

IPR&D SPARK NEWSLETTER

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LEGAL WATCH

US Supreme Court Rejects Appeal over Patent Validity in Postal Service Case

Contributor: Subin Khullar

Nov' 2024: The U.S. Supreme Court declined to reconsider a decision invalidating a patent held by Return Mail Inc. at the request of the U.S. Postal Service (USPS). Return Mail had sought to revisit patent eligibility standards, which critics argue create uncertainty in intellectual property law. The case began in 2011 when Return Mail sued USPS for allegedly violating its patent on technology for processing undelivered mail. In 2022, a federal claims court invalidated the patent, deeming it an abstract idea automated by computers. The U.S. Court of Appeals for the Federal Circuit upheld this decision in February. Return Mail petitioned the Supreme Court in July, arguing that current patent eligibility standards stifle innovation. However, the Supreme Court declined to take up the case ([Source 1](#); [Source 2](#)).



LEGAL WATCH

U.S. Court Blocks Sun Pharma's LEQSELVI Launch, Grants Preliminary Injunction

Contributor: Sonia Buntel

Nov' 24: A US district court of New Jersey granted a preliminary injunction delaying the launch of LEQSELVI due to a patent infringement case filed by Incyte Corporation. Sun Pharma plans to appeal this decision while adhering the injunction. In July 2024, the US FDA approved LEQSELVI (deuruxolitinib) 8 mg tablets for treatment of severe alopecia areata in adults. A patent infringement suit seeking preliminary injunction was filed by Incyte Corporation and Incyte Holdings in a US District Court of New Jersey to prevent the launch of LEQSELVI ([Source](#)).

Logical Fallacy in Patent Law: Analyzing Abolkheir's Challenge to the Soundness of Non-obviousness Test

Contributor: Subin Khullar

Nov' 24: Dr. Mo Abolkheir, in his recent work published in the Journal of Intellectual Property Law and Practice, argues that the current interpretation of 'inventive steps' in patent law places undue emphasis on the inventor's imaginative capacity rather than the invention itself. He identifies this as a logical fallacy, which he terms "inventio ad hominem." Bhuwan Sarine, a third-year law student, analyzes this perspective, noting that patent laws inadvertently assess the inventor's cognitive skills instead of focusing solely on the invention. This subjective approach complicates patentability assessments and increases the risk of post-grant invalidation. Abolkheir suggests reforms, including a half-causation framework, to address this issue. However, critics argue that his analogy and proposed solutions may not be entirely practical, as the inventor and invention are inherently linked. Despite these criticisms, Abolkheir's work sparks a necessary discussion on potential reforms in patent law, especially with the increasing influence of AI, highlighting the need for a more objective assessment mechanism ([Source](#)).

Senate Judiciary Subcommittee Holds Back Two Key Patent Reform Bills

Contributor: Eeshan Mishra

Nov' 24: The US Senate Judiciary Subcommittee on Intellectual Property advanced the Inventor Diversity for Economic Advancement (IDEA) Act, aimed at reforming the patent system. Sponsored by Senator Mazie Hirono, the IDEA Act has bipartisan support and mandates the US Patent & Trademark Office to voluntarily collect demographic data from US patent inventors, with confidentiality safeguards and biannual reports to Congress. Additionally, the subcommittee considered the Patent Eligibility Restoration Act (PERA) and the Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act, both sponsored by Senators Christopher Coons and Thom Tillis. PERA seeks to revise patent eligibility standards, while the PREVAIL Act proposes changes to post-grant and inter partes review proceedings. Although these bills are progressing, they are unlikely to become law before the new Congress begins in January 2025 ([Source](#)).



INDUSTRY NEWS

Asia Leads the Charge in Global IP Filings: Latest WIPO Report

Contributor: Mukesh Kumar

Nov' 2024: The World Intellectual Property Organization (WIPO) recently published its 2023 report, highlighting a significant rise in global patent filings. China led the way with 1.64 million applications, and Asian nations collectively received two-thirds of all patent filings, underscoring the region's dominance in intellectual property. India showed remarkable growth, with a 15.7% increase in patent filings, while the United States, Japan, and Korea also ranked among the top five. The report also noted strong performances in trademarks and industrial designs, with China maintaining its lead in both categories. Global trademark filings returned to pre-COVID-19 levels, and industrial design filings saw a 4% increase. The report emphasized the importance of Asian IP offices in the global landscape, with China, Korea, and Japan contributing significantly to the overall growth. Additionally, the United States remained the top country for patent applications filed abroad, continuing its leadership in this area since 2013 ([Source 1](#); [Source 2](#)).

