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National News

Finding Inventive Step

Prior to the Amendment of the Indian Patents Act, 1970 in 2005, there was a dearth of case laws on the issue of 'inventive step' or 'novelty' required to be shown in a Patent for its grant. In such a phase there was only one Supreme Court decision of *Biswanath Prasad Radhey Shyam v Hindustan Metal Industries* that dwelled into discussion of 'necessary patentable improvement', 'novelty' and 'inventive step' in an invention for the grant of valid patent rights.

In this case the Respondent was granted patents for a device and method for manufacturing utensils, introducing improvement, convenience, speed, safety and better finish to the prior existing method. The Respondent was informed that the Plaintiff was using a similar technique for manufacturing utensils and therefore sent a Cease and Desist notice to the Plaintiff to desist from using the technology. The Plaintiff did not adhere to this request of the Respondent and thereby a suit was instituted by the Respondent against the Plaintiff to which the Plaintiff filed a counter-claim for revoking the Patents. The Plaintiff claimed that the Respondent's patent did not include any new manufacture, improvement or novelty. The suits filed by the Plaintiff and the Respondent were referred to the High Court where both were consolidated and tried together. The single judge of the High Court ruled that the patent of the Respondent ought to be revoked on the grounds of lack of inventive step or novelty in the invention; this decision was reversed by the Division Bench. An appeal was filed before the Supreme Court by the Plaintiff. The apex Court upon assessing the facts of the case upheld the Single judge's ruling. It was observed that for an invention to be patentable it was necessary that the improvement on something already known should be more than simply 'workshop improvement' and should independently satisfy the 'inventive step' criteria. Furthermore, mere grant of patent by the Controller does not in itself validate a patent; the same may be subject to challenge before a High Court at a later stage. In the present case the apex Court failed to find any merit in the Respondent's arguments justifying the grant of patent; it was noted that there was no inventive step involved; there was only a slight change in the mode of application but the same was not more than 'workshop improvement'.

This case was decided in the year 1978 and though the prevalent law (for deciding the case) was the Design and Patents Act, 1911 the underlying principle of 'inventive step' was similar to that included in the Act of 1970. The ratio

of this case was revisited in the *Novartis AG v Union of India* where the requirement of 'inventive step' was considered necessary for the grant of Patent.

The one that started it all

The Indian government has been constantly picked on by the international community for not providing stringent IP protection. In 2005, pursuant to TRIPs Agreement, the Indian Patent Act, 1970 was amended in compliance with TRIPs requirements. Simultaneously, Section 3(d) was introduced in the Act, to ensure that no claim over new forms of known substances (salts, isomers) can be made for the grant of patents, unless there is a proof of "enhanced efficacy" in the drug by use of such new form. The impact of this provision was observed in the case of *Novartis AG v Union of India* which went on to become one of the most defining judgments in India for determining patentability.

At the heart of the issue was Novartis' patent application over its drug 'Glivec' (the salt imatinib in the form of mesylate) which is used for the treatment of leukemia and had been applied for grant of patent in India in 1998. Prior to this application, in 1993 Novartis had obtained patent registration for the salt imatinib in U.S.A. and U.K. but not in India. When the patent application for Glivec was examined in India, the Patent Controller stated that it did not satisfy the requisite under Section 3(d) of the Patent Act, 1970. Novartis claimed that the manner in which the molecules were packed into a solid form at the time of manufacturing the drug was different from its previous patent. Furthermore, the efficacy of imatinib mesylate at the time of obtaining patents in 1993 was not known hence, the Controller's requirement for proving enhancement of efficacy in this case was not valid. Novartis was unable to make a successful argument in this case. This matter was appealed by Novartis before the Madras High Court and in 2007, it was transferred to the IPAB. The IPAB did not find any enhancement of efficacy as was being claimed by Novartis for Glivec and held that it failed to satisfy the requisite under Section 3(d). A Special Leave Petition was filed before the Hon'ble Supreme Court of India by Novartis. The case was heard de novo by the apex Court and it was ruled that Novartis' attempt to get patent over a known substance without proving enhanced efficacy would amount to 'ever greening.'

This verdict of the Supreme Court prevented Novartis from gaining a patent monopoly over Glivec for another 20 years, thereby allowing the Indian generic companies to manufacture cheaper versions of the drug which is used for the treatment of leukemia. The difference in prices of the original drug (INR 1.2 lakh/month) and that of the generic drugs (INR 5,000-8,000/per month) is vast and this price difference also has an impact on the accessibility of the drugs in India. The Supreme Court's decision sparked a discussion in the IP community and till date continues to be a point of discussion for the developed countries when entering into trade relations with India. This decision though specific to the facts of the case is a precedent which discusses the importance of Section 3(d) in the Indian Patents Act, 1970.

