



Intellectual Property Practice

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Newsletter

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Editorial

In this new era of pharmaceutical product patents, opposition serves as a legal tool for both generic and pioneer pharmaceutical companies to challenge the validity of a claimed invention. It is perhaps stating the obvious, that the existing opposition system under the Patents law was strengthened with the object of mitigating the rigors of this new regime.

During the transition phase, when India was making advances for a complete TRIPS compliant regime, speculations were rife that after January 1, 2005 there would be a deluge of oppositions against the mailbox applications. Has this prophecy come true? If not, what are the underlying reasons? What is the current opposition scenario in India? The answers to all these questions are embedded in our current issue.

As Intellectual Property Laws grant certain exclusive rights to the owner of the property, it is imperative that there are enough inbuilt procedural safeguards against the abuse of these rights or to remedy any wrongful grant. The usual way in which this is achieved is by providing for opposition and revocation of such rights. Generally speaking, the opposition proceedings precede the grant of the right and the revocation proceedings succeed it. However, in the light of post-TRIPS changes, the foregoing does not hold true for the patent applications in India as now there exists both pre-grant and post grant opposition.

This edition of our Newsletter focuses on the nuances of opposition, revocation and enforcement procedures under the Intellectual Property Laws in India. It shall highlight how effectively ‘oppositions’ and ‘revocations’ can be used as the ‘balancing tools’ in the interest-dialectics between the generic and knowledge based pharmaceutical companies.

In our humble endeavour to contribute to the growth of Intellectual Property Law, we have created an online Intellectual Property Resource Centre (IPRC), which is accessible at www.lexorbis.com

We would greatly appreciate if you could send your valuable comments on our newsletter as well the IPRC at mail@lexorbis.com

We thank you for finding time to read this Newsletter. ●

The Lex Orbis Publication & Research Group

“TamiFlu”, India and the Compulsory Licensing Dilemma!

The panic of a potential bird-flu pandemic has again brought into light the ongoing conflict between patents and health rights. Due to its geographical location, India is highly susceptible to the outbreak of the Avian Flu that killed several people in East and South East Asia. The Ministry of Health, Government of India has set up a task force to give its recommendations on the matter. Roche owns patents on oseltamivir with the brand name “Tamiflu”, the only drug effective against H5N1 strain of the Bird Flu virus.

In August 2005, a national consultation for assessing India's preparedness to meet this imminent danger was held wherein concern over the insufficiency of stock of medicines was expressed. The International Health

commission, which is still pending, is difficult to reconcile with the existing statutory provisions.

Even in the presence of Roche's mailbox application, the companies like Cipla are contemplating manufacturing and marketing “Tamiflu” in India. Under proviso 2 of Section 11 (A) of the Patents Act, liability for infringement will accrue only from the date of grant of the patent application. Can the Government by notification exclude generics from their liabilities for infringement computed from the date of grant of a patent to Roche through Mail Box route? There is no provision in the Act to cover this action.

Is the ‘Government Use’ a possible route? The Patents Act permits the government to use or authorize the use of an



Agencies like WHO are contemplating production of this anti-viral in India and Thailand. Roche has sought permission from the Union Health Ministry to market “Tamiflu” in India and pursuant to this request its mailbox application (Application No. 396/DEL/96) is being processed on fast track.

The pending patent application of “Tamiflu” raises a set of fundamental questions. What is the legal basis for the Government to mandate Roche to grant compulsory license to a generic drug maker for Tamiflu, if a patent application for Tamiflu is still pending? The Indian patent law envisages grant of Compulsory Licenses only for granted patents and not when an application is pending. The grant of Compulsory License with respect to an invention, the appli-

cation after an application for a patent has been filed in the Patent office, for the purposes of government. Under these provisions the authorization can be given even before the grant of patent in India. However it is to be remembered that the ‘use for the government purposes’ means the use of the invention only on a non-commercial basis. The government has also the power to acquire the invention from the applicant for a public purpose.

Sweeping powers are given to the Central government to meet any emergency arising out of health crisis in India. Considering the peculiar circumstances of this case, the route that the government will adopt to tackle the situation is uncertain and may raise a variety of jurisprudential conundrums! ●

Patent Opposition

Post 2005!

“The grant of invalid patents is a serious evil insomuch as it tends to the restraint of trade and to the embarrassment of honest traders and inventors...”

Fry Committee (1901)

Part from the extensive examination conducted by the Patent Office, opposition provisions act as the most important check in the procedure for the grant of a patent. Patent laws in different national jurisdictions vary with respect to such checks in the grant procedure. For instance, the US Patents Law does not provide for opposition. Instead anyone can request for re-examination upon issuance of a patent, on grounds of patentability in view of a relevant new prior art citation. Australia also follows the US system of re-examination. In Chinese patent law, the mechanism of pre-grant opposition was substituted with procedures for post-grant opposition or revocation by the amendment in 1992. UK Patents law provides for representation on grounds of patentability in case of published pending applications, wherein any person may make observations in writing to the comptroller, stating reasons for the observations.

