NEWSLETTER

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Centre for CIPROM intellectual property management

Intellectual Property advocacy in the fields of:

- IP Infrastructure
- IP Policy
- Patent Law
- Copyright
- IP Valuation
- Technology Transfer
- Licensing
- Collaborations
- M & A
- Innovation Research
- Data Management
- Balance for Rights & Obligations

EDITORIAL

A seminar on the Biodiversity Act and Rules is both timely and significant in view of the key amendments introduced in the 2023 Act and related Rules. It is indeed heartening to note and appreciate that top authorities from the NBA are participating in this event of national importance being conducted by Serigen Mediproducts Pvt. Lt, Venture Centre, Pune and GNANLex Associates LLP.

A seminar on Recent Amendments to the Biological Diversity Act and Rules is being jointly organized by the Venture Centre, Serigen and GNANLex at Venture Centre, Pune, on the 10th of November, 2025 from 10 am to 2pm in hybrid mode.

Dr. B. Balaji, Member Secretary, NBA, will deliver the keynote address. Dr. K. P. Raghuram, Technical Officer, NBA, will be joining the deliberations, including the panel discussion.

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NATIONAL BIO-DIVERSITY ACT AND RULES

The National Biodiversity Act (2002) and Rules (2004) were enacted and implemented by India, many years prior to the Nagoya Protocol (2014) which was to provide guidelines on global implementation of the provisions on Convention n Bio Diversity (CBD. There were many vague definitions and provisions in the 2002 Act, so much so, that there have been very large number of litigations even upto NGT (National Green Tribunal), High Courts and Supreme Court. The anomalies in the earlier provisions covered by the 2002 Act and 2004 Rules were set right and rectified in the 2023, Biodiversity (amendment) Act and the 2024 Rules which followed.

Major amendments were to Section 3(2)(ii), Section 4, Section 5 and Section 6 and others.

In context of these amendments and consequent provisions and procedural changes, the Seminar as proposed on November 10, 2025will be extremely beneficial to the community and industry.

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ROCHE V. NATCO: SUPREME COURT UPHOLDS DELHI HIGH COURT'S REFUSAL OF INJUNCTION IN THE RISDIPLAM PATENT DISPUTE

Case Title: F. Hoffmann La Roche AG and Another v. Natco Pharma Limited

Jurisdiction / Court: High Court of Delhi (Original Side Commercial Division) CS (COMM) 567/2024 and connected matters

Date of Delhi High Court Division Bench Judgment: 9th October 2025

Date of Supreme Court Order (SLP): 17th October 2025

Patent in Dispute: Indian Patent No. IN 334397 titled "Compounds for Treating Spinal Muscular Atrophy".

Subject Matter: The active pharmaceutical ingredient Risdiplam marketed by Roche under the brand name EVRYSDI for treatment of Spinal Muscular Atrophy

Factual Background

the compound Risdiplam (C22H23N7O) and corresponding preparation methods. The patent term runs from 11 May 2015 to 11 May 2035.

Natco Pharma was alleged to have developed and manufactured Risdiplam in India without authorization and filed a patent application titled "Improved Process for the Preparation of Risdiplam and its Intermediates" (Application No. 202241055182 dated 26 September 2022). Roche sought an interim injunction restraining Natco from manufacturing or selling Risdiplam, claiming infringement of its patent rights. Natco, in response, challenged the validity of the suit patent under Sections 64(1)(e) and (f) of the Patents Act, alleging lack of novelty and obviousness.

Legal Issues

1. Whether Risdiplam as claimed in IN 334397 was anticipated or inherently disclosed in Roche's earlier genus patent WO 2013/119916 (WO 916) or its corresponding US patent (US 9586955).

2. Whether the invention claimed in IN 334397 lacked an inventive step and was obvious in view of the genus patent disclosures, given

WO 916 only by substitution of a CH group with a Nitrogen atom.

3. Whether public interest considerations justified the denial of an interim injunction, considering the drug's critical use for patients with Spinal Muscular Atrophy.

Court's Findings and Reasoning

The Delhi High Court held that mere coverage of a compound within a broad Markush genus does not amount to its specific disclosure. Therefore, the anticipation challenge raised under Section 64(1)(e) was not conclusively proven but remained a credible issue for trial.