India's tryst with compulsory licensing

Prior to 2005, the Indian Patents Act, 1970 allowed for only process patents and not product patents, as a result India became the hub for several generic manufacturing Companies. The 2005 amendment allowed for grant of product patents as well, it was during this time that there was an influx of patent applications filed by foreign pharmaceutical companies. A major reason for flourishing of the generic pharmaceutical industry lies in the fact that the drugs supplied by them is at a lesser price in comparison to that of the original pharmaceutical company; prior to 2005 the generic industry functioned smoothly however with the new amendment there was a threat to this industry and the affordability of drugs in India.

The Indian government though compliant with TRIPS, also included an important exception to patent rights in the form of Section 84 providing for compulsory licensing. This Section lists certain grounds on the basis of which a party may apply to the Controller of Patents for compulsory licensing. This exception was tested in the IPAB's decision in the case of *Bayer Corporation v Union of India, the Controller of Patents and Natco Pharma*. In this case Natco had filed an application for compulsory licensing with the Controller of Patents for the drug Nexavar manufactured and patented by Bayer Corporation for the treatment of Kidney cancer. Bayer challenged this application on the grounds that it had shown the 'working' of the drug in India and that it was being supplied in sufficient quantity meeting the requirement of the patients in India. Natco contended that the price of the drug Nexavar, as sold by Bayer, was INR 2,80,000 for 1 month's supply whereas, it could sell the same drug at less than INR 10,000 per month. Natco also produced documents showing that it had initially applied for grant of voluntary licensing in compliance with Section 84(4) but the same was rejected by Bayer therefore, it was now eligible to apply for compulsory licensing. The Controller granted the compulsory license. This order was appealed before the IPAB; the IPAB perused the facts of the case and held that the Controller was correct in granting compulsory licensing since; accessibility and affordability of Nexavar was in public interest.

This decision of the IPAB was criticized by several pharmaceutical companies and was seen as an impediment to the development and growth of the pharmaceutical industries in India. It was held that the grant of compulsory licensing would curb R&D in the pharmaceutical industry. While there are criticisms to the decision it cannot be ignored that affordability of drugs is indeed a major concern in India where the prices of drugs may not match the income of the average citizens. It is necessary to note that compulsory licensing is an exception which must be applied upon careful consideration of facts and circumstances of the case.

No bias

Pursuant to the Supreme Court verdict in Novartis v Union of India and Natco v Bayer, there were allegations of bias against the Indian judiciary while deciding cases against Indian generic manufacturing companies. This notion was countered by the Delhi High Court, through its decision in *Merck Sharp and Dohme Corporations v. Glenmark Pharmaceuticals Ltd.*

In the year 2013 Merck, filed a case for patent infringement against Glenmark alleging that the company had infringed its patent rights by making use of its patented salt 'Sitagliptin' in their drugs 'Zita' and 'Zita Met' intended for diabetes treatment. Merck has been manufacturing its diabetes medicines 'Januvia' and 'Janumet' using the salt Sitagliptin, is available in the U.S. since 2006 and in India since 2008. Merck stated that the salt was a primary component of the drug and it could not be manufactured or used by Glenmark without their prior permission. Glenmark, argued that the patent (of Merck) ought to be revoked under S. 64(1) (f) – lack of adequate disclosure regarding the patent. The Court in the present case, while deciding upon the issue of 'adequate disclosure' sought an opinion from an independent technical expert who submitted, that based on the drawing of the chemical structure and the information provided by the plaintiff , an individual skilled in this field could easily produce the phosphate salt of Sitagliptin, the expert further stated that the suit patent clearly gave an indication of 'any number of pharmaceutically acceptable salts produced from Sitagliptin'. It was concluded that Glenmark had succeeded in manufacturing Sitagliptin Phosphate Monohydrate therefore, it could not be agreed with by the Court that the patent disclosure was too broad. The Court ruled that the patent had been adequately disclosed and there was no insufficiency whatsoever. Glenmark also argued that they had used a different process to manufacture Sitagliptin Phosphate Monohydrate (salt used by them in their drugs Zita and Zita Met). The Court rejected this argument on the basis that no evidence had been adduced by Glenmark to prove the same. It was accepted by the Court that while that Sitagliptin Phosphate had enhanced efficacy, it was also true that the base salt was still Sitagliptin which was patented by Merck; hence, the use was infringing.

The Court injuncted Glenmark from selling, distributing, marketing or exporting its drugs Zita and Zita-Met since it was infringing the patent of Merck. The case was heard and decided in a short span of time, in May 2015, the apex Court had instructed the High Court to dispose the matter as soon as possible and by October 2015 the High Court decided the case. This case assured the foreign pharmaceutical Companies that the Indian Courts were ready to injunct domestic companies from infringing their IP rights.