In light of the product patent regime for pharmaceuticals, opposition has become a very important tool not only for thwarting frivolous claims from getting accepted but also for obtaining commercial benefits. The Patent Office has begun the publication and examination of WTO/Mail Box applications and efforts are being made to study the scope and content of inventions claimed in the Mail Box applications. Many provisions of the Patents Act provide flexibility to read limitations into as well as to expand the scope of these provisions. The possible interpretation of these provisions by expanding the meaning thereof will be the line of argument that the knowledge-based companies would like to resort to. On the contrary, Indian generic pharmaceutical companies would prefer to read as much limitations in the provisions as possible. One such contentious provision would be Section 3 (d) of the Patents Act. It provides that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of the known substances are to be considered the same unless they differ significantly in properties with regard to efficacy. Whereas the pioneer drug companies will claim significant difference in efficacy, the generic companies would try to prove otherwise. All this makes Patent Opposition very tricky but important affair in India.

There are two stages in which opposition to the grant of patent can be launched. They are: ‘pre-grant opposition’ and ‘post-grant opposition’. This two-tier opposition system has added on to the above complexities. The third amendment to the Indian Patents Act, 1970 brought about significant changes in law, both substantial and procedural. One of the procedural changes was- introduction of post-grant opposition and amendment of the earlier provision of ‘opposition after acceptance of application’ to ‘representation by way of opposition’.



Unlike the earlier pre-grant opposition, any person can file ‘representation’, after the publication of patent application but before the grant of patent. Now, if we look at the procedure of pre-grant opposition, we can see an imbalance in the rights conferred on an opponent vis-à-vis an applicant. A person filing the representation has to support his/her observation with a statement and evidence, if any, and he/she can also request for a hearing, if so desired. The Examiner shall consider any such representation, only when a request for examination has been filed for the patent application. Based on the representation, the Examiner shall consider the application and shall intimate the applicant in case the application for the patent needs to be amended or the patent is to be refused. The applicant

has one chance to reply to the Controller's notice in a month's period, but he/she cannot request for a hearing. As such the applicant's chance to counter the representation is limited to written reply. However, the Patent Draft Rules, 2005 propose an amendment to rule 55(4), giving a chance to the applicant to be heard, so as to make the procedure more fair and just for the applicant.

The grounds for filing the representation introduced by the (Amendment) Act, 2002, are retained as such. The similar grounds are available for post-grant opposition also. The difference in the two oppositions is of the person eligible to file the opposition, i.e. only 'interested person' can file post-grant opposition whereas 'any person' can file pre-grant opposition. Whereas the former has to demonstrate specific interest in making an opposition the latter need not. The Patents (Amendment) Ordinance, 2004, however, had grounds based only on the patentability of the invention for filing representation, which was expanded to include the current grounds in the 2005 (Amendment) Act.

In principle, the similar grounds for opposition, in both pre-grant and post-grant opposition provide two oppositions for a case. Unlike the representation at UK Patent Office or the re-examination at USPTO, the representation at Indian Patent Office (IPO) is not limited to patentability of the invention. As such, the present provisions practically leave negligible difference between the pre-grant and post-grant opposition. Further, the law provides an opportunity to be heard during the pre-grant opposition as well. These provisions bring the pre-grant proceedings closer to the post-grant proceedings, thereby extending the opposition period from the publication of application under Section 11A till the expiry of 12 months period from the publication of patent under Section 43(2).

Now let us analyze the post-grant opposition proceedings in order to appreciate the differences between the two stages of opposition. Upon receiving a notice of opposition, the Controller shall notify the patentee and shall constitute an Opposition Board, which shall conduct the examination. The Opposition Board shall consist of three members, one of the members being nominated as the Chairman of the Board. In the post-grant opposition proceedings, the opponent has an opportunity to submit reply evidence against the patentee's evidence. The function of the Opposition Board is to examine the notice of opposition, statements and evidences, and submit a reasoned report on each

As such, the existence of a robust generic pharmaceutical industry and the presence of more than 7000 applications in the Mail Box, can lead to a deluge of patent oppositions.

ground of opposition contained in the notice of opposition along with its recommendation, within a period of three months.

The Examiner who has examined the application is disqualified from becoming a member of the Opposition Board. On one hand, this provision precludes the apprehension of bias from the mind of the opponent, on the other hand the examiner who has initially examined the application, and therefore understands the case and can provide better advise, is no

more a part of the opposition proceedings. The shift of opposition from pre-grant to post-grant would avoid unnecessary delay in the grant of a patent.

It was expected that there would be an upsurge in the opposition proceedings after the introduction of product patent regime. However, there have not been much opposition filings (as published in the Patent Office Journal, till October 7, 2005). Out of those that have been filed, very few oppositions are related to the field of pharmaceuticals. More than 500 Mail Box applications have been published for pre-grant opposition. However, till now, very few representations have been filed against these Mail Box applications. Hence the speculation of an upsurge in opposition in post-product patent regime has not come true.

