of his application within three months from the date of the notice and shall also serve a copy of the same to the opponent.

(5) On consideration of the statement and evidence filed by the applicant, the Controller may either refuse to grant a patent on the application or require the complete specification to be amended to his satisfaction before the patent is granted.

Post Grant Opposition: Section 25(2) provides that after grant of a patent but before the expiry of a period of one year from the date of publication of the grant, any person interested may give notice of opposition to the Controller in the prescribed manner on the grounds as mentioned under the said provision. The grounds prescribed under Section 25(2) for post-grant opposition are the same as that in a pre-grant opposition.

Further, the Act under Section 25(2) and 25(3) provides for "*constitution of Opposition Board*" and "*upon receipt of the recommendation of the Opposition Board and after giving the patentee and the opponent an opportunity of being heard, the Controller shall order either to maintain or to amend or to revoke the patent*" respectively. Rule 55A of the Patents Rules, 2003, prescribes that notice of opposition under Section 25(2) shall be filed at the Patent Office on Form 7 given in Schedule II of the Rules.

The procedure regarding constitution of the Opposition Board and its proceedings along with the steps involved in the post-grant opposition proceedings are given under Rules 56 to 62. To put the procedural steps briefly:

Rule 56 empowers the Controller to constitute the Opposition Board comprising of three members as prescribed under the sub-rules and the notice of opposition along with documents filed therewith are examined by the Board and a joint recommendation is to be given within three months from the date on which notice of opposition and documents were forwarded to them.

Rule 57 stipulates that the Opponent, along with his notice, needs to send a written statement comprising nature of his interest, the facts of the case, evidence, and relief which he seeks, further, a copy shall be served to the Patentee.

Rule 58 provides that a reply statement and evidence, if any, by the Patentee shall be filed at the IPO along with serving a copy to the Opponent, within two months from the date of receipt of written submission. In case the Patentee chooses to not reply to the opposition or fails to reply within said two months, the patent is deemed to be revoked.

Further, under Rule 59, the Opponent may within one month from the receipt of Patentee's reply file at the IPO along with serving a copy to Patentee, further evidence strictly confined to the matters in the Patentee's evidence.

Subsequent to completion of evidence and upon receiving recommendation of the Opposition Board, Rule 62 enables that the Controller, subject to the formal request(s) along with prescribed official fee, to appoint a hearing of the opposition and may require the members of the Board to be present in such a hearing. Finally, after duly hearing the parties desirous of being heard and considering the recommendation by the Opposition Board, the Controller shall decide the opposition and notify his reasoned order/decision to the parties.

Accordingly, the enabling Section 25 of the Act and corresponding Rules, prescribe as to how to file opposition against grant of a patent and steps which shall be followed during the opposition proceedings. Apart from the literal difference in time to oppose [i.e., before or after grant], there are other salient differences which shall be kept in mind by both the

parties - Opponent and the Applicant/Patentee:

1. Who can file the opposition: While pre-grant opposition can be filed by any person, the post-grant opposition can be filed by a person interested. It is pertinent to note that the Act, under Section 2(1)(t) also defines *"person interested"* as a person engaged in, or in promoting, research in the same field as that to which the invention relates. Therefore, an additional qualification is placed under the post-grant opposition, that the Opponent needs to satisfy/establish before the Controller or Opposition Board that it is a person interested within the meaning of the Act.
2. When to file and procedural timelines: While a pre-grant opposition can be filed at any time after publication of the application till the grant of patent, a post-grant opposition shall be filed within one year from the date of publication of the grant of patent. Further, a pre-grant opposition along with evidences, etc. is to be considered by the Controller only after request for examination has been filed in an application for patent, whereas the post-grant opposition is carried out as per the procedure and timeline prescribed under Rules 56 – 62 as detailed above.
3. Filing of reply evidence by Opponent: In a post-grant opposition, the Opponent is given an additional opportunity to submit evidence in reply to evidence of the Patentee, whereas, in pre-grant the opponent needs to furnish all evidence and also request for hearing if desired at the first instance itself, i.e., along with its notice of opposition.
4. Opposition Board: There is a specific provision of constitution of the Opposition Board under post-grant opposition proceedings and the recommendation of the Board is to be taken under consideration by the Controller. The same is not the case with respect to the pre-grant opposition.
5. Hearings: How the hearing is to be conducted during a post-grant opposition is specifically prescribed under Rule 62, however, with respect to pre-grant opposition no such provisions are laid out.