INDUSTRY NEWS

USPTO Bans In-House GenAI Use Amid Security Concerns

Contributor: Christy George

Nov' 24: The U.S. Patent and Trademark Office (USPTO) has banned staff from using generative artificial intelligence (GenAI) tools due to security concerns and issues like bias and unpredictability. This ban, effective since April, restricts employees from using tools such as OpenAI's ChatGPT for work tasks. However, staff can use state-of-the-art GenAI models within the AI Lab for testing and prototyping. Jamie Holcombe, USPTO's CIO, emphasized the agency's commitment to innovation while ensuring responsible AI use. USPTO joins other federal agencies in promoting proper AI usage, aligning with efforts to address algorithmic bias and security risks. The ban also prohibits using AI-generated outputs like images or videos, although some approved AI programs are allowed for specific tasks, such as searching the agency's public database ([Source](#)).

EU Commission Imposes First-Ever Fine for Patent Misuse and Disparagement: Teva Fined €462.6 Million

Contributor: Dinesh Sharma

Nov' 24: The European Commission fined Teva €462.6 million for abusing its dominance with the drug Copaxone. Teva misused patent procedures by filing and withdrawing divisional patents to extend protection, creating barriers for competitors and delaying market entry. Additionally, Teva conducted a disparagement campaign against a competing product, spreading unfounded safety concerns. This is the first time the Commission has fined for both types of conduct, emphasizing its stance against practices that hinder competition and delay access to affordable medicines. Teva plans to appeal, arguing the decision is based on extreme and unsupported legal theories ([Source](#)).

Fujitsu Wins Japan Patent Office Commissioner's Award

Contributor: Brahmadev Sharma

Nov' 24: Fujitsu's invention for accelerating scientific computing has won the Japan Patent Office Commissioner's Award at the 2024 Kanto Regional Commendation for Invention. Developed in 2009, this technology enables high-speed, high-precision scientific computing by reducing the number of instructions required for preprocessing mathematical functions. This innovation has been utilized in the K computer and the supercomputer Fugaku, as well as in Arm®-based server products ([Source](#)).

TECHNO-SPOTLIGHT

NIH Develops AI Tool to Streamline Clinical Trial Matching for Patients

Contributor: Ganesh B

Nov' 24: Researchers at the NIH have created TrialGPT, an AI algorithm that efficiently matches patients with relevant clinical trials. By analyzing patient summaries and ClinicalTrials.gov listings, TrialGPT identifies and ranks suitable trials, providing detailed enrollment explanations. It matches the accuracy of human clinicians while reducing screening time by 40%. This tool could speed up clinical trial recruitment, improve access for underrepresented populations, and enhance medical research. Further real-world assessments are planned to ensure its fairness and effectiveness ([Source](#)).

Big Pharma Companies Doubles Down on China

Contributor: Rani Holani

Nov' 24: With its announcement to invest \$1 billion in China by 2030, Pfizer has joined other pharmaceutical giants like Eli Lilly, Bayer, and Roche in expanding their presence in China.

The company plans to introduce 60 innovative drugs and new indications to Chinese patients by 2030, collaborating closely with local stakeholders to enhance access to essential medicines and vaccines.

These investments underscore a rare positive development in the Chinese market ([Source 1](#), [Source 2](#)).

Sanofi Joins J&J, Eli Lilly in Proposing 340B Rebate Model

Contributor: Rani Holani

Nov'24: Sanofi plans to introduce its own rebate model for 25 drugs, including the high-selling anti-inflammatory injectable Dupixent, starting early next year.

With this model, Sanofi is following the example of J&J and Lilly, both of which filed lawsuits against the federal government this month after the Health Resources and Services Administration (HRSA), which oversees the 340B program, took action to block their rebate plans.

HRSA has recently received inquiries from manufacturers regarding various proposed rebate models for the 340B Program. HRSA is currently reviewing these inquiries, which could significantly and unilaterally change the administration of the program. Congress is currently considering potential reforms to the 340B program, which may include requiring hospitals to be more transparent about how they utilize the savings from the program.

The 340B Drug Pricing Program is a U.S. federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices. The goal of the program is to enable these entities, which typically serve vulnerable and underserved populations, to stretch their resources further, thereby increasing access to medications and comprehensive healthcare services for patients in need ([Source](#)).