Under section 83 of the Indian Trademarks Act, 1999, Intellectual Property Appellate Board (IPAB) was established to hear patent cases, as it would be technically equipped to handle such cases. However, till date the IPAB has not been notified to hear patent cases. The low number of oppositions in the pharmaceutical field is probably due to the ambiguities in the Patent law and the inability of the IPAB to hear disputes relating to the patent oppositions. Since both the generic and knowledge based companies can take advantage of the nebulous provisions, the companies fear uncertainties in the outcome of the disputes.

As such, the existence of a robust generic pharmaceutical industry and the presence of more than 7000 applications in the Mail Box, can lead to a deluge of patent oppositions. The absence of a specialized adjudicatory body and ambiguities in the Patents law has diffused this explosive situation to a great extent. In the times to come, when these ambiguities are removed, and loopholes plugged, opposition system under the Indian Patent Law would become most efficacious among all the patent opposition systems across the world. ●

Is EMR an Inviolable Right Under the Patents Law? - A Study of GLIVEC Case

Preface

Though the Exclusive Marketing Rights have now been scrapped off the Statute book, the controversy over the scope and nature of the rights still continues. The erstwhile Indian Patent law makes provision for the grant of exclusive marketing rights for a product, in respect of which the patent application has been filed in India, if certain statutory conditions are satisfied. EMR once granted, gives an exclusive right to sell and distribute the product in India. If any person markets the product with respect to which the EMR has been granted, he shall be liable for infringement. The question arises as to whether in a proceeding for infringement the defendant can raise the issue of validity of the patent that forms the basis of grant of EMR? Would the Courts allow overriding of EMR granted after due scrutiny? To what extent the Courts in India would take into account the public health issues in granting temporary injunction in case of alleged infringement of EMR? The recent case *Novartis AG and Anr V. Mehar Pharma and Anr, 2005(30) PTC (Bom)*, elucidates these issues.

Facts of the Case

The plaintiff Novartis AG had obtained an EMR in respect of their anti-cancer drug "GLIVEC" composed of "B-Crystalline form of Imatinib Mesylate Salt" in 2003 and were importing the drug from Switzerland for sale in India. The defendants were the largest manufacturers and suppliers of the same drug in India under the name of "VEENAT".

The plaintiffs filed a notice of motion in the suit seeking a restraint order against the defendants from manufacturing for sale, selling, marketing and exporting their anti-cancer drug under the brand name of "VEENAT" during the term of their EMR.

Arguments Advanced by Novartis

The plaintiffs argued that by virtue of EMR, they have an exclusive right to sell or distribute "B-CRYSTALLINE FORM OF IMATINIB MESYLATE IN ITS DOSES FORMS" all over India, for a period of five years from the date of grant of EMR. The validity of EMR for GLIVEC cannot be challenged as it was granted by the Patent Office after conducting intense examination for a period of one and half years. Further, at the prima-facie stage of the case, the Court should not go into the question of validity of 'grant of patent' in other countries that forms the basis of grant of EMR in India.

The Indian Patent Law allows examination of the application for EMR only on two aspects namely: (a) whether the invention is one declared unpatentable under the law or; (b) whether the invention is one relating to atomic energy. The question of 'anticipation by prior publication' or any other ground that may be raised in objection to the grant of patent, cannot be examined at the stage of grant of EMR. Further, the expert evidence proves that the "B-Crystalline form of Imatinib Mesylate Salt" is a new product and/or process involving inventive step. The contention of the defendant that "B-Crystalline form of Imatinib Mesylate Salt" is not a new product or process involving an inventive step, is unsubstantiated.

The plaintiffs have spent millions of dollars in research and development of the drug. If injunction is not granted, the



plaintiffs will suffer grave and irreparable damage and also harm to their reputation.

Defenses Raised

The defendants challenged the validity of the claim for patenting of "B-Crystalline form of Imatinib Mesylate Salt" on the ground that the claim was anticipated by disclosure in Canadian patent application filed by plaintiff in 1993. EMR can only be granted with respect to a product that is new and not obvious to a person skilled in the art. Therefore, the grant of EMR to the plaintiff was invalid. Further, as patent rights are territorial in nature, grant of patent in one country does not entitle the same grant in other countries. For obtaining the patent, substantive and procedural requirements of the concerned country should be complied with.

The most important issue raised by the defendant was that of the public health. Around 30, 000 people in India suffer from cancer. The cost of “GLIVEC” comes out to Rs. 4000 per day per patient whereas the cost of “VEENAT” comes out to Rs. 300 per day. The patients cannot afford such highly priced imported medicine of the plaintiff. Sale of the defendant’s drug has exceeded Rs 10 crores and drug worth several crores is in the pipeline. Moreover above thirty thousand patients in India use “VEENAT”, the drug of the defendant. If injunction were granted to the defendant, it would cause great prejudice to public health and public interest and create grave public health crisis.

