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Article

The Risdiplam saga: Delhi High Court adjudicates patent infringement suit between Roche and Natco

By Vindhya S Mani, Harshita Agarwal and Surbhi Nautiyal

The first article in this issue of IPR Amicus discusses a recent decision of the Delhi High Court in a patent infringement suit between Roche and Natco. The authors believe that the decision, particularly the analysis of inventive step, may be wanting, especially in applying the concept of 'bioisosterism'. They also note that despite evidence of enhanced efficacy, improved pharmacokinetic profile, and therapeutic advantages over known compounds, the Court appeared to have adopted a simplistic assessment of inventive step based on a simpliciter application of the bioisosterism concept. However, according to them, the order, while detailed and ostensibly rooted in public interest, raises concerns about the way the credible challenge test is applied, especially in aspects of substantive technical assessment concerning inventive step.

The Risdiplam saga: Delhi High Court adjudicates patent infringement suit between Roche and Natco

By Vindhya S Mani, Harshita Agarwal and Surbhi Nautiyal

Introduction

In a suit for infringement of Roche's Patent No. IN 334397 titled 'COMPOUNDS FOR TREATING SPINAL MUSCULAR ATROPHY', a species patent *inter alia* claiming a compound having an International Non-Proprietary Name ('INN') Risdiplam¹, against Natco for preparing for commercial production of Risdiplam API; the Single Judge of the Delhi High Court by order dated 24 March 2025² denied grant of interim injunction in favour of Roche mainly on the basis that Natco was able to demonstrate *prima facie* that there exists a credible challenge to the validity of Patent No. IN 334397.

However, shortly thereafter the Hon'ble Division Bench of the Court, on an appeal³ by Roche against the Single Judge's order, directed on 26 March 2025, that the status quo regarding

launching of Natco's product be maintained. The said status quo order continues to operate till the date of writing this article. The Division Bench is considering the appeal, and the next date of hearing is 21 April 2025.

Background of the case

The Suit Patent in dispute, *i.e.*, IN 334397 ('IN'397') was granted in favor of Roche on 11 March 2020. IN'397 is a species/selection patent for the product 'Risdiplam' which is essentially a compound used in the treatment of a rare disease *i.e.*, Spinal Muscular Atrophy ('SMA'). US 9969754 ('US'754') is the US counterpart of IN'397. Further, US 9586955 ('US'955') is the corresponding patent for PCT patent application no. PCT/US2013/025292, published as WO 2013/119916 A2 ('WO'916'). WO'916 is the international genus patent for the

¹ Risdiplam is the API in the Roche's commercial product, which is marketed in various countries worldwide, including, India, under the brand name, 'EVERYSID®'. Risdiplam is an oral prescription medicine indicated for the treatment of SMA in patients two months of age or older. SMA is a rare genetic neuromuscular disorder caused by the mutation of the

Survival Motor Neuron 1 gene, leading to a deficiency of SMN protein, which affects motor nerve cells, diminishing the ability to walk, sit, eat and breathe.

² 2025:DHC:1907

³ FAO(OS) (COMM) 43/2025

Suit Patent. Roche also filed an application for Patent Term Extension ('PTE') in respect of US'955 before the United States Patent & Trademark Office ('USPTO').

Dispute arose when Roche became aware of a listing for Risdiplam on Natco's website. Upon investigating further, Roche found that Natco was preparing for the commercial production of Risdiplam. Additionally, Natco was also pursuing a patent application *i.e.*, 202241055182, for manufacturing Risdiplam. Aggrieved by the same, Roche instituted the present suit alleging infringement of their Suit Patent by Natco. Owing to the public interest angle *qua* accessibility of 'Risdiplam' coupled with its high costs, two intervenors though not formally impleaded but were heard by the Ld. Single Judge.

Roche's arguments

Roche asserted that the Suit Patent *inter alia* claiming Risdiplam, which is set to expire in May 2035, is valid and enforceable. Natco violated their patent rights because they already initiated commercial production and are in the process of launching Risdiplam, thus admitting infringement.

Roche asserted that Risdiplam cannot be anticipated or rendered obvious based on the disclosure in WO'916 as it does

not specifically teach or disclose Risdiplam and no one can find Risdiplam as a specific example in WO'916. It was asserted that a person of ordinary skill in the art ('POSA'), not being aware of Risdiplam without hindsight bias, could not narrow down to the structure of Risdiplam from various Markush Structures in WO'916.

Further, it was argued that the Suit Patent enjoys a strong presumption of validity being an old patent filed in the year 2016 and claiming priority since the year 2014. Corresponding patents with claims directed to the specific compound *i.e.*, Risdiplam were granted in about 60 countries, even after the consideration of WO'916 in such jurisdictions, and the same have not been revoked/invalidated in any jurisdiction. Moreover, no challenge to the novelty/anticipation of the Suit Patent was raised by the Indian Patent Office.

Regarding public interest and accessibility of Risdiplam, Roche stressed that the expenses borne during the development of a new drug are exorbitant unlike Natco, which being a generic only had to bear costs for manufacturing. Therefore, striking a balance is necessary between the interest of innovators and the generic industry.

Natco's arguments

Natco argued that both, the genus- WO'916, and Indian Species Patent, IN'397, relate to compounds for the treatment of the same condition, namely SMA. Further, Compound 809 disclosed in the prior art document WO'916 was referred, to demonstrate that Risdiplam was already disclosed.

Regarding the differences between the chemical structures of compound 809 and Risdiplam, Natco asserted that any modifications or substitutions which result in the same chemical and physical properties, and are necessary to arrive at the compounds claimed in the Suit Patent from the compounds disclosed in the WO'916, are routine and predictable by a person skilled in the art, being disclosed in prior art itself.

Natco while highlighting the issue of 'evergreening of patents' submitted that, a species/selection patent can be granted despite the grant of a genus patent, only if it is demonstrated that the species patent has significant technical advancement and enhanced therapeutic efficacy over the genus patent. However, the Suit Patent fails to disclose any such advantage over WO'916.

Natco argued that Roche had received a Patent Term Extension ('PTE') for US'955 premised on an express admission that Risdiplam is a new medication with its discovery

attributable to US'955. On the aspect of public interest and accessibility of Risdiplam it was argued that while Natco will be manufacturing the drug in India, Roche will be only importing Risdiplam into the country thus, its intent being to only profit off the drug.

Intervenors' arguments:

The intervenors (both patients of SMA) primarily argued about the unaffordability of Risdiplam, that made the drug inaccessible to several patients suffering from SMA. The intervenors highlighted the drug's exorbitant price which resulted from the patent monopoly exercised by the Roche thus, keeping Risdiplam beyond the reach of many.