Pharmaceuticals and deceptive similarity

The Indian Trade Mark statute recognizes the right of proprietors of unregistered marks to claim passing off. The standards for determining 'deceptive similarity', while deciding cases of 'passing off', were unsettled since there were different standards laid down by various High Court and Supreme Court rulings. This issue was resolved by the Supreme Court in its ruling in the case of *Cadila Healthcare Ltd. v Cadila Pharmaceuticals.*

At the heart of the case was a trade mark dispute between two drugs named 'Falcigo' (used by the Plaintiff) and 'Falcitab' (used by the Defendant), both used for treatment of cerebral malaria. The Plaintiff alleged that the Defendant's drug 'Falcitab' was deceptively similar to its mark 'Falcigo' and the sale of similar drugs would amount to passing off. The Defendants submitted that since the drugs were Schedule L drugs i.e. drugs sold only to hospitals and clinics and not available over the counter, there was a limited likelihood of confusion. The Lower Court and even the High Court ruled in the Defendants' favor. A Special Leave Petition was filed before the Supreme Court by the

Plaintiff. The Supreme Court assessed that there was an imminent need to consider that the goods in respect of which passing off was being claimed were medicines which have a direct effect on the health of patients. The apex Court observed in its decision that while doctors are aware of different drugs in the market, they are not infallible and any error in their judgment could have disastrous consequences. The Court also took into consideration that English language is not known to masses in India therefore, if there is a slight difference in the spellings of the marks, people will not be able to distinguish between the two. Summarily the Court laid down the following factors to be considered at the time of determining deceptive similarity:

– Nature of marks: Word or label mark;

– Phonetic and Conceptual similarity between marks;

– Nature of goods for which marks are used;

– Nature, Character and performance of goods;

– Sophistication of purchasers; and

– Trade Channels.

This decision represented a clear overlap between trade mark laws and public interest (in the form of public health). The standards set out to determine passing off cases continue to be guidelines for the courts across the country and limit the possibility of overlooking any important perspective that needs to be taken into consideration while deciding such cases.

Defensive Trade Mark Registration

The registration of a mark gives the proprietor an exclusive right to use that mark for the goods/services for which it has been registered. However, it does not mean that such registration *suo motu* provides protection for all the goods covered in that class, irrespective of use of the mark by the proprietor. This principle was enunciated by the Supreme Court in the case of *Vishnudas v The Vazir Sultan Tobacco Ltd.*

In this case the Petitioner was engaged in the business of manufacturing Zarda and quiwam under the mark 'Charminar' and applied for registration of the mark under class 34. The Respondent objected to the Petitioner's trade mark application on the grounds that it was already the registered user of the mark 'Charminar' for cigarettes in class 34. The Petitioner also applied for rectification of the trade mark register for registration of the Respondent's mark broadly for 'manufactured tobacco'. The Advocate for the Petitioner argued that though the Respondent was the registered proprietor of the mark 'Charminar' in class 34 under the heading of 'manufactured tobacco', it was using the mark only for cigarettes and had never manufactured or shown any intention to manufacture zarda and quiwam

i.e. other forms of manufactured tobacco. It was also argued that there is a marked difference between the products of the Petitioner and the Respondent therefore, the use of an identical mark would not create any confusion in the minds of the consumers. The Court found merit in these arguments of the Petitioner and ruled that the term 'class' *"may subsume or comprise a number of goods or articles which are separately identifiable and vendible and which are not goods of the same description as commonly understood in trade or in common parlance."* The Court found it only fair to allow registration of marks intended for certain goods to be specific to such goods alone rather than for a broad class of goods. The Court also allowed the Petitioner's rectification application.

This decision addresses the important issue of trade mark squatting, the Indian Trade Mark Act, 1999 under S.47 lays down that if a mark is not used for five years, any person aggrieved may apply for rectification of the register and removal of registration of such mark which is not being used. The intention to use the mark is extremely important to misuse of provisions of the trade mark law and allow an honest and *bonafide*proprietor to register its mark for the goods/services offered. This case continues to be a binding precedent for all future cases on Defensive Trade Mark Registration.

Trans Border Reputation

The Indian Trade Mark Act, 1999 allows a proprietor of an unregistered mark to take an action for passing off against another entity. However, an essential ingredient of the tort of passing off is to establish the use of the mark for the goods/services provided in India. It is necessary to reiterate that Trade mark is a territorial right but it was soon observed by the Indian judiciary that strict adherence to this understanding was creating a disadvantage for reputed international marks which had not yet ventured into the Indian markets.