While one cannot take sides as to the more effective way to contest the grant of a patent, nevertheless, it is advisable not to leave out an opportunity to oppose by way of pre-grant opposition and to represent the case strongly at the first instance itself, that too when the application is pending consideration before the Examiner and the Controller.

"Compulsory Licensing" – Every request for compulsory license will not be granted and special powers of the Government in exceptional circumstances

Aayush Sharma

The issue of compulsory licensing of patents has been deliberated, discussed and commented upon at several forums. In India, the first compulsory license which was granted by the Patent Office on March 9, 2012 to Natco Pharma, an Indian company, for generic production of Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer, is very well known example of grant of compulsory license. After the said decision of grant of compulsory license, the pharma companies started paying a lot of attention in selecting composition/drugs to apply for patent in India, drafting of specifications, launch of new drugs, licensing and assignments of related patents, drug pricing in India, etc. Under the Patents Act, 1970 (the Act), the enabling provision for compulsory license is Section 84, which stipulates conditions for grant of a compulsory license, viz., if (a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) the patented invention is not available to the public at a reasonably affordable price, or (c) the patented invention is not worked in the territory of India.

Before applying for the compulsory license under above mentioned conditions, the applicant is first required to make an attempt to get a voluntary license from the patentee. When the applicant is unable to procure a licence at reasonable and equitable terms within the prescribed period (6 months), the applicant can file a request for compulsory licensing before the Controller. In BDR Pharmaceuticals Pvt. Ltd. Vs Bristol Myers Squibb, the Controller rejected BDR Pharmaceuticals' application for compulsory license for BMS cancer drug SPRYCEL. The Controller unequivocally said that before going to the merits of the case, the threshold requirement of establishing a prima facie case of the applicant who is desirous of having the compulsory licence must be satisfied. Further, Controller in the said case observed that BDR Pharmaceuticals had not made any credible attempt to procure a voluntary license from the Patentee and hence the conduct of BDR did not satisfy the statutory requirement the application shall negotiate for a license from the Patentee in good faith for at least 6 months. In view of the same, the Controller refused the BDR Pharmaceuticals' application for compulsory license.

Special Provisions upon notification by the Government of India for compulsory license: Section 92 of the Act deals with the compulsory license which are granted and reviewed by the Government of India for public interest in case of national emergency, extreme urgency or public non commercial use. The said section enables the Government of India to notify to the public such extreme circumstances, whereupon, any person interested can apply for a compulsory license and the Controller in such case may grant to the applicant a license over the patent on such terms and conditions as he thinks fit. In settling the terms and conditions of a licence granted, the Controller shall assure that the articles manufactured under the licensed patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

Section 92 also states various public health crises relating to acquired immuno deficiency syndrome, human immune deficiency virus, tuberculosis, malaria or other epidemics.

Compulsory licence under section 92A: For exports of patented pharmaceutical products in certain exceptional circumstances (*The Indian Patents Act had introduced the section 92A in the 2005 amendment which was exactly the replica of the Doha Declaration)*

Under TRIPS agreement, Article 31(f) has provided a provision in case of exceptional circumstance and on mutual requirement between the two countries; the compulsory license can be issued. According to the said Article and Section 92A of the Act, the compulsory licence shall be available 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. This provision is applicable for countries which allow importation of the patented pharmaceutical products from India. Upon receipt of an application in the prescribed manner, the Controller shall grant a compulsory licence mainly for manufacture and export of the concerned pharmaceutical product(s) to such country under reasonable terms and conditions. Interestingly, this Section is silent on royalty to be given to the Patentee; however, the same totally depends upon the Controller to provide "adequate" remuneration (pursuant to Art 31 [h] of TRIPS) to the patentee.