On obviousness, the Court found that the change from CH to Nitrogen was a routine

Bioisosteric substitution well known in medicinal chemistry and that the same inventors were involved in both the genus and species patents. The "person in the know" standard, developed in the AstraZeneca v Intas case, was deemed applicable in this context. Thus, the Court concluded that Risdiplam was obvious in view of prior art and denied Roche's request for an interim injunction.

noted that Risdiplam is the only approved oral treatment for SMA in India and that restricting access could severely affect patients. Balancing patent rights with public welfare, the Court refused interim relief.

Additional Observations

The suit patent has not faced any pre-grant or post-grant opposition in India.

Natco also alleged non-compliance by Roche under Section 8 of the Patents Act regarding disclosure of corresponding foreign filings.

Interventions by patient advocacy groups emphasized accessibility and affordability, which influenced the Court's decision on the balance of convenience.

Supreme Court Proceedings

Following the Division Bench decision, Roche filed a Special Leave Petition before the Supreme Court of India.

On 17 October 2025, the Supreme Court dismissed the SLP, refusing to interfere with the concurrent findings of the Single Judge and Division Bench. The Court observed that since the orders under lower courts had taken consistent views, no interference was warranted.

Roche reiterated its arguments regarding the extensive research behind Risdiplam, the absence of patent invalidation in any of 62 foreign jurisdictions, and the absence of any opposition in India. It also argued that a limited "gap" between coverage and disclosure is permissible and that the "person in the know" test had no statutory basis.

The Supreme Court declined to impose any embargo on the export of Natco's generic versions of Risdiplam. However, it directed the Delhi High Court to endeavor to dispose of the main suit expeditiously.

Implications

The Supreme Court's order confirms the Delhi High Court's approach that interim injunctions in pharmaceutical patent disputes must be assessed through both legal and public interest lenses.

The decision reinforces judicial reluctance to grant injunctive relief where strong challenges to validity exist and where access to essential medicines is at stake.

It further underscores the evolving distinction between coverage and disclosure and endorses the continued relevance of the "person in the know" test in determining obviousness.

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PHILIPS V. BATHLA: DELHI HIGH COURT UPHOLDS PATENT RIGHTS IN VCD TECHNOLOGY

Delhi High Court | CS(COMM) 533/2018 | Judgment dated 13 October 2025 | Justice Mini Pushkarna

Background

The Delhi High Court has ruled in favor of Koninklijke Philips N.V. ("Philips") in a long-standing patent infringement dispute against M. Bathla & Anr. The case involved unauthorized use of Philips' Indian Patent No. 175971, titled "Digital Transmission System," which underpins the MPEG-1 and MPEG-2 audio compression standards used in Video Compact Discs (VCDs).

Philips alleged that the defendants replicated and sold VCDs using its patented technology without obtaining a license, despite multiple invitations to join its global licensing program.

The Court's Findings

products employed Philips' patented MPEG-1 compression system and that their replication activities constituted infringement. The Court relied on expert testimony from Professor K.R. Ramakrishnan (IISc Bangalore), which confirmed the use of the patented process in the defendants' VCDs.

The defendants' arguments—that they only replicated discs or used unrelated technology—were rejected. Their failure to produce technical evidence led to an adverse inference under Section 104A of the Patents Act.

Although the patent expired in 2010, the Court awarded **compensatory and punitive damages** for the period of unauthorized use.

Significance

The judgment strengthens enforcement of **Standard Essential Patents (SEPs)** in India, affirming that compliance with international standards such as MPEG does not excuse license obligations. It also highlights that withholding process details can result in adverse inferences, reinforcing the evidentiary position of patent holders in process patent cases.

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WHEN "CELEBRATIONS" FINALLY MEANT CELEBRATION: MARS AND CADBURY END A 25-YEAR TRADEMARK BATTLE

Delhi High Court | Order dated 10 October 2025 | Justice Sanjeev Narula

After twenty-five years of litigation, two of the world's leading confectionery companies, Mars Incorporated and Cadbury (India) Ltd., now part of Mondelez International, have amicably resolved their dispute over the trademark "CELEBRATIONS."

The long-standing conflict centred on the right to use the mark for their respective chocolate assortments. For decades, both companies pursued multiple proceedings before the Trade Marks Registry and the Delhi High Court, each asserting exclusive rights over a word that symbolises festivity and joy.