In the case of *N.R. Dongre & Ors. v Whirlpool Corporation & Ors*. the Supreme Court of India held that the proprietor of a reputed foreign trade mark could claim trans-border reputation in India and prevent any subsequent adopter of the mark from registering and/or using the same in India. This principle of trans-border reputation was further elaborated upon in the case of *Milmet Oftho Industries & Ors. v Allergan Inc.* . In this case, the Appellant was an Indian Company using the mark 'OCUFLOX' and the Respondent was a foreign pharmaceutical Company which had been selling pharmaceuticals under the mark 'OCUFLOX' in several countries and had also filed for trade mark registration in India, which was pending at the time of deciding the suit. It was the case of the Respondent that since it had a trans-border reputation and was using the mark since 1992, (the Appellant was using it since 1993) he was a prior and bona fide user. The Calcutta High Court agreed with the Respondent's arguments and granted an injunction in his favor. This was appealed before the apex court.

The Supreme Court upheld the principles of tarns-border reputation enunciated in the Whirlpool decision but added that while deciding trans-border reputation it was necessary to take into consideration whether the proprietor of such mark had any intention to use the mark in India, if yes, only then such claim could be upheld. It was also ruled that 'prior use' of the mark was an important point to be considered, if a proprietor in India has been using the mark prior

to the foreign proprietor then even if the Indian proprietor is not well known, its right to use the mark will be protected. Therefore, the ultimate test for deciding a case of passing off was based on prior use of the mark. This decision provided with much needed clarity on the subject of trans-border reputation and has been referred to in several judicial decisions.

Waltzing through idea-expression dichotomy

The law of copyright is based on the premise that one can only protect the expression but not the idea in general however, in certain instances it becomes difficult to demarcate between the two, since there may be an overlap. The Supreme Court in the case of *R.G. Anand v Delux Films & Ors* imported the understanding of idea-expression dichotomy as laid down by the U.S. Supreme Court and enunciated this principle in greater detail.

The Plaintiff was a popular drama writer, he wrote a play in 1953 titled 'Hum Hindustani', it was dramatized in 1954 and in the same year the Plaintiff was contacted by the Respondent for the purpose of making a film based on the play. In 1955 the Respondent announced the production of the movie 'New Delhi' which was dealing with the subject matter of provincialism, similar to the Plaintiff's theme in the play 'Hum Hindustani'. The Plaintiff filed a case for copyright infringement stating that the Respondent had plagiarized his play. The trial Court and the High Court dismissed this allegation of the Plaintiff and held that the Plaintiff was the copyright owner of the play Hum Hindustani' but the Respondent's movie was not infringing the Plaintiff's copyright. The Plaintiff further filed a Special Leave Petition before the Hon'ble Supreme Court. The Apex Court held that the play and the movie shared a common theme but there was a difference in the expression. To substantiate this understanding, the Court ruled that substantial similarity between two works can be ascertained by considering the reaction of the reader/spectator/viewer, if they form the opinion that one work is an imitation of a pre-existing work a case of copyright infringement is established. It was further ruled that the same idea could be developed in a different manner, there exists a possibility of overlap however, it is necessary to note the overall impression that the work leaves in the minds of the viewers.

This was the first time when an Indian Court dwelled into details of idea-expression dichotomy and recognized that copyright laws are not meant to cage but encourage creativity by allowing a variety of expressions to a common idea.

Moral Rights

The moral rights of authors have been recognized under Article 6 *bis* of the Berne Convention (oldest copyright convention). The Indian Copyright Act, 1957 under S. 57 acknowledges that an author has a statutory as well as a moral right over his/her work. These moral rights exist with the author even after an assignment of their rights, for instance, even if Chacha Chaudhary's rights were assigned to another party (by original author Pran's estate), the

assignee cannot use the character for any degrading purpose like porn, drugs, etc. doing so will amount to infringement of moral rights and Pran's estate can sue the new owners for infringement.

The Indian courts have also respected the moral rights of the author, the most popular case on the subject was that of *Amar Nath Sehgal v UoI* (Delhi High Court) where the plaintiff was a sculptor and had sold one of his sculptures to the government of India. After a few years he found his work disfigured, and in a poor condition; he demanded the return of the parts of mural by asserting his moral rights in the same. The Court upon hearing the case held that the Plaintiff was correct in making such an assertion under Section 57 since the government was guilty of having violated the integrity. The Court recognized the right of the author to claim back the remnants of the disfigured mural.

The Court's decision is a victory for content creators in India and is a landmark case since it recognizes the emotions, the labor and efforts put forth by the creator of a work that even after such work is assigned, it cannot be ignored that the creator has certain moral rights over the work. This judgment is often cited in common law countries like Singapore for arguing that while economic rights may be assigned, the moral rights are always vested in the author.