Single Judge's findings

In an order spanning several pages, the Ld. Single Judge ruled against granting an interim injunction in favour of Roche, largely based on the following considerations:

I. On the aspect of *prima facie* case:

1. *Anticipation by Prior Publication- Section 64(1)(e) of the Patents Act, 1970 (Act):*

The primary issue analysed by Single Judge was whether Risdiplam is explicitly or implicitly

disclosed in WO'916, which has been cited as prior publication/prior art by Natco. While citing *Bayer Healthcare LLC v. NATCO Pharma Limited*⁴, and *Schering Corporation v. Geneva Pharmaceuticals, Inc*⁵, the Single Judge held that disclosure can be implicit/inherent, and there is no stringent rule that it ought to be explicit in nature. Thus, if from the prior art, it can be inferred that there is disclosure, though implicit/inherent, that would be a valid ground for challenging the validity of a patent based on lack of novelty.

The Ld. Single Judge also referred to a lawsuit filed by Roche against Natco in the United States, for infringing the US'955, by launching Risdiplam. Thus, by asserting patent rights over Risdiplam under US'955, as per Roche's own admission, Risdiplam is covered by US Patent US'955. The Judge also placed reliance on the US FDA Orange Book Listing for Risdiplam, wherein the product Risdiplam is categorically claimed for US Genus Patent, US'955, which is equivalent to the International Genus Patent, WO'916.

The Ld. Single Judge reasoned that for the purposes of establishing a *prima facie* view and for considering the issue regarding credible challenge being raised by the defendant while considering the application for grant of interim injunction, the various statements made by the plaintiffs in foreign jurisdiction are material and relevant.

The Ld. Single Judge also referred to the Hon'ble Division Bench's (DB) findings in *Astrazeneca AB & Another vs. Intas Pharmaceutical Limited*⁶, and held that in cases where all or some of the inventors are common, the test while considering 'anticipation by publication', would be from point of view of 'person in the know', and not in the context of 'person ordinarily skilled in the art'. The Ld. Single Judge held that all the four inventors of the Suit Patent, are also the inventors of the International Genus Patent, besides the other inventors of the International Genus Patent and therefore, pertinent for the purposes of considering an application, wherein an interim relief is sought.

⁴ 2023 SCC OnLine Del 3921

⁵ 339 F.3d 1373 (2003)

⁶ 2021 SCC OnLine Del 3746

Accordingly, the Single Judge held that Natco raised a *prima facie* credible challenge to the validity of the Suit Patent regarding the issue of anticipation by prior publication.

2. *Lack of inventive step – Section 64(1)(f) of the Act*

The Ld. Single Judge referred to the Hon'ble Division Bench's (DB) findings in *Astrazeneca AB & Another vs. Intas Pharmaceutical Limited*⁷, wherein the DB held '*when the inventor is the same, the tests of 'obvious to person skilled in the art', cannot be in the context of person ordinarily skilled in the art', but has to be seen in the context of a person in the know*'. Observing that at least four inventors of WO'916 were common inventors in the suit patent as well, the Ld. Single Judge remarked that the issue of obviousness would have to be assessed from the point of '*a person in the know*'.

Thereafter, the Ld. Single Judge drew an analogy between the chemical structures of Risdiplam and Compound 809 from WO'916. The Ld. Single Judge observed that the major difference in the structures is the presence of Nitrogen (N) in Risdiplam and

Carbon-Hydrogen (C-H) group in Compound 809.

It was observed that WO'916 discloses 835 compounds of which, Pyrimidine is a constituent in almost all the compounds, including, Compound 809. Pyridine is also a constituent in most of the compounds. As per the scientific definition, Pyridine has just one Nitrogen atom, whereas, Pyrimidine, has two Nitrogen atoms. On account of myriad occurrences of the Nitrogen atom in the various compounds, the Ld. Single Judge held that it is *prima facie* established that it would have been obvious to a person skilled in the Art/person in the know that Nitrogen is a dominant component of most of the compounds disclosed in WO'916 and such person skilled in the Art/ person in the know would have easily been motivated to use the Nitrogen atom instead of the Carbon atom, while looking at Compound 809 in the International Genus Patent. On this basis, it was held that Natco has *prima facie* established that the compounds claimed in the Suit Patent represent routine optimization of compounds disclosed in the prior

⁷ 2021 SCC OnLine Del 3746

art. Further, it was noted that it is common practice in the field of pharmaceuticals to make iterative modifications to chemical structures in order to improve properties such as potency, selectivity or metabolic stability.

Supplementing the foregoing findings, the Ld. Single Judge also analysed the concept of 'Bioisosters' while also referring to '*Grimms Hydride Displacement Law*', a hypothesis devised in 1925 for explaining Bioisosteres. As per the hypothesis Nitrogen and C-H are in the same group of isosteres and often considered as bioisosteres, thus the Ld. Single Judge held that substitution of C-H group with Nitrogen would be obvious to a '*person in the know*' or a person skilled in the art working in the domain of medicinal chemistry for optimization of compounds disclosed in the prior art *i.e.*, WO'916.

Further, at the interim stage, the Ld. Single Judge did not consider the comparative data demonstrating the 'Effective Concentration' value (EC1.5x) of compounds described in the complete

specification of the Suit Patent, as the data was heavily contested by Natco. The Court opined that the data would have to be examined further based on expert testimony and the same must be done at the trial stage.

Thus, the Ld. Single Judge was of the *prima facie* view that Natco had been able to establish vulnerability of the suit patent on account of lack of inventive step based on the disclosure in the cited prior art document.

Bioisosterism – A deeper analysis

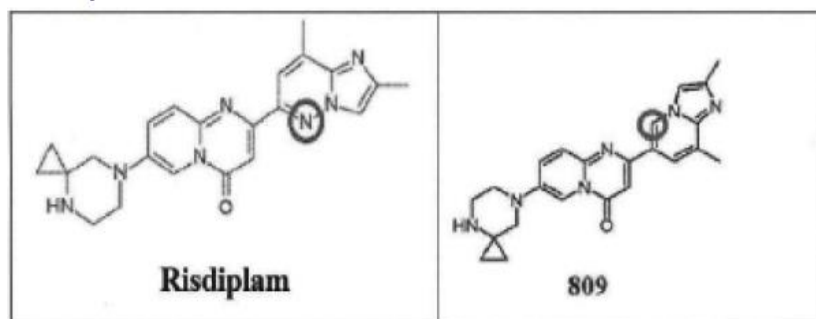
Bioisosters' are defined as subunits or groups or molecules which possess physicochemical properties of similar biological effects⁸. The concept of Bioisosterism refers to replacing atoms or groups with others that have similar physical or chemical properties to achieve similar biological effects. This phenomenon is increasingly being used in drug design for developing new compounds that are therapeutically active⁹. In Chemistry, Grimms Law describes the similarity between groups which have

⁸ Bioisosterism: A Useful Strategy for Molecular Modification and Drug Design, Lídia Moreira Lima and Eliezer J. Barreiro, Current Medicinal Chemistry, 2005, 12, 23-49

⁹ Supra 8

the same number of valence electrons but different number of atoms¹⁰. The law also points out similarities in groupings of element in the same row of the periodic table.