Decision

The Bombay High Court on perusal of the arguments advanced by both the parties and also the evidence adduced in support of the arguments, arrived to the conclusion that interlocutory injunction should not be granted unless there is a real probability of the plaintiff succeeding



on the trial. Where the patent is of a recent date, no interim injunction should be granted. The Court felt that injunction should not be granted in those cases where a serious question as to the validity of the patent raised by the defendant, is to be tried in the suit.

Further, the Court felt that the disclosure of the compound as well as the salt is made in the patent application filed by the plaintiff in Canada in 1993. This disclosure raises a serious question as to whether the subject matter of EMR is a new product or not. Also, as the patent is of recent origin, the plaintiff should not be granted temporary injunction. In the opinion of the Court, the plaintiffs also failed in establishing that if the injunction is not granted to them, they will suffer irreparable loss or damage.

The balance of convenience was found to be tilting in favour of defendants as the drug in question was a life saving drug and was not being manufactured by the plaintiffs in India. The Court observed:

“The plaintiffs do not manufacture the drug in India. Therefore the plaintiff will rely on the international transport system for making the drug available in India in the required quantity. If due to any problem, the plaintiff cannot make the drug available in required quantity in India, it obviously will be disastrous for the patients”

The Court thus refused temporary injunction and instead directed the defendant to maintain an account of their trade and to give an undertaking to pay damages in case the plaintiffs win the case. The Bombay High Court refused to follow the decision of Madras High Court stating that the latter did not properly consider the law of temporary injunction.

Comments and Conclusions

It is respectfully submitted that the approach of Bombay High Court in the instant case was not at all pro-innovation. The license given by the Court to the defendants to manufacture and sell the drug in India made a complete mockery of the legislative intent behind incorporation of exclusive marketing rights in the Patent Law. The conferment of right, however exclusive, becomes a farcical exercise if the appropriate remedy is denied at the apposite stage.

In contrast to the opinion of the Bombay High Court, the Madras High Court observed (in a similar case involving Novartis) that when the statute protects a right, balance of convenience loses its significance, especially when the parties in opposition do not have a legal ground in their favour. There is a presumption that the patent and EMR has been granted in the Convention country after appropriate tests. At the interlocutory stage the Court will not go into such deep issues.

If the stand taken by the Court in the instant case is adopted, it will become commonplace to argue that the plaintiff’s drugs are preposterously priced, unaffordable for the people and hence grant of temporary injunction would be prejudicial to public health. The Court’s concern for public health seems to be ill founded. It was rightly observed by Madras High Court in the case of *Novartis AG & Anr V. Adarsh Pharma & Anr 2004(29) PTC 108(Mad)* that the Patent Law is well equipped to deal with public health issues. The Central Government is empowered to allow the sale of the drug by a person other than the person in whose favour the EMR is granted, if it is satisfied that such a grant is necessary or expedient in public interest.

It would be fallacious to state that the Court by denying temporary injunction was striking a balance between public and private interest rather it was allowing one commercial interest to take over the other. It is difficult to see how the patent rights can be enforced against a defendant who puts a grab of public interest on his purely commercial stakes. ●

Revocation of Designs - Law and Practice

Design registration plays a crucial role in protecting the rights of designers and promoting industrial progress by keeping industries competitive in this age of rapid modernization and globalization. Practical utility coupled with aesthetic appeal, influences the consumer in choosing a particular article of merchandise. Therefore, where the practical efficiency of any two given articles is same, visual appearance plays the decisive role. The object of design law is to ensure that the originator or creator of a profitable and aesthetic design is not deprived of his reward as a result of unauthorized application of his design by others. This is achieved by protecting novel designs devised to be applied to particular articles that are manufactured and marketed commercially by industrial process or means.

Revocation of Registered Designs

The Design Law does not provide for opposition to the registration of Designs. In order to protect the rights of bona fide designers certain provisions for cancellation and rectification of the registered design have been incorporated in the Act. After registration of the design, any person can make a petition for cancellation to the Controller on the ground that the impugned 'design'

- has been previously registered in India; or
- has been published in India or elsewhere prior to the date of registration; or
- is not new or original; or
- is not registrable under the Designs Act; or
- is not a design within the meaning of the Act

For the purposes of registration, first-to-file rule is applicable and consequently if a newly registered design is same as an earlier registered design in India, it will become a ground of cancellation. The second ground for cancellation is 'prior publication' of the design in India. Publication occurs only if the design is either made available to the public or if it is shown or disclosed to some person without any obligation to keep it secret.