In the year 2004, Canada became the first country to implement "*Doha style compulsory license*" for the export of generic version of patented drugs to countries with calamitous public health problems. The Canadian Pharma company APOTEX had agreed to license hiv/ AIDS drugs and obtained a two-year-compulsory license on the nine Canadian patents for manufacturing 15.6 million tablets and exporting them to an African country - Rwanda[12]. Another case can be seen in the Indian jurisdiction on 15th September, 2007 when a Hyderabad-based generics manufacturer Natco Pharma Ltd filed an application for a compulsory license before the Controller. Natco had a licence from Nepal to import Erlotinib, patented in India by Swiss firm Roche under the brand name Tarceva, and Sunitinib, patented by US firm Pfizer Inc under the name Sutent. Natco Pharma contends that the generic versions can be manufactured at one-fifth the cost of the patented drug of the innovators and since Nepal is regarded as a least developed country [LDC], accordingly, Natco does not need to establish that Nepal has insufficient manufacturing capacity and hence Natco was legally permitted to obtain a compulsory license to override the patents for public health reasons (*relying on Section 92A & Article 31 of the TRIPS Agreement*).

Apart from granting the power to the Government of India to notify the national emergency or extreme urgency, the said provision is silent on further parameters according to which the discretion could be exercised by the Government. Another important question is whether the public non-commercial use requirement (*as in*

12 https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and#_edn1

section 84) shall be seen in context of a national emergency or health crisis, or rather that same is an independent criterion.

Predatory Pricing: A Synopsis on the Indian Telecom Sector

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INTRODUCTION:

Predatory pricing poses a dilemma that has perplexed and intrigued the antitrust community for many years. On the one hand, history and economic theory teach that predatory pricing can be an instrument of abuse, but on the other side, price reductions are the hallmark of competition, and the tangible benefit that consumers perhaps most desire from the economic system.[13]

As the name suggests, Predatory pricing is the practice pricing of goods or services at such a low level that other firms cannot compete and are forced to leave the market. Thought this practice was mostly used by the government agencies to put a check on the unlawful activities and control monopolies of the agencies, it acted as a redressal mechanism rather than a threat to the equality and freedom as promised under the law.

The Competition Act, 2002 outlaws predatory pricing, treating it as an abuse of dominant position, prohibited under Section 4. Predatory pricing under the Act means the sale of goods or provision of services, at a price which is below the cost, as may be determined by regulations, of production of the goods or provision of services, with a view to reduce competition or eliminate the competitors. Predatory pricing is pricing one's goods below the production cost, so that the other players in the market, who aren't dominant, cannot compete with the price of the dominant player and will have to leave the market. The CCI in InRe: Johnson And Johnson Ltd.[14] said that "*the essence of predatory pricing is pricing below one's cost with a view to eliminating a rival*."

ROLE OF COMPETITORS IN PREDATORY PRICING:

When a single entity in the market rises almost instantaneously, it is mostly because of the abuse of dominant position and predatory pricing which follows. These two principles are seen to intertwine to form a bridge between legal and economic boundaries, and overlap over the existing players in the market. Such activities are basically found to be illegal, however it is just one of the many most frequently used ways in which that enterprise or group may abuse its position of dominance.

Predatory Pricing is mostly dependent upon the use/misuse of dominant position. As per the Section 4(2) of the Competition Act, 2002 dominant position has been described as:

"*DOMINANT POSITION*" means a position of strength, enjoyed by an enterprise, in the relevant market, in Bohemia, which enables it to-

i) Operate independently of competitive forces prevailing in the relevant market; or

ii) Affect its consumers or competitors or the relevant market in its favour;

For an entity to attain a dominant, it is important that the entity has control and has the influence to affect the relevant sector of market to the tune of 50 per cent or more, provided that the other rival players hold a much less share in the active market. Thought the economic strength of the entity does play a vital role, however conditions like the presence of other players in the relevant section of the industry/market plays an important role in ascertaining whether the entity is capable of exercising a dominant position.

Michael E. Porter of the Harvard Business School[15] developed an analysis of the name

[13] PREDATORY PRICING:STRATEGIC THEORY AND LEGAL POLICY - Patrick Bolton, Joseph F. Brodley and Michael H. Riordan

[14] In Re: Johnson And Johnson Ltd., (1988) 64 Comp Cas 394 NULL

[15] Michael E. Porter, The Five Competitive Forces that Shape Strategy, Harvard Business Review 86 (1979)

Porter's 5 forces, which shows that the five conditions mentioned below are prerequisite to show abuse of dominance:

i. The bargaining power of customers (buyers)
ii. The threat of the entry of new competitors
iii. The bargaining power of suppliers
iv. The threat of substitute products or services
v. The intensity of competitive rivalry

In *Hoffmann-La Roche & Co. AG v Commission of the European Communities* the concept of 'abuse of dominant position' has been defined as:

"The concept of abuse is an objective concept relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators , has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition."