The Ld. Single Judge held for a *'person in the know'*, in the field of medicinal chemistry it would be obvious to substitute the C-H group with Nitrogen, to further explore the effects of such substitution on the drug's biological activity by perusing the prior art document (genus -WO'916). Chemical structures of Compound 809 and Risdiplam are reproduced hereinbelow for reference.



In the present case, the distinguishing feature of Risdiplam is in providing a solution to the problem

of treating SMA. However, while making such an observation on the aspect of obviousness of the Suit Patent, it appears the Ld. Single Judge may not have considered whether this information was already available with a *'person in the know'* about the probable impact of such a substitution (C-H to N) on the pharmacological activity of the drug in question.

In T 0467/94, the Board of Appeals, European Patent Office ('Board') while dismissing an objection on lack of inventive step based on bioisosteres, held that- *'In this context, the Examining Division held in their decision that the replacement of the alkoxy group by the methoxypropoxy group would have been obvious in the light of the concept of modern bioisosterism considering that an -O- atom and a -CH₂- group were classical isosters. However, in the Board's judgment, when deciding upon inventive step in relation to pharmacologically active compounds, it is not essential whether a particular substructure of a compound could be replaced by another known isosteric one, but whether information was*

¹⁰<https://pubs.rsc.org/en/content/articlelanding/1979/cs/cs9790800563/unauth#:~:text=Grimm2%20enunciated%20his%20hydride%20displacement,%2C%20NH2%2C%20OH%2C%20Hal>

available on the impact of such a replacement on the pharmacological activity of the specific group of compounds concerned..... In the present case, the Examining Division did not provide any evidence that the replacement a -CH₂- subgroup in said alkoxy substituent of the group of compounds defined in documents (2) and (4) by an -O- atom would have no substantial influence on their pharmacological properties. Moreover, documents (2) and (4) - as indicated above - unambiguously disclose that at the 4-position of the pyridinium ring only particular substituents are suitable, so that the skilled person would have expected that this is an essential requirement for having the desired anti-ulcer properties.'

In T 0643/96, the Board held that –

'4.2.3.3. The above quoted argument of the Examining Division (see No. 4.2.2) amounts in fact to an allegation that the existing structural differences between the compounds known from document (1) and those now claimed are so small that a skilled person would have known that such differences have no essential bearing on the properties important for solving the technical problem (T 0852/91, No. 8.2 of the Reasons for the Decision, not

published in the OJ EPO). The validity of this argument hinges on the applicability of the concept of bioisosterism from which the skilled person would have drawn this knowledge.

The Board agrees that this concept belongs to the common general knowledge of those skilled in the art but, in the Board's judgement, it has to be applied with caution when deciding upon inventive step. In the field of drug design any structural modification of a pharmacologically active compound is, in the absence of an established correlation between structural features and activity, a priori expected to disturb the pharmacological activity profile of the initial structure. This holds true also for an alleged case of bioisosterism, which is one option of a structure-activity relationship, as long as it is not an established case of bioisosterism (see also T 0548/91, No. 6.4 of the Reasons for the Decision, not published in the OJ EPO).

A careful evaluation of all relevant circumstances is therefore required as to whether or not that a priori assumption can indeed be overcome with the aid of

the concept of bioisosterism (which in essence is not a law of nature of general validity but rather an empirical rule, which in each particular case needs to be experimentally verified in order to establish whether or not it fits).

In document (3) the concept of bioisosterism is discussed. It is explained that in any bioisosteric replacement a considerable number of different, independent parameters could be considered: 'The extent to which the replacement is useful will depend upon which of these parameters is important and which ones the bioisostere can best mimic ... Usually one will not know which role(s) the various parts of the molecule play(s) in its action and this determination will be part of the structure-activity study'. The document concludes, inter alia, that 'Whether the same or a different biological activity results from the replacement will be governed by the role(s) which that moiety fulfils in the molecule and whether parameters affecting that role have been disturbed' (page 565, lines 16 to 19, and the last three lines; page 566, lines 3 to 5).

This clearly confirms that the concept of bioisosterism - at least in the circumstances of this

case - is to be considered at most as providing some general guidance to the skilled person developing a research program in the particular pharmacological field, but certainly not as a pointer to the solution to the existing technical problem as now claimed (see also T 0309/91, No. 4.2.4 of the Reasons for the Decision, not published in the OJ EPO).

4.2.3.5. However, when deciding on inventive step in relation to pharmacologically active compounds, what is essential is not whether a particular sub-structure of a chemical compound is replaced by another known isosteric one, but whether information was available on the impact of such a replacement on the pharmacological activity profile of the (group of) specific compound(s) concerned. The Examining Division did not refer to, nor is the Board aware of, such information.

In T 0156/95, the Board held that –

'The Board accepts that =N= and =C- are well known isosteric groups. However, when deciding on inventive step in relation to pharmacologically active compounds, what is essential is not whether

a particular sub-structure of a chemical compound is replaced by another known isosteric one, but whether information was available on the impact of such a replacement on the pharmacological activity profile of the (group of) specific compound(s) concerned.'

Therefore, it appears from the order that the Ld. Single Judge has not considered whether a person skilled in the art had any information based on any disclosure, as to the impact on the pharmacological activity profile of the compounds, on replacing the C-H group by the Nitrogen. Accordingly, it appears that the Court did not consider the nuance of applying the bioisosterism concept as has been applied in the EU.

On the ground of Section 64(1)(d) (non-patentability), the Ld. Single Judge observed that no finding could be given at this stage, as it was not argued by Natco. On the grounds of Section 64(1)(j) (misrepresentation) and Section 64(1)(m) (Section 8 non-compliance), the Ld. Single Judge did not give any finding on the basis that it is subject matter of trial.

II. On the aspect of balance of convenience

In assessing balance of convenience at the interim stage, the Ld. Single Judge noted that Roche does not manufacture their drugs in India but imports the same. In contrast, Natco intends to manufacture the drug in India and make the product available at a price that is nearly 80-90% lesser than Roche's price. Further, the Court noted that Roche's Patient Assistance Program ('PAP') covers a very miniscule number of patients, compared to the number of patients who are suffering from SMA in India. Therefore, it was held that Roche's PAP does not resolve the issue of accessibility of the drug in question to SMA patients and therefore, it cannot be stated that balance of convenience for grant of injunction, lies in Roche's favour.

III. On the aspect of irreparable damage/prejudice

In evaluating irreparable damage at the interim stage, the Ld. Single Judge observed that Roche is importing the drug at highly exorbitant price, which shows that Roche intends to monetize the drug, and therefore, Roche can be compensated in damages if they succeed post-trial. Accordingly, the Ld. Single

Judge held that if the injunction is refused, no prejudice will be caused to Roche.