The third and the most important ground for cancellation of registration is 'lack of novelty or originality'. It is not necessary that the design per se should be novel. Novelty may reside in the application of a known shape or pattern to new subject matter. Also, the whole design need not be new; it is sufficient if some part of it is new or original. The test for determining the novelty is an objective one. The novelty is to be distinguished by the eye of the customer from the previously existing variants. Thus in *Bright Auto Industries v Chawla (1978) IPLR 28*, the Court observed:

'One has to consider and look at the design in question with an instructed eye and say whether there is or there is not such a substantial difference between that which has been published previously and the registered design to say that at the date of registration that was a new or original design and therefore properly registered.'

The fourth ground for cancellation is that the design is not registrable under the Act. Under the Designs Act, 2000 a design cannot be registered if (a) it is not new or original; or (b) has been disclosed to the public any where in India or in any other country by publication in a tangible form or by use in any other way prior to the filing date, or where applicable, the priority date of the application for registration; or (c) it is not significantly distinguishable from known designs or combination of known designs; or (d) it comprises or contains scandalous or obscene matter.

It is necessary that the design should be applied or capable of application to any article by any industrial process or means. Further, the article must have an existence independent of the applied design. So, the design as applied to an article should not be integral part of the article.

The cardinal principle of design law is that the features of a design are judged solely by the eye. Therefore, the design must appear and should be visible on the finished article, for which it is meant. Any design in the inside arrangement of a box, money purse or almirah may not be considered for showing such articles in the open state, as those articles are generally put in the market in a closed state. However, when any design suggests any mode or principle of construction or mechanical or other action of a mechanism, a suitable disclaimer in respect thereof is required to be inserted on its representation, provided there are other registrable features in the design.

Finally, the design should not include any trademark or property mark or artistic works as defined under the Trade Marks Act, 1999; Indian Penal Code, 1860; and the Copyright Act, 1957 respectively.

Procedure

Under the Design Rules, two different procedures are followed in case of an application by the registered proprietor and in case of an application by any person other than the registered proprietor.

Procedure when the applicant is a registered proprietor: A petition to the Controller for the cancellation of the registration of a design has to be made in duplicate in Form 8,

accompanied by a statement in duplicate setting out the nature of the applicant's interest and the facts upon which the application is based.

Procedure when the applicant is not the registered proprietor: When the applicant is not the registered proprietor, the Controller shall transmit a copy of the petition along with the statement to the registered proprietor. If the registered proprietor intends to oppose the application he must within the time specified by the Controller, leave at the office a counter-statement setting out the grounds on which he intends to oppose the application and has to within the same time, deliver to the applicant a copy of the counter-statement.

After a copy of the counter-statement is delivered to him, the applicant may leave at the office, evidence by way of



affidavits in support of his case and has also to deliver to the registered proprietor a copy thereof. On receiving the evidence furnished by the applicant, registered proprietor may, leave at the office evidence by way of affidavits in support of his case and also deliver to the applicant a copy thereof.

After a copy of evidence furnished by the registered proprietor is delivered to him, the applicant may leave at the office, evidence in reply, by way of affidavits and has also to deliver to the registered proprietor a copy of such evidence. No further statement of evidence is required to be left by either party except by leave of or on requisition by the Controller. Under these rules the period for filing the counter-statement or for leaving evidence is one month,

which can be extended upto three months on a petition for extension of time made by the concerned party.

The Controller after completion of filing of the statement and the evidence or at such other time as may be decided by him, appoints a hearing of the petition for cancellation and gives the parties 10 days' notice of such hearing. If either party desires to be heard, he has to give to the Controller a notice in Form 20 of his intention to attend the hearing. If at the hearing either party intends to refer to any publication, he has to give to the Controller and to the other party at least 5 days notice of such intention, together with details of the publication to which he intends to refer.

After hearing the party or parties desirous of being heard or without a hearing, if neither party desires to be heard or attends the hearing, the Controller decides on the petition and the opposition, if any, and notifies his decision to the parties. An appeal can be made from the order of the Controller to the High Court. Further the Controller may also refer any such petition to the High Court, which then decides on the petition so referred.

Rectification of the Register

The Designs Act also provides for the rectification of the register by the Controller, whereby he may make, expunge or vary any entry in the register. The grounds for rectification are:

- non-insertion in or omission from the register of designs of any entry; or
- entry made in such register without sufficient cause; or
- entry wrongly remaining on such register; or
- an error or defect in such register,

In an application for rectification although the Controller has no power to cancel the registration, he has the power to expunge the whole entry on the ground that the entry has been made in such register without sufficient cause; or any entry has wrongly remained on such register. An appeal can be made to the High Court against the order of rectification passed by the Controller. The Controller may also refer any application for rectification to the High Court for decision and the High Court shall dispose of the application so referred. If the High court passes any order rectifying the register, the same will be served on the Controller and the latter on receipt of such notice will have to rectify the register accordingly.

Conclusion

Thus by using the provisions of revocation contained in the Designs Act, 2000 a bona fide designer can get relief against fraudulent registration of the designs. However, the cost factor can be very high and the process for getting the relief can be protracted. ●

Trademark Opposition in India

Preface

In today's consumer oriented market, the trademarks play a significant role in indicating the reputation and goodwill of a business. The Opposition provisions are important in as much as they can be utilized to prevent others from free riding on this hard-earned reputation. Opposition to the registration of a similar/identical mark is an also important strategy in the management of brand names.