Though it has been repeated iterated, but being in a dominant is not illegal per-se. Further, "Abuse" is an objective term and it comprises every conduct which might adversely affect the structure of a market in which competition is weakened. Hence, the being on a entity in a business in a dominant position is not illegal but the misuse of such dominant position is illegal. The position of the company has also been laid down in Section 2 of the Sherman Act, 1860 and under Art 82 of the EC Competition Law. Predatory pricing by such an enterprise which spans enough business to be classified as a dominant player, can be one such abuse.

LEGAL REMEDIES AGAINST PREDATORY PRICING:

To ensure a healthy competition in the market amongst the players the Competition Act, 2002, has been introduced in replacement of the Monopolies and Restrictive Trade Practices Act, 1969, seeks to ensure the welfare of the consumers. Upon realizing the risk and challenges posed by predatory pricing, which mostly a clear abuse of the 'dominant position' in the market, which per-se is illegal; the dealings of predatory pricing in India, as expressed under the Competition Act, 2002, have been borrowed from the English Competition Act, 1998 and the Clayton Anti-Trust Act, 1914. The provision reads as below:

Section 4(2) (a) of the *Competition Act, 2002* states that:

There shall be an abuse of dominant position under Sub-section (1), if an enterprise,-

(a) directly or indirectly, imposes unfair or discriminatory-

(i) condition in purchase or sale of goods or service; or

(ii) price in purchase or sale (including predatory price) of goods or service. Explanation.- For the purposes of this clause, the unfair or discriminatory condition in purchase or sale of goods or service referred to in Sub-clause

(i) and unfair or discriminatory price in purchase or sale of goods (including predatory price) or service referred to in sub- clause

(ii) shall not include such discriminatory condition or price which may be adopted to meet the competition;

As per explanation (b) at the end of Section 4 predatory pricing refers to a practice of driving rivals out of business by selling at a price below the cost of production.[16] Denial of market access briefly referred to in this section, if read conjunctively, is expressly

[16] Hovenkamp, H., Federal Antitrust Policy-The Law of Competition and its Practice 339 (3rd ed., 2005)

prohibited under Section 4 (2) (c) of the Competition Act, 2002.

The Section 4 of the Competition Act, 2002 corresponds to Clause 4 of the Notes in clauses of the Competition Bill, 2001 which reads as follows:

This clause prohibits abuse of dominant position by any enterprise. Such abuse of dominant position, inter alia, includes imposition, either directly or indirectly, or unfair or discriminatory purchase or selling prices or conditions, including predatory prices of goods or services, indulging in practices resulting in denial of market access, making the conclusion of contracts subject to acceptance by other parties or supplementary obligations and using dominant position in one market to enter into or protect other market.[17]

However, in 2007, Section 4 of the Competition Act, 2002 was amended by the Competition (Amendment) Act, 2007. The objects and reasons of such amendment were given in the Notes on clauses of the Competition (Amendment) Bill, 2007 which says that: This clause seeks to amend Section 4 of the Competition Act, 2002 relating to abuse of dominant position. The existing provisions of Section 4 apply only to an enterprise and not to the group of enterprises. Clause (c) Sub-section (2) of Section 4 states that there shall be an abuse of dominant position if an enterprise indulges in practice or practices resulting in denial of market access.

CASE STUDY:

The Indian Telecom in the past 6 months has witnessed a turmoil, which was caused by a new entrant in the telecom market by the name of "Jio", a product of the conglomerate of Reliance Group of Industries. The services under the offer which was first launched as an "employee-only" offer (i.e. Unlimited Calling for life and Unlimited Data Benefit) were made open to the general public which this resulted in the torrent and surge of the masses to avail the proposed benefits. From what was already prognosticated not only did the move trigger profusion of clientele, but also instilled the rivals with a sense of fierce competition.

This further resulted in multifold reduction in the prices of the services of all other leading service providers which then painted this insurgence of competition as an act of intentional sabotage. Though the allegations can't be discarded as foul cry, but the consumer centric market has welcomed the new entrant and the competition with open hands which further makes it difficult for others to form a basis of competition.

Predatory pricing as the name suggests is the pricing of goods or services at such a low level that other firms cannot compete and are forced to leave the market. Thought this practice was mostly used by the government agencies to put a check on the unlawful activities and control monopolies of the agencies, it acted as a redressal mechanism rather than a threat to the equality and freedom as promised under the law.