IV. Public interest

The Ld. Single Judge after considering the aspects of unaffordability and inaccessibility of Risdiplam, held that the impact on public interest in the grant of an interim injunction would have to be considered, particularly in the case of pharmaceutical inventions. The Ld. Single Judge noted that a drug which is the only one available for treatment in India, for a rare disease, its availability to the public at large at very economical and competitive prices, is a material factor which a Court should consider at the time of dealing with an application for interim injunction.

Conclusion

The order delivered by the Ld. Single Judge, particularly the analysis of inventive step, may be wanting, especially in applying the concept of bioisosterism.

Despite evidence of enhanced efficacy, improved pharmacokinetic profile, and therapeutic advantages over known compounds, the Court appears to have adopted a simplistic assessment of inventive step based on a simpliciter application of the bioisosterism concept. The order leans heavily on the 'obvious to try' standard without acknowledging the specific challenges and unpredictability inherent in pharmaceutical research. The order appears to indicate that once a genus or class of compounds is known, any advancement within that class is routine optimization — an undesirable precedent that fails to consider the unpredictable and uncertain nature of drug development process.

The order, while detailed and ostensibly rooted in public interest, raises concerns about the way the credible challenge test is applied, especially in aspects of substantive technical assessment concerning inventive step.

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Articles

Not all marks are created equal: The curious case of distinctiveness

By Divya Vishvapriya and Kriti Sood

The second article in this issue of the newsletter discusses how the Courts are increasingly realizing that distinctiveness in trademarks may not necessarily be inherent, it can also be created *via* use. The article elaborately examines these changing interpretations, concentrating on significant rulings that have influenced India's trademark protection laws. The authors discuss the different categories of distinctiveness and note that although descriptive and generic trademarks often encounter significant challenges, recent legal developments indicate a more business-oriented and practical perspective - considering composite marks that blend generic terms with unique stylization or design; evidence of acquired distinctiveness, such as consumer surveys, advertising expenditures; and brand recognition.

Not all marks are created equal: The curious case of distinctiveness

By Divya Vishvapriya and Kriti Sood

Not every trademark wears a crown and flaunt in the branding courtroom. Some trademarks stutter in, sounding like generic supporting characters, while others shout uniqueness and charm. Enter the concept of **distinctiveness**, the VIP pass in the trademark world. At the Trademarks Registry, generic, merely descriptive, or undifferentiated trademarks are frequently rejected. However, recent judicial trends show a shift toward a more nuanced, context driven evaluation. Courts are increasingly realizing that distinctiveness may not necessarily be inherent, it can also be created *via* use. This article examines these changing interpretations, concentrating on significant rulings that have influenced India's trademark protection laws.

Introduction

The distinctiveness of a trademark has been regarded as a cornerstone of protection, both in relation to registration and enforceability of trademark. The primary function of a trademark is to distinguish the goods or services of one entity from those of another. To fulfil this role, a trademark must be

distinctive, either inherently or through acquired secondary meaning.

Understanding non-distinctiveness in trademark law

Section 9(1)(a) of the Trade Marks Act, 1999 ('Act'), stipulates that a mark devoid of distinctive character shall not be registered, and reads as:

'The trademarks which are devoid of any distinctive character, that is to say, not capable of distinguishing the goods or services of one person from those of another person shall not be registered.'

This section is essential in determining whether a trademark is eligible for registration under the Act. It essentially bars the registration of trademarks that fail to distinguish the goods or services of one trader from those of others. Distinctiveness is a core principle of trademark law because a trademark must serve as a source identifier for consumers, indicating the origin of the goods or services.

A crucial filter in determining the registrability of a mark is rooted in the very purpose of trademark protection ensuring

that a trademark functions as a badge of origin. In essence, a trademark must enable consumers to identify the source of goods or services and differentiate them from those offered by others in the marketplace. The doctrine of distinctiveness is, therefore, central to the integrity of the trademark system, as it upholds both consumer protection and fair competition.

Distinctiveness may manifest in two forms: inherent and acquired. Inherent distinctiveness is present when a mark, by its very nature such as a coined word or an arbitrary expression can distinguish the goods or services of one entity from another.

Inherent distinctiveness

The ability of a trademark to differentiate one entity's goods or services from another without requiring proof of past usage in the marketplace is known as inherent distinctiveness. Examples include coined terms like 'Kodak' (which have no dictionary meaning) or arbitrary uses like 'Apple' for computers (while it is a common English word, it has **no logical or direct connection** to the goods or services it's used for).

Categories of distinctiveness

Indian Courts, much like their counterparts in jurisdictions such as the United States, frequently draw upon the classical

spectrum of distinctiveness; a conceptual framework for evaluating whether a trademark is eligible for protection. This spectrum, originally formulated in the U.S. jurisprudence as the Abercrombie classification, has found persuasive relevance in Indian case laws, offering a structured approach to assessing the registrability of trademarks.

The spectrum categorizes trademarks into five distinct types, arranged in descending order of inherent distinctiveness. At the top are *fanciful marks*, which are invented or coined terms with no prior meaning in any language, such as 'Kodak' or 'Xerox.' These trademarks are inherently distinctive by nature, as they are uniquely created to serve as brand identifiers. Next are *arbitrary marks*, which consist of real, dictionary-defined words that bear no logical relationship to the goods or services offered 'Apple' for computers being a classic example. These too are inherently distinctive because they do not describe or suggest the nature of the product. *Suggestive marks* form the third category, requiring a degree of imagination, perception, or mental pause to connect the mark with the goods or services. For example, 'Netflix' suggests entertainment and streaming services but does not directly describe them, making it inherently distinctive as well.

The remaining two categories, *descriptive* and *generic* trademarks are not considered inherently distinctive and face significant hurdles in the registration process. *Descriptive marks* directly refer to a characteristic, quality, function, or purpose of the goods or services. For instance, 'Cold & Creamy' for ice cream or 'Quick Wash' for laundry services plainly describe the product attributes. Finally, *generic marks*, which refer to the common or class name of the product itself (e.g., 'Soap' for a cleansing bar), are entirely barred from registration under Section 9(1)(a) of the Act as they fail to distinguish the origin of the goods or services. Generic terms are considered part of the public domain and cannot be monopolized by any one entity.

This spectrum not only helps Courts and registrars assess the degree of distinctiveness but also underpins much of the legal reasoning in trademark refusal cases. It ensures that only those trademarks that truly serve the function of source identification either inherently or through acquired distinctiveness are granted the legal protections that accompany trademark registration.