This protracted contest has now concluded with a joint application filed by the parties under Order XXIII Rule 3 of the Code of Civil Procedure, 1908, recording a comprehensive settlement agreement dated 3 July 2025. Under the terms of the agreement, both sides agreed to withdraw all oppositions and rectifications related to the

"CELEBRATIONS" mark, thereby bringing an end to all associated disputes.

Justice Sanjeev Narula, while decreeing the matter in terms of the settlement, commended both Mars and Cadbury for choosing reconciliation over rivalry. The Court observed that the resolution marks a fitting end to a quarter-century of legal proceedings and restores the true meaning of the word "CELEBRATIONS."

In a notable gesture of goodwill, the companies voluntarily undertook to distribute confectionery assortments valued at five lakh rupees each to schoolchildren across Delhi ahead of Diwali. The distribution will take place under the supervision of the Directorate of Education, Government of NCT of Delhi, and the Delhi State Legal Services Authority. The Court appreciated this act, observing that genuine celebration lies in sharing and generosity.

The Court also directed that, where schools restrict the distribution of high-sugar products, nutritionally balanced alternatives of equivalent value may be provided. The initiative was recognised as a symbolic conclusion to a long-standing rivalry and as an example of responsible corporate conduct.

By resolving the matter amicably, Mars and Cadbury have brought to an end one of India's most enduring trademark disputes. The Delhi High Court's order reflects that even the most complex and competitive commercial conflicts can be concluded through goodwill, understanding and mutual respect.

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ELI LILLY AND CIPLA PARTNER TO EXPAND ACCESS TO TIRZEPATIDE IN INDIA

Eli Lilly and Company (India) Pvt. Ltd. (Lilly) and Cipla Limited have entered into a distribution and promotion agreement for **Yurpeak® (tirzepatide)**, marking an important collaboration aimed at broadening access to this innovative therapy in India.

Under the agreement, Cipla will distribute and promote **Yurpeak®**, the second brand of tirzepatide in India, while Lilly will continue to manufacture and supply the product. Tirzepatide was first launched by Lilly in India in March 2025 under the brand name **Mounjaro®**, and Yurpeak® will be offered at the same price point to ensure affordability and accessibility.

This strategic partnership reflects Lilly's commitment to expanding access to breakthrough treatments for chronic diseases. Winselow Tucker, President and General Manager, Lilly India, stated that the introduction of a second brand strengthens Lilly's mission to make life better for people and enhances access for patients in regions beyond Lilly's existing presence.

Achin Gupta, Global Chief Operating Officer of Cipla, emphasized that the partnership marks Cipla's entry into the obesity care segment with the same dedication and scale that have defined its respiratory and chronic therapy initiatives. He added that Cipla remains committed to advancing patient care by ensuring that innovative global therapies reach a wider population.

Tirzepatide is a dual agonist of the glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptors. It is approved as an adjunct to diet and exercise for the management of **type 2 diabetes** and **chronic weight management** in adults with obesity or overweight conditions accompanied by related comorbidities.

Yurpeak® will be available in **KwikPen®** form, a prefilled multi-dose pen with six dosage strengths ranging from 2.5 mg to 15 mg, allowing healthcare professionals to tailor treatment plans to individual patient needs.

India currently faces one of the world's highest burdens of diabetes and obesity, with over 100 million adults living with diabetes and nearly an equal number affected by obesity. This collaboration between Lilly and Cipla aims to address these pressing health challenges through broader accessibility and improved patient reach.

Both companies reaffirmed their shared goal of providing innovative, effective, and affordable healthcare solutions, combining global scientific excellence with local distribution expertise.

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INDIA TAKES PRIDE AS JUSTICE PRATHIBA M. SINGH BECOMES CHAIR OF WIPO'S ADVISORY BOARD OF JUDGES

India has achieved a moment of immense pride in the field of intellectual property. **Justice Prathiba M. Singh** of the **Delhi High Court** has been appointed **Chair of the World Intellectual Property Organization (WIPO) Advisory Board of Judges** for the **2025-2027 term**, marking the first time that an Indian and an Asian judge has been entrusted with this prestigious global position.