L&T Technology Services Deepens Software Product Development, Platform Engineering & AI Expertise

Contributor: Mukesh Kumar

Nov' 24: L&T Technology Services Limited (LTTS) has agreed to acquire Silicon Valley-based Intelliswift to enhance its offerings in Software Product Development, Platform Engineering, Digital Integration, Data, and AI. Intelliswift serves 4 of the top 5 hyperscalers and over 25 Fortune 500 companies. This acquisition will enable LTTS to expand into Retail and Fintech markets and strengthen its AI and software capabilities for global clients. The move supports LTTS' goal of reaching USD 2 billion in the medium term and boosts its presence in Silicon Valley. The acquisition will provide innovative advancements and end-to-end automation solutions, benefiting LTTS' strategic client partnerships and enhancing its digital engineering suite ([Source](#)).

Fujitsu Develops Policy Twin, A New Digital Twin Technology

Contributor: Mukesh Kumar

Nov' 24: Fujitsu has developed Policy Twin, a digital twin technology designed to enhance the effectiveness of local government policies in societal issues. This technology simulates the social impact of policies, identifying measures that double both cost savings and health improvements in preventive healthcare trials. Policy Twin converts written policies into machine-readable flowcharts, generates new policy candidates, and simulates their outcomes using machine learning. Field trials demonstrated significant improvements in medical expense savings and health outcomes. Fujitsu plans to offer Policy Twin for municipal preventive healthcare services starting December 6, 2024, and aims to launch a broader service for the healthcare sector by fiscal year 2025 ([Source](#)).

Muddy Machines Acquires Key Assets and IP from Fox Robotics

Contributor: Atul Kumar Pal

Nov' 24: Muddy Machines Ltd. has acquired key assets and intellectual property from Fox Robotics Ltd., enhancing its lineup of autonomous agricultural robots. The acquisition includes the Hugo RT platform, now renamed Squirrel, which autonomously transports materials on farms with a 200 kg payload. This complements Muddy Machines' existing robot, Sprout, designed for precision agriculture tasks like weeding, planting, and spraying. The integration aims to address labor challenges in horticulture, increasing worker productivity and operational efficiency. This strategic move positions Muddy Machines to offer a comprehensive suite of robotic solutions, benefiting the horticulture sector by improving efficiency and reducing labor dependency ([Source](#)).

DXC Technology and ServiceNow Extend Strategic Partnership to Fast-track Generative AI Value for Businesses

Contributor: Mukesh Kumar

Nov' 24: DXC Technology has extended its strategic partnership with ServiceNow to accelerate generative AI (GenAI) adoption for businesses globally. They have established a Center of Excellence (CoE) combining DXC's industry expertise with ServiceNow's GenAI solutions to streamline AI implementation. This initiative aims to help customers quickly realize value from AI investments, optimize technology performance, and enhance efficiency. The partnership has already saved DXC nearly 10,000 hours monthly in IT operations. This collaboration is expected to drive significant business transformation and improve customer experiences across various industries ([Source](#)).



IT Investments and Larger Budgets are a Priority for CPG Tech Leaders in 2025

Contributor: Apoorv Nayal

Nov' 24: Consumer Goods Companies are set to revamp their IT Infrastructure across the globe in 2025. Key transformative steps that are expected to be followed across the industry include:

Strengthening the Supply Chain: a lot of emphasis has been put on improving supply chain resilience via planning and data driven insights to tackle challenges like inflation and disruption.

Tech-enabled Experience and Manufacturing: The leadership is focusing to improve personalization options for the customer as well as using advanced practices for smart manufacturing.

Modernizing ERP: To further improve business agility and operational efficiency, leaders are set to take measures to improve the dated back-office systems ([Source](#)).

Coca Cola Takes a Step Back by Introducing its New 2035 Packaging Sustainability Targets

Contributor: Apoorv Nayal

Dec' 24: Coca Cola announced its new 2035 sustainability goals which are focused more on packaging design and collection after use. These goals replace the previous 2025 and 2030 targets related to recyclability, recycled content and reusable packaging.

The company's updated goals aim to incorporate 35-40% recycled material in primary packaging (plastic, glass and aluminum), including increasing the recycled plastic use to about 30-35% globally. It also focuses on partnering to collect used packaging. The beverage company aims