Acquired distinctiveness

The theory of acquired uniqueness, sometimes referred to as secondary meaning, allows descriptive trademarks that are not initially unique to become registrable, in contrast to

intrinsically distinctive trademarks. This legal notion acknowledges that a mark may become so strongly linked to a specific source over time and via widespread and ongoing usage in commerce that it no longer serves as a descriptive mark but rather as a distinctive identification of origin.

Under Indian context, the Act categorically provides a proviso to Section 9 of the Trade Marks Act, 1999 categorically stating that '*a trade mark shall not be refused registration if before the date of application for registration it has acquired a distinctive character as a result of the use made of it or is a well-known trade mark*'. Thus, a trademark though originally generic or descriptive becomes associated in the minds of consumers with a particular source through extensive and exclusive use over time. This form of distinctiveness often requires substantial evidence, such as market surveys, sales data, advertising expenditures, and media recognition, to demonstrate that the public perceives the mark as indicative of a specific origin.

Judicial interpretations: Case law insights

The refusal of a trademark on the grounds of non-distinctiveness has become a significant concern in the Indian trademark landscape. Over the years, Indian Courts have dealt with various cases where trademark applications were challenged for their lack of inherent distinctiveness.

*Umang Dairies Limited v. Registrar of Trade Marks*¹¹, In the present case, the Delhi High Court examined whether the trademark 'White Magik' for dairy products was inherently distinctive or simply descriptive. The Registrar maintained that the mark was descriptive because it utilized common English terms.

In contrast, Umang Dairies argued that 'White Magik' was a unique term with no direct association to dairy products. Umang Dairies further presented significant evidence, including sales figures, marketing expenditures, and consumer surveys, to illustrate that the mark had gained distinctiveness through extensive market presence. The Court concluded that 'White Magik' possessed inherent distinctiveness, as the combination of words did not explicitly describe the nature or quality of the dairy products. Additionally, the evidence of prolonged use was adequate to establish acquired distinctiveness, permitting the mark's registration. This case emphasizes the intricate evaluation of distinctiveness, especially for composite marks, and highlights the necessity of

providing robust evidence of use to counter objections related to descriptiveness under Section 9 of the Trade Marks Act, 1999.

Mocemsa Care v. Registrar of Trade Marks (2024)¹², In this case, the application for the trademark 'MOCEMSA CARE' submitted by Mocemsa Care was denied by the Registrar of Trade Marks due to its lack of distinctiveness as outlined in Section 9(1)(a) of the Trade Marks Act. The trademark was considered descriptive of the healthcare services offered, which included care solutions.


The Delhi High Court affirmed the Registrar's ruling, concluding that 'MOCEMSA CARE' did not exhibit inherent distinctiveness and that there was inadequate evidence to demonstrate acquired distinctiveness through its use. The Court noted that trademarks that directly describe the nature or quality of goods or services are not inherently distinctive, and simply appending a generic term like 'CARE' does not render a descriptive mark distinctive without substantial proof of consumer recognition. This case highlights the stringent interpretation of Section 9(1)(a) and underscores the necessity

¹¹ C.A.(COMM.IPD-TM) 145/2021 (Decided on February 21, 2023, by DELHC); MANU/DEOR/41667/2023

¹² MANU/DE/2183/2025

of providing strong evidence of secondary meaning for the registration of descriptive trademarks.

*Ticona Polymers, Inc. v. Registrar of Trade Marks*¹³, In this case, the Delhi High Court addressed whether a trademark could be dissected during examination to assess its eligibility under Section 9(1)(a) of the Act. The appellant's mark 'COOLPOLY' was challenged on the grounds of lacking distinctiveness, being a combination of the descriptive words 'COOL' and 'POLY.' The Court held that the mark should be considered in its entirety, emphasizing that dissecting the mark into individual components could lead to unjust outcomes. The decision underscored the importance of assessing the overall distinctiveness of a mark rather than focusing on its parts in isolation.

*Anjay Bansal v. Assistant Registrar of Trade*¹⁴: In this case, the Madras High Court examined the eligibility for registration of the mark  which faced objections on the basis that the trademark was descriptive and lacked distinctiveness as per Section 9 of the Act.

The Court ruled in favor of the Applicant, noting trademark has been used since 2005, therefore the mark has acquired

distinctiveness. Further, the trademark has been applied in a device form consisting of various elements, the word 'people' written in an indigo-green colour; the word 'source' written in green; and unique shape of the alphabet, 'o' being styled so as to resemble a magnifying glass with the image of a person within the alphabet 'o' making the trademark distinctive in totality. The Court also took note of the invoices and financial annual reports of recent years and concluded that refusal order is unreasoned and confirming trademark shall proceed towards advertisement. This ruling confirms that a composite mark can be eligible for registration even if one of its components is descriptive, as long as the trademark is used.

Conclusion

In the context of Indian trademark law, it is evident that distinctiveness is essential; it serves as the prerequisite for protection. A trademark, whether inherently distinctive or acquired through use, must differentiate itself to qualify for safeguarding under Section 9(1)(a) of the Act.

Although descriptive and generic trademarks often encounter significant challenges, Courts are moving away from a uniform approach. They are increasingly acknowledging the