WHETHER CASE STUDY FITS INTO THE DEFINITION OF PREDATORY PRICING:

Concentration of the power has time and again been proven to be the least effective remedy to prevent it from falling into the hands of the undeserving. In a scenario where development and business economy form two different sides of the coin, money always changes the equation and the outcome goes for a toss. Despite repeated denials by the Reliance Group of Industries about the "Predatory Pricing" & being a dominant player in the market, the conglomerate has surely affected the Indian telecom sector and the major players, left right and centre; it would be worth waiting to understand the course of events which follow. However at present given the illustrious reputation and the sky rocketing user base, coupled with throw away prices breaking the market stereotype of telecom sector

[17] H.K. Saharay, Textbook on Competition Law, (1st ed., 2012)

LEGAL PRECEDENTS:

The most valuable observation relating to predatory pricing and abuse of dominance was made by Lord Denning, M.R. in Registrar of Restrictive Trading Agreements v. W.H Smith & Son Ltd.,[18] while construing the English Law in Restrictive Trade Practices Act, 1965 that there was a time when traders used to join hands, and combine, so as to keep the trade all for themselves, so that prices can be decided according to them, because of the monopoly. This also lead to the shutting down of all new entrants who might cut prices or even produce and sell better quality goods. Therefore, the Parliament had to step in, both for the benefit of the new entrants and the consumers, and had to hold these trade practices void unless they were done in the interest of public interests. Therefore, the law made any such agreement void and also asked the traders to get all their trade practices registered. However, Lord Denning observes that the traders who combined did not tell the law about it, and it was done in dark; without the law or the consumers knowing about it. Neither putting such agreement in writing, nor words were required, "a wink or a nod was enough" for them to combine and turn the whole market into a monopoly and control everything in it. Therefore, the Parliament came up with another law to get rid of these practices, and so, it included not only agreements but also arrangements to keep the predatory pricing in control. This observation by Lord Denning was aptly discussed when Parliament of India amended Section 4 of the Competition Act, 2002 by the Competition (Amendment) Act, 2007 and is also reflected in the amendment.

In MCX Stock Exchange Ltd v. National Stock Exchange of India Ltd., DotEx International Ltd. and Omnesys Technologies Pvt. Ltd[19], the CCI while laying down the test for predatory pricing said that:

"before a predatory pricing violation is found, it must be demonstrated that there has been a specific incidence of under-pricing and that the scheme of predatory pricing makes economic sense. The size of Defendant's market share and the trend may be relevant in determining the ease with which he may drive out a competitor through alleged predatory pricing scheme-but it does not, standing alone, allow a presumption that this can occur. To achieve the recoupment requirement of a predatory pricing claim, a claimant must meet a two-prong test: first, a claimant must demonstrate that the scheme could actually drive the competitor out of the market; second, there must be evidence that the surviving monopolist could then raise prices to consumers long enough to recoup his costs without drawing new entrants to the market."

CONCLUSION:

Market has always been a consumer centric business model which harnesses the potential of the players in a fair and healthy competitive environment. Amongst many other challenges present, the most important is to abolish the system of concentration of power. As essential it is for the consumer to derive the value for money for the goods they want, it is equally important that the companies have a fair playing ground to establish themselves as a reliable and trustworthy entity.

Whilst all the competitors in the market have diverse backgrounds and economic portfolios, it should be understood that principles of fairness apply to each of them individually. Predatory Pricing may in some cases be implemented and considered as a check by the Govt agencies to rule out unlawful market entities or business practices. Interestingly given the developing affairs of the Indian Economy the market is often vulnerable to new entrants who struggle to establish themselves, however the same doesn't seem to the case with "Jio" a part of the conglomerate of the Reliance Group of Industries. Thought what may have been

[18] Registrar of Restrictive Trading Agreements v. W.H Smith & Son Ltd., (1969) 3 All ER 1065

[19] MCX Stock Exchange Ltd v. National Stock Exchange of India Ltd., DotEx International Ltd. and Omnesys Technologies Pvt. Ltd , 2011 Comp LR 0129 (CCI)

appearing as an act of predatory pricing, as has been accused by the other major players in the relevant market sector, it shall be interesting to watch what the course of actions which further go on in the sectors of telecommunications in India.