The **World Intellectual Property Organization (WIPO)**, a specialized agency of the **United**

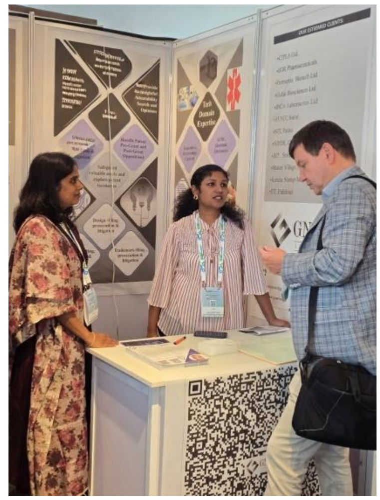
Nations, is the world's leading body for the promotion and protection of intellectual property rights. Its **Advisory Board of Judges** comprises eminent jurists from across the globe and plays a crucial role in guiding WIPO's collaboration with judiciaries, fostering consistency and capacity-building in IP jurisprudence worldwide.

Justice Singh's appointment has been widely celebrated as a matter of national pride. The official account of **India at the United Nations, Geneva**, hailed the appointment as a significant milestone, noting that she will now lead a distinguished group of international judges shaping WIPO's global judicial engagement on IP issues.

Union Finance Minister **Nirmala Sitharaman** described the appointment as a "landmark achievement for India and the Asian region," commending Justice Singh's "remarkable contribution to IP jurisprudence" and her scholarly work, including her two-volume treatise on patent law.

Union Minister for Commerce and Industry Piyush Goyal called it "a moment of great pride for Bharat," adding that Justice Singh's leadership "reflects India's growing stature in the global innovation ecosystem and will further strengthen engagement with WIPO."

Justice **Prathiba M. Singh** was elevated as a permanent judge of the Delhi High Court in 2017 and previously served as **Chairperson and Presiding Judge of the Court's first-ever Intellectual Property Division** during 2021–22. Before her elevation, she was a leading IP practitioner, appearing before the Supreme Court of India, the Delhi High Court, and the Indian Patent Office. She has been instrumental in several policy reforms, including streamlining procedures in the Copyright Office and patent examination system, and has advised Parliamentary Committees on IP legislation.



Justice Singh also currently serves as **Co-Chair of the World Health Organization's Working Group on Regulatory Considerations on Artificial Intelligence in Health**, underscoring her multifaceted contribution to law, technology, and innovation.

Her appointment as Chair of the WIPO Advisory Board of Judges is not only a personal accolade but also a reflection of India's rising prominence in shaping global intellectual property discourse. It stands as a proud moment for the nation and an inspiration for the Indian IP community.

GNANLEX ASSOCIATES LLP PARTICIPATES IN BIO CONNECT 3.0, KERALA 2025

Event Dates: October 9–10, 2025

Venue: The Leela, Kovalam, Thiruvananthapuram, Kerala

GNANLex Associates LLP, an intellectual property law firm, participated in **Bio Connect 3.0 – Kerala 2025**, an event focused on advancing innovation and collaboration within the biotechnology and life sciences sectors. The conference, held under the theme **"I2I - Innovation to Industry: Leading the Way Towards a Healthier and Sustainable Future,"** brought together industry leaders, researchers, innovators, and policymakers to explore pathways for sustainable growth in India's bioeconomy.

Ms. Bessy Titus and **Ms. Christine Xavier** attended the event on behalf of GNANLex Associates LLP. Their participation highlighted the firm's ongoing engagement with emerging technologies and its focus on supporting innovation through effective intellectual property protection and legal advisory services.

Bio Connect 3.0 provided a valuable opportunity to exchange perspectives on the intersection of biotechnology, IP, and innovation policy, while fostering connections with stakeholders working toward a sustainable and innovation-driven future.

GNANLex Associates LLP remains committed to contributing to India's innovation ecosystem by providing specialized IP expertise that bridges scientific advancement and industry application.

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NATIONAL INTELLECTUAL PROPERTY AWARDS 2025 – DEADLINE EXTENDED

The Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM) has announced an extension for the submission of applications for the National Intellectual Property Awards 2025.

The new deadline for submission is 30th October 2025. Applications submitted up to this date will be considered for evaluation under all 13 award categories.

The National Intellectual Property Awards recognize and honour outstanding contributions and achievements in the field of patents, trademarks, designs, and geographical indications in India.

Applicants are encouraged to submit their entries before the revised deadline.

For further details and submission guidelines, please visit the official website: www.ipindia.gov.in

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