¹³ 2023 SCC OnLine Del 1234

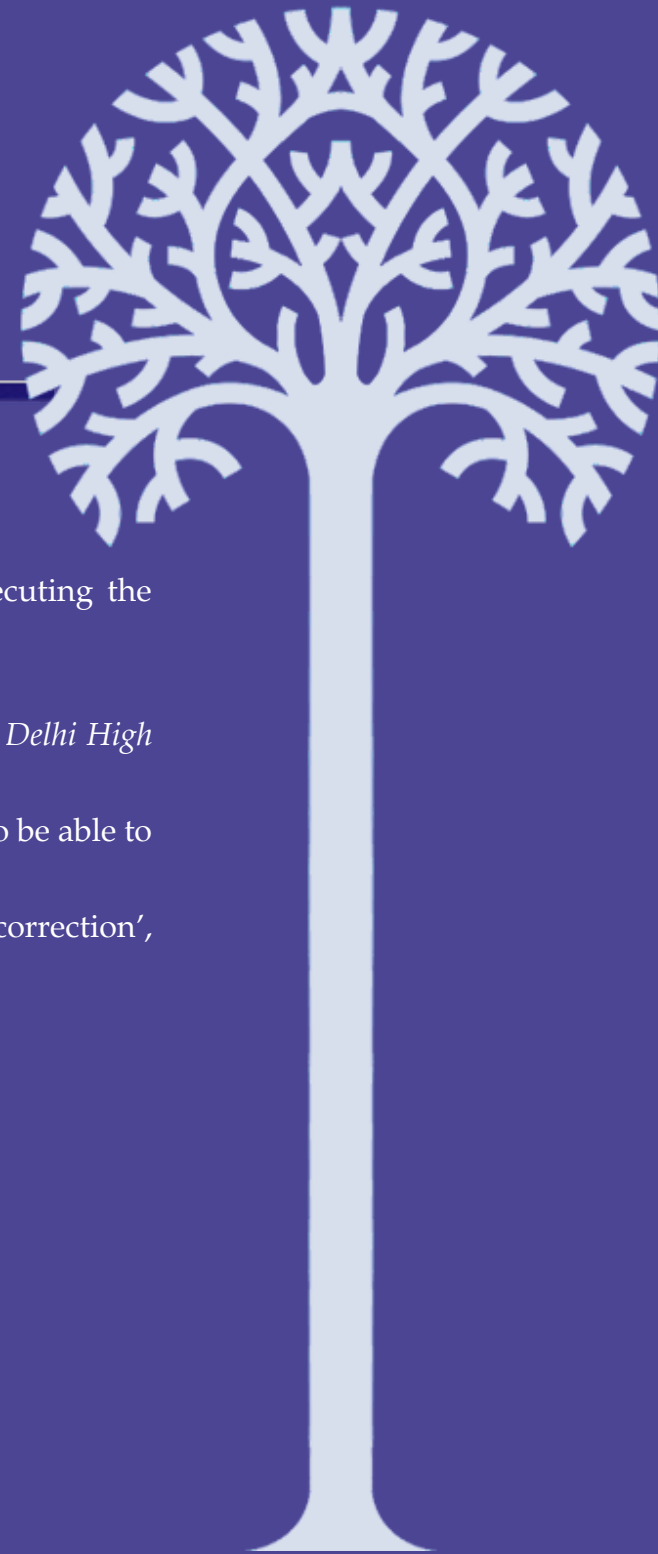
¹⁴ 2023 SCC OnLine Mad 7463

significance of secondary meaning, which can be established through consistent usage, effective branding, and market awareness. Recent legal developments indicate a more business-oriented and practical perspective: **composite marks** that blend generic terms with unique stylization or design may achieve success where straightforward terms do not, and **evidence of acquired distinctiveness**, such as consumer surveys, advertising expenditures, and **brand recognition** is

being given considerable weight. This evolution suggests that the critical factor is not the initial nature of a mark, but its effectiveness in the marketplace. In the current branding environment, functionality takes precedence over form, and Courts are prepared to protect trademarks that resonate with consumers, even if they are not found in the dictionary.

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Ratio Decidendi



- Intersection of Design and Copyright laws – Supreme Court of India formulates two-pronged approach
- Patents – Writ petition against rejection of pre-grant opposition – *Court permits to lodge post-grant opposition and allows interim order, restraining the patent applicant from prosecuting the petitioner, to continue till disposal of such opposition – Madras High Court*
- Patentability under Section 3(k) – Scope of 'Business method' – *Madras High Court*
- Trademark – Suit for passing off need not be stayed for decision on rectification application – *Delhi High Court*
- Copyright – Registration as copyright society or being a member of such society is mandatory to be able to issue license for exploiting assigned copyrighted work – *Delhi High Court Division Bench*
- Patents – Appeal dismissed on the basis that claim scope was expanded and did not amount to 'correction', 'disclaimer' or 'explanation' under Section 59 of the Patents Act, 1970 – *Delhi High Court*

Intersection of Design and Copyright laws – Supreme Court of India formulates two-pronged approach

In a dispute involving intersection of copyright and design laws, the Supreme Court of India has formulated a two-pronged approach to solve the conundrum caused by Section 15(2) of the Copyright Act, 1957, to ascertain whether a work is qualified to be protected by the Designs Act, 2000.

Accordingly, it was held that the first test shall consider whether the work in question is purely an 'artistic work' entitled to protection under the Copyright Act or whether it is a 'design' derived from such original artistic work and subjected to an industrial process. As a second step, the Apex Court advises that if such a work does not qualify for copyright protection, then the test of 'functional utility' will have to be applied to determine its dominant purpose and then ascertain whether it would qualify for design protection under the Design Act.

Section 15(2) of the Copyright Act provides that design, which is capable of registration under the Designs Act, but is not registered so, will lose its protection under the former Act if the article to which the design has been applied is reproduced more than 50 times by an industrial process. The crux of the issue was

whether Proprietary Engineering Drawings are correctly classifiable as either a 'design' under the Designs Act or an 'artistic work' under the Copyright Act.

The Supreme Court in this regard also observed that it must be kept in mind that the overarching objective is to ensure that rights granted under either regime serve their intended purpose without unduly encroaching upon the domain of the other. It in this regard noted that the legislative intent is to harmonise the two statutes so that while an 'artistic work' qualifies for copyright protection, its commercial or industrial application—i.e., the 'design' derived from the original work for industrial production—is subject to the limitations set out in Section 15(2) of the Copyright Act.

The Apex Court thus directed the Commercial Court to consider the issue afresh and conduct trial by adopting an Occam's Razor approach to ascertain the true nature of the 'Proprietary Engineering Drawings'.

[Cryogas Equipment Private Limited v. Inox India Limited and Others – Judgement dated 15 April 2025 in Special Leave Petition (C.) Nos. 28062/2024 and 28017/2024, Supreme Court]

Patents – Writ petition against rejection of pre-grant opposition – Court permits to lodge post-grant opposition and allows interim order, restraining the patent applicant from prosecuting the petitioner, to continue till disposal of such opposition

Disposed of a writ petition filed against the rejection of the Patent office to allow a pre-grant opposition, the Madras High Court has permitted the petitioner to lodge a post-grant opposition within 30 days of receipt of the order. The High Court also allowed the earlier interim order of the Court, restraining the patent applicant from prosecuting the petitioner, to continue till disposal of the post-grant opposition by the Patent office.

On maintainability of the writ petition against the rejection of the pre-grant opposition, the Court noted that the principles laid down by the Delhi High Court in the case of *Ucb Farchim Sa v. Cipla Ltd. & Others* [2010 SCC OnLine Del 523] regarding the existence of an alternative remedy should be borne in mind, but they do not lead to the conclusion that this Court's power under Article 226 is ousted or even whittled down in such circumstances. The Delhi HC had held that jurisdiction can be exercised only if the petitioner is not the interested person.

Reviewing the decision-making process of the impugned order, the Court noted that there was the absence of any reference to the affidavits of various person-skilled-in-the-art in the impugned order. The Court for this purpose upheld the submission of the petitioner that reference to cited prior arts (as cited by one affidavit) in the impugned order cannot be equated with the consideration of affidavits by way of evidence. The High Court was also *prima facie* of the view that no 'obviousness' analysis was undertaken and that the Controller, without independent reasoning, had proceeded to accept the contention of the patent applicant while rejecting that of the opponent.

However, noting that the petitioner was a 'person interested' under Section 2(1)(t) of the Patents Act, 1970, and had alternative remedy available, the Court proceeded to a workable and balanced alternative. Accordingly, the High Court permitted the petitioner to lodge a post-grant opposition, though the period of one year after grant of the patent had lapsed.