Grounds for Opposition

The grounds for opposition under the Trademarks Act, 1999 have been bifurcated into: absolute grounds and relative grounds. Whereas the former are independent and deal with the inherent characteristics of the mark, the latter are relative to the earlier trade marks. Opposition can be made on the grounds that the mark:

- (a) is devoid of any distinctive character; or
- (b) consists exclusively of marks or indications which may serve to designate the kind, quality, quantity, intended purpose, values, geographical origin or the time of production of the goods or rendering of the service or other characteristics of the goods or service; or
- (c) has become customary in the current language or in the bonafide and established practices of the trade; or
- (d) is of such a nature as to deceive public or to cause confusion; or
- (e) comprises or contains scandalous or obscene matter; or
- (f) consists of the shape of goods which results from the nature of the goods themselves or is necessary to obtain a technical result or gives substantial value to the goods.
- (g) The mark due to its similarity or identity with an earlier trademark and the similarity or identity of the goods and services covered, is likely to cause confusion in the minds of the prospective consumers; or
- (h) The mark is identical with or similar to an earlier trademark which is a well known trademark and even though the goods specifications are different, the use of the mark would be detrimental to the distinctive character or repute of the earlier trademark; or
- (i) The use of the mark in India is prevented by virtue of any law on passing off or law of copyright.

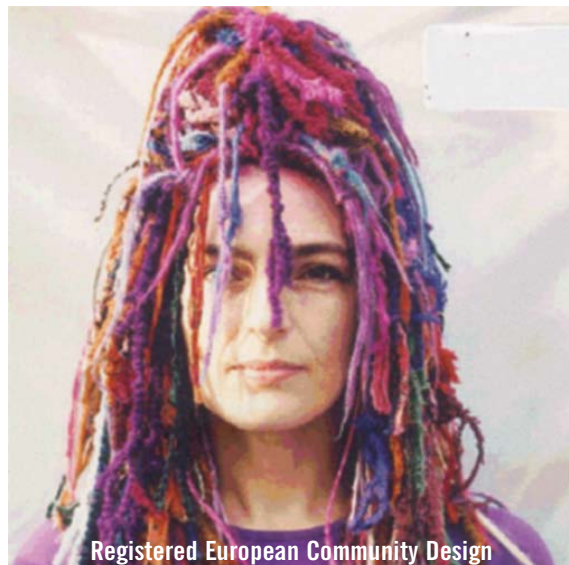
The grounds (a) to (f) are absolute grounds and (g) to (i) are relative grounds under the Act.

The Procedure

Within three months from the date of advertisement of the mark in the Trade Marks Journal any person may give notice of opposition. On an application by the opponent, the Registrar can extend this time by a further period not exceeding one month. In the recent decision of *Anil Kumar Chanani V. Tommy Hilfiger Licensing Inc.* 2005 (31) PTC

445 (Reg.) it was held that an application for extension of time for filing opposition can be made after a period of three months but before four months from the date on which the Journal containing the advertisement is made available to the public. Rule 47(6) that prescribes the time limit of three months for filing an application for extension of the time to file opposition does not bar an extension application filed after the said period.

If a notice of opposition is filed within this period, the application enters the opposition proceedings which involves serving a copy of the notice of opposition by Registrar on the applicant, the applicant's counter statement (within 2 months from the date of receipt of notice of opposition), the evidence by opponent, the further evi-



dence by the applicant, and hearing, if any and the Registrar's decision allowing or rejecting the opposition.

An appeal against the order of the Registrar can be filed before the Intellectual Property Appellate Board within three months from the date of decision of the Registrar. An appeal from the order of IPAB lies to the High Court with- in whose jurisdiction the Trademark Registry falls.

Conclusion

Opposition plays the twin role of protecting the interest of the trademark owners as well as that of the consumers. It prevents the registration of a trademark that is likely to confuse the consumers and is detrimental to the interests of the proprietor of an earlier trademark. It thus thwarts any unscrupulous attempt to divert the customers of a bet- ter-known trademark. ●

Rectification of Copyright Register—Remedying a Wrongful Grant

Preface

The Copyright Act protects the rights of the authors of original copyrightable works. The registration of the work has not been made mandatory for the purpose of enforcement of copyright, and therefore registration does not confer any new right on the owner. When a copyright is registered, it only gives a presumption that the person shown is the actual author. This presumption is not conclusive but in the absence of any evidence to the contrary, there is no need to provide further proof of ownership.

Legally speaking, registration of the copyright per se does not establish that what is registered is in fact and in law a copyrightable subject matter. In *Camlin v National Pencil AIR 1986 Del 444* it was held that this is so because the expenditure of skill and labour on any work which originated from its author is sine qua non for the existence of copyright, and unless the original work on which skill and labour has been expended by its author is produced in court to prima facie show that the work has originated from the author, it cannot be said that there is copyright in the work.

Rectification Proceedings

Under the Copyright Act, there is no provision for opposition and revocation of the Copyright. However, any wrongful grant can be remedied through an action for rectification of the Copyright Register. The Copyright Board can also order rectification of Register on the application of Registrar of Copyright or of any person aggrieved, on the following grounds:

- any entry wrongly omitted in the register, or the expunging thereof; or
- any entry wrongly made in, or remaining on the register; or
- any error or defect in the register.

The decision of the Board is final on questions relating to rectification of Register. In certain cases, Registrar has the power to amend or alter the Register of Copyright by correcting any error in any name, address or particulars, or correcting any other error, which may have arisen therein by accidental slip or omission. He can exercise this power either on his own motion or on an application by any interested person. The 'interested person' can be the owner of copyright, publisher, licensee, assignee etc. For recording

changes in the Register, application has to be made on Form V accompanied by the necessary filing fee. The opportunity of hearing is given by the Registrar to the person affected by such rectification.

The Copyright Office is required to maintain certain indexes arranged alphabetically in form of cards. These are (a) a general Author Index; (b) a general Title Index; (c) An Author Index of works in each language; and (d) a Title Index of works in each language. Further, the Register of copyrights contains the name or title of the works, name and address of the authors, publishers, owners of copyright and other particulars. This register as well as the indexes thereof is kept open for public inspection and any person can take copies of, or make extracts from the Register of Copyrights or indexes on payment of appropriate fee.

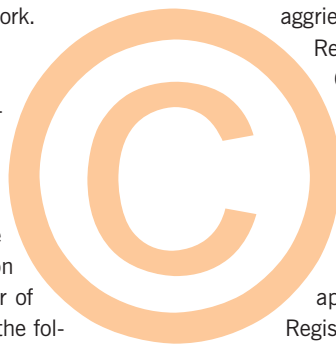
Appeals

Appeal can be made against the decision of the Registrar of Copyright and the Copyright Board. If a person is aggrieved by any final decision or order of the Registrar of Copyrights, he can appeal to the Copyright Board within three months from the date of the order or decision. In calculating the time of three months, the time taken in granting a certified copy of the order or record of the decision, is excluded. No appeal will lie against an order or decision of the Copyright Board made in an appeal against an order or decision of the Registrar of Copyright.

The jurisdiction of High Court depends on the place where the appellant actually and voluntarily resides or carries on business or personally works for gain. The Code of Civil Procedure determines the appeal from the decision of the High Court.

Conclusion

As the registration of Copyright was made optional, the legislature did not find it necessary or important to provide for opposition to the grant of Copyright. Judicial pronouncements upholding that 'irrespective of registration copyright vests in the person who is the original creator of the subject matter of copyright', has further obviated any need for opposition. Though unlike the Patent and Trademark law, there is no provision for opposition, any abuse of the copyright can be remedied by launching rectification proceedings. ●



'Bolar' Exception in the Indian Patents Law

What is 'Bolar' provision?

'Bolar' provision is an exception to the general rules of patent infringement. 'Bolar' provision allows the manufacturer of generic drugs to use a patented invention, without the patent owner's permission and prior to the expiry of the patent, for the purposes of obtaining marketing approval for his generic drug. Once the market approval is obtained, the generic drug maker can market the generic version of the patented drug as soon as the patent expires. This is often referred to as the "Bolar" provision.

How is 'Bolar' provision an exception to the general rules of patent infringement?

The general rule of patent infringement is that the patentee has the exclusive right to prevent third parties, who do not have his/her consent, from making, using, offering for sale, selling or importing (for any of these purposes) the patented product. If the patent is for a process, the patentee has the exclusive right to prevent unauthorized use of the patented process by any third party. Further, the patentee also has the exclusive right to prevent third parties from using, offering for sale, selling or importing a product directly obtained through the patented process.

The patentee can enforce the above rights by instituting a suit for infringement of his/her patent. The relief which the Court may grant in a patent infringement suit includes an injunction, and at the option of the patentee (plaintiff), either damages or an account of profits. The patentee could also seek seizure, forfeiture and destruction of the infringing goods and any materials and implements used to manufacture the infringing articles.

The above are the general rules concerning patent infringement, and as said, the 'Bolar' provision acts as an exception to these rules. Accordingly, certain acts are not considered as infringing a patent, if performed 'solely for uses reasonably related to development and submission of information required to obtain regulatory approval for the manufacture, construction, use, sale or import of any product'.

What is the impact of 'Bolar' provision on the Indian Patents Law?

This provision as contained in Section 107A of the Patents Act, 1970 (amended) has a key role in the TRIPS compliant Indian patent regime. Even if a drug molecule is patented, generic drug maker can make use of the patented invention for purposes of getting marketing approval for a generic version of that drug molecule. All studies and trials required for securing the marketing approval for a drug (in this instance from the Office of the Drug Controller of India)

can be carried out by the generic drug maker even during the term of the patent. When the patent expires, the generic drug maker can introduce the product in the market.

What is the rationale behind 'Bolar' exception?

When the generic drug makers have to wait until after the expiration of patent to start regulatory testing, the patent term in effect gets extended beyond 20 years. It would then depend upon how fast a generic drug maker can perform all the regulatory tests after the expiry of the patent. As the regulatory testing takes considerable time, the patent term would be extended to a substantial period of time. This would in turn deprive the public prompt access to the new medicinal products at low prices. The philosophy underpinning 'bolar' exemption is that the additional market benefits resulting for the extended patent term are not warranted by the patent law.

To what extent is the basic drug research within the ambit of 'Bolar' exception?

The applicability of 'Bolar' exception to drug discovery research raises certain concerns. Basic drug research at the pre-clinical phase is years behind any submission to the Drug Approval Authorities. Therefore whether the 'Bolar' exception extends to even pre-clinical research has been a key concern in many countries. In its decision in *Merck KGaA v Integra Life sciences* in June this year, the United States Supreme Court addressed the question-whether the use of patented invention for purposes of pre-clinical research is exempted from infringement under Section 271(e)(1) of the patents act? Reading the provision very broadly, the US Supreme Court held that the use of a patented invention does not amount to infringement if there is reasonable basis to conclude that the findings of the experiment would support the submissions to the FDA.

In the earlier cases, the Court of Appeal for the Federal Circuit accepted the argument that research at the pre-clinical phase is far too behind any FDA submission and that the findings of the experiments may not eventually form part of any FDA submissions. The Supreme Court through the instant decision has reversed this position. It is indeed a good news for generic drug makers.

Is 'Bolar' exception within the framework of TRIPS Agreement?

A Dispute Settlement Panel of WTO has confirmed that 'Bolar' exception is well within the framework of the TRIPS Agreement. In its report adopted on 7 April 2000, in a case titled "*Canada - Patent Protection for Pharmaceutical Products*" (*WT/DS114/R Dtd. 17 March 2000*), WTO dis-

India's Tryst with the TRIPS Continues!

An Expert Committee reviews the amended Patents Law

India's attempt to read further limitations into the TRIPS Agreement continues. The Government of India has appointed an Expert Group to make recommendations on two contentious patent law issues, namely:

(a) Whether it would violate the TRIPS Agreement if India excludes 'Non-NCE pharmaceutical product inventions' from patentability?

(b) Whether it would be consistent with the TRIPS Agreement to exclude micro-organisms from patentable subject matter?

The Expert Group was constituted pursuant to a commitment made by the Commerce Minister in the Parliament, during the debate on the Patents (Amendment) Bill, 2005. The Expert Committee was appointed by a Government Notification dated April 06, 2005. The Committee already had several sittings and is in the process of hearing out the views of various stakeholders. The Notification appointing the Committee does not specify any time frame for making the recommendations to the Government. But, as the Committee comprises very eminent personalities, a delay in making the recommendations is highly unlikely.

It is certain that the recommendations of the Committee will once again open up the Pandora's box. The recommendations of the Committee - answering either way, the questions referred to it, will definitely lead to heated public

debates. Thus India's tryst with the TRIPS Agreement continues. This is the latest political background of India's attempt to comply with the obligations under the TRIPS Agreement.

Several deeper questions emanate from the legal and technical intricacies surrounding the terms of reference to the Committee. On a preliminary reading, the questions being addressed by the Committee seem to have premised on foregone conclusions. The Committee's enquiry can proceed on two possible lines - the first line of enquiry could be premised on the overriding economic, public health and related social ramifications of India granting patents for 'non-NCE pharmaceutical product inventions' and 'micro-organisms'. The attempt to base the enquiry on the wider economic, public health and related social context may make the Committee's recommendations more controversial in India and less acceptable at the WTO.

The second line of approach could be more legal, thus interpretational. The enquiry can thus traverse through the trajectory of an interpretational process, finding room to read limitations in the relevant provisions of the TRIPS Agreement. The objective of this enquiry will be to make the TRIPS the 'TRIPS Minus'. This line of approach, if adopted with caution and care, may find a higher level of acceptability at the WTO. However, the technical intricacies of this approach may overshadow the efforts to highlight the public health perspectives. ●

pute settlement panel ruled that the Canadian patent law allowing exemption from infringement for research-related use of patented inventions is consistent with the provisions of TRIPS Agreement.

Article 30 of the TRIPS Agreement permits limited exemptions from infringement, provided the exemptions do not conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.

The Canadian Patents Act in Section 55.2(1) provides that "It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product".

The above provision more or less conforms to Article 107A(a) of the Indian Patents Act. ●

If you have any suggestions, comments or queries, please feel free to email at: mail@lexorbis.com

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