Further, the High Court allowed its earlier interim order, restraining the patent owner from prosecuting the petitioner on the basis of the patent, subject to certain conditions, to continue till disposal of the post-grant opposition.

The petitioner was represented by Lakshmikumaran & Sridharan Attorneys here. [[Adiuvo Diagnostics Private Limited v.](#)

Union of India – Order dated 25 March 2025 in W.P.(IPD)No.23 of 2023 and W.M.P.(IPD)Nos.5 & 7 of 2023, Madras High Court]

Patentability under Section 3(k) – Scope of ‘Business method’

The Madras High Court has held untenable the rejection of patent claim directed at the deployment of software, including applications, for the purpose of enabling verification of calls without routing such calls through the billing system.

According to the Court, the monopoly claim was not directed at a method of conducting business for rejection under Section 3(k) of the Patents Act, 1970 but was directed at a method of using software for the said purposes so as to improve the system’s functionality.

The patent in the dispute was titled ‘Methods for Acquiring Billing and Usage Data in an IMS Environment’. The matter was remanded back for redetermination to examine whether the claimed invention is excluded from patent protection on account of being a computer programme *per se* or algorithms.

[*Tekelec, Inc. v. Controller of Patents* – Judgement dated 25 March 2025 in (T)CMA(PT)/106/2023, Madras High Court]

Trademark – Suit for passing off need not be stayed for decision on rectification application

The Delhi High Court has held that the suit for passing off need not be stayed for the decision on rectification application filed by the respondent in the suit. Allowing the petition against the Trial Court decision to stay the proceedings in a suit for passing off, the Court noted that the reliance by the Trial Court on the decision of the Division Bench of the Court in *Amrish Aggarwal Trading as Mahalaxmi Product v. Venus Home Appliances* [2024 SCC Online Del 3652] was wrong.

The Court in this regard noted that the earlier decision was only in respect of an infringement suit, and that the inadvertent reference to ‘passing off’ in paragraph 44 of the said decision was in the nature of an *obiter dicta*. According to the Court in the present dispute, there is nothing in the earlier decision to indicate that the intent of the Division Bench was to stay the proceedings in the suit insofar as relief of passing off is concerned.

The High Court also noted in this regard that Section 124 of the Trade Marks Act, 1999 applies only in the context of a suit for infringement of a trademark. In fact, Section 27(2) of the Act itself

clarifies that nothing in the Trade Marks Act would affect an action for passing off of goods.

Further, considering the jurisprudence on '*obiter dicta*', the Court was of the view that the observation of the Division Bench was not binding.

[*Balar Marketing Pvt. Ltd. v. Lakha Ram Sharma Proprietor of Kundan Cable India* – Decision dated 27 March 2025 in CM(M)-IPD 5/2025, Delhi High Court]

Copyright – Registration as copyright society or being a member of such society is mandatory to be able to issue license for exploiting assigned copyrighted work

The Division Bench of the Delhi High Court has held that issuance or grant of licenses for exploiting of works in respect of which a person claims copyright can *prima facie* only be done if such person is a registered copyright society or a member of a registered copyright society.

In the facts of the case, it was held that the respondent-PPL cannot be permitted to, without registering itself as a copyright society or becoming a member of any registered copyright society, issue or grant licences for the sound recordings in its

repertoire, assigned to it under Section 18(1) of the Copyright Act.

The Court in this regard noted that PPL was an association of persons and was carrying on the business of granting licences in respect of the copyrighted works assigned to it under Section 18(1), and thus Section 33(1) read with sub-section (3) was applicable to them. According to the Court, the requirement, as envisaged by Section 33(1), which prohibits the carrying on of business of issuing or granting licences in respect of any copyrighted work or any other rights conferred by the Copyright Act, except under or in accordance with the registration under Section 33(3) to a copyright society, is absolute and non-negotiable.

The Division Bench for this purpose also rejected the submission of the respondent in respect of the proviso to Section 33(1), according to which the owner of copyright has the right to grant licence in respect of his own works. The respondents had contended that since they were the owners of the copyrights assigned to them, they could thus issue/grant licences without registering as copyright societies. Rejecting the submission, the High Court opined that such an interpretation will make Section 33(1) redundant and render the words '*except under or in*

accordance with the registration granted under sub-section (3)', in Section 33(1), completely otiose.

The High Court in this regard also noted that even the proviso to Section 33(1) provides the owner has the right to grant licences consistent with his obligation as a member of the registered copyright society, and hence, the requirement of being a member of a registered copyright society, whether under Section 33(1) or under the first proviso thereto is absolute and non-negotiable.

Further, allowing the appeal, the Division Bench of the High Court disagreed with the Single Bench decision of the Bombay High Court and held that even while exercising the right conferred by Section 30, to issue licenses in respect of the works assigned to it, in respect of which it claims ownership under Section 18(2), the respondent has still to act in accordance with the registration granted under Section 33(3).

The impugned decision of the Single Bench was reported in March 2025 issue of LKS IPR Amicus, as available [here](#). [Azure Hospitality Private Limited v. Phonographic Performance Limited – Judgement dated 15 April 2025 in FAO(OS) (COMM) 41/2025, CAV 106/2025, Delhi High Court]

Patents – Appeal dismissed on the basis that claim scope was expanded and did not amount to ‘correction’, ‘disclaimer’ or ‘explanation’ under Section 59 of the Patents Act, 1970

In a case where the patent applicant amended/changed the claim category from ‘method of treatment claims for non-small cell lung cancer’ to ‘product claim being an anti-cMet antibody drug conjugate’ (*inter alia* without any disease limitation), after the Controller raised objections under Section 3(i) of the Patents Act, 1970, the High Court has held that the amendment does not fall under the purview of a ‘correction’, ‘disclaimer’ or ‘explanation’, as specified under Section 59(1) of the Patents Act, 1970.

The amended claims in the case covered an anti-cMet antibody-drug conjugate (ADC), while the originally filed claim covered a method of treating solid cancer using anti-cMet antibody-drug conjugate (ADC). The amended claims also omitted the limitation and reference to the cancer for which the anti-cMet antibody-drug conjugate was intended and eliminated previous references to dosing schedules, specific patient population, IHC thresholds or combination therapies. The Court also noted that

amended claims 5 to 8 relating to compositions were added, that were not disclosed or covered in the originally filed claims.

Accordingly, the High Court held that the proposed amendments are not in the nature of a 'correction', because correction cannot be a substantial change, i.e., changing the scope of unamended claims but should be limited to correcting obvious mistakes or clerical errors, without broadening the scope of the unamended claims. It was thus held that changing an entire claim category from 'method' to 'product' cannot be a mere correction of an error.

Further, the amendments were also not held to be falling within the scope of 'explanation' or 'disclaimer'. The Court in this regard noted that a 'disclaimer' typically excludes some specific subject matter to narrow the scope and avoid prior art or clarify what is not claimed. However, the applicant had here done the opposite and expanded to a product claim, rather than disclaiming any subject matter. Also, it was noted that the newly filed claims went beyond mere explanation and surpassed the

original disclosure intent, as they broadened the patent's scope by removing the original treatment limitations.

According to the Court, this kind of broadening, which introduces entirely new categories of claims and expands legal protection beyond the original disclosure, is not a mere refinement or rectification of existing language.

It may be noted that while dismissing the appeal filed against the refusal of patent application, the Court appears to have differed with (*Allergan*- did not address the nature of amendments, i.e., disclaimer, correction or explanation) and distinguished (in *Allergan*-amended claims pertained to the same disease) the earlier decision of the Coordinate Bench in *Allergan Inc. v. Controller of Patents* [2023 SCC OnLine Del 295].

[*Abbvie Biotherapeutics Inc & Anr. v. Assistant Controller of Patent Designs* – Judgement dated 16 April 2025 in C.A.(COMM.IPD-PAT) 44/2023, Delhi High Court]



News Nuggets

- High Court advises Controller General to adopt a technical solution to get proof of receipt of email
- Distinctiveness of a combination mark cannot be negated by dissecting the mark
- Trademark having AU characters is deceptively similar to the mark having UA characters
- Using copyrighted data for AI training – Industry seeks changes in Copyright Act and clarification on 'fair dealing'
- USA's creative community is against more relaxed copyright laws for training AI
- Trademark 'Josh' for torches and flashlights – Eveready granted injunction
- 'Taj' recognized as 'well-known mark' in hospitality

High Court advises Controller General to adopt a technical solution to get proof of receipt of email

The Madras High Court has advised the Controller General of Patents, Designs & Trademarks to adopt a technical solution whereby proof of receipt of the e-mail by the recipient is available to the Registrar of Trademarks. The applicant-petitioner in the case had submitted that they were not able to respond to the notice of opposition due to its non-receipt, while the Registrar of Trademarks had placed on record a document pertaining to the despatch of e-mail in respect of the opposition. It was however the submission of the petitioner that there was no proof of receipt of such mail by them.

Setting aside the impugned order which had deemed the trademark application 'abandoned', the Court also restored the opposition. The applicant/petitioner was allowed time to respond to the opposition.



Allowing the petition, the Court in *R. Dilip Kumar v. Registrar of Trademarks* and *Vignesh Kumar Sivakumar v. Assistant Registrar of Trademarks* [Both Orders dated 3 April 2025] also reiterated that Rule 18(2) of the Trade Mark Rules, 2017 is not in consonance with Section 21(2) of the Trade Mark Act, 1999. The Court in this regard relied upon its previous decision, which pointed out that

while the Rules provide for deemed service upon *dispatch* of e-mail to the trademark applicant, according to Section 21(2), time limit for the applicant to file a counter statement runs from the date of *receipt* of the notice of opposition.

Distinctiveness of a combination mark cannot be negated by dissecting the mark

The Delhi High Court has reiterated that the distinctiveness of a combination mark cannot be negated by dissecting the mark. It was noted that the same must be assessed as a whole, instead of proving its components to be distinctive by itself. The issue involved registration of a device mark ^{Oh that!} NATURAL. The Trademark office had in the dispute *Mocemsa Care v. Registrar of Trademarks* [Decision dated 26 March 2025] refused the subject application on the grounds that the applicant had brought the common general words along with an exclamation mark in between the words, which are used in day-to-day life by common general public.

Trademark having AU characters is deceptively similar to the mark having UA characters

The Delhi High Court has held that the defendant's mark , having characters AU is deceptively similar to the mark 

with UA, which was the acronym of the petitioners name 'Urban Armour'. According to the Court, the defendant had, in its impugned mark, cleverly imitated the interlocking U & A mark and element of the petitioner's registered and prior trademarks. The Court was hence of the view that by presenting its mark as AU instead of UA, the defendant-respondent sought to mislead the consumers through interchangeable use of the overlapping characters, causing confusion and passing off.

Directing cancellation of the AU mark, the Court in *Under Armour Inc. v. Ashwani* [Order dated 6 March 2025] also noted that the petitioner was using the UA marks since the year 1996 in the USA and had applied for registration of the mark in India, in the year 2004. It was also noted that as per evidence on record, the marks of the petitioner had acquired immense goodwill and reputation worldwide, including, in India.

Using copyrighted data for AI training – Industry seeks changes in Copyright Act and clarification on 'fair dealing'

As per news reports, the Indian industry has urged the government to review the legality of using copyrighted data for training Artificial Intelligence (AI). According to the *ET LegalWorld* news report, as available [here](#), while amendments

have been suggested in the Copyright Act, clarification has also been sought on the 'fair dealing' exceptions. The industry has similarly also called for guidelines on AI-generated works, privacy, transparency, and for regulating deepfakes. According to the experts, legal certainty is needed to promote AI adoption. The news report also in this regard highlights that Industry Association Nasscom has sought guidelines on issues such as the scope of computer-generated works and human authorship requirements for AI-generated works.

USA's creative community is against more relaxed copyright laws for training AI

The US creative community is against the recent proposals from the tech giants (Open AI and Google) that argue US copyright law should allow AI companies to train their systems on copyrighted works without permission or compensation to rights holders. As per *Times of India* news report, as available [here](#), more than 400 Hollywood celebrities have submitted an open letter to the US President Administration opposing efforts by the technology companies to weaken the copyright protections for AI training.

Trademark 'Josh' for torches and flashlights – Eveready granted injunction

The Delhi High Court has granted injunction to Eveready for use of trademark 'Josh'. As per *ET LegalWorld* news report dated 19 March 2025, as available [here](#), the Court while allowing the petition, restrained the defendants M/s. Mahalaxmi Industries, from using the trade mark 'JOSH' for torches and flashlights, holding that such use amounts to infringement of Eveready's trade mark 'JOSH'. The news report states that the Court had noted that Eveready was consistently using the trademark 'EVEREADY JOSH'/'JOSH' since 2009 and had substantial market presence with impressive sales figures for over the past 15 years.

'Taj' recognized as 'well-known mark' in hospitality

The Delhi High Court has recognized 'TAJ' as a well-known trademark under Section 2(1)(zg) of the Trademarks Act, granting it protected status for hotels and related services in the hospitality industry. As per *ET LegalWorld* news report dated 19 March 2025, as available [here](#), the Court highlighted the long-standing use, widespread geographical reach, public recognition, goodwill, and extensive promotion and revenue associated with the marks, both in India and globally, as factors fulfilling the criteria outlined in Sections 11(6) and 11(7) of the Trade Marks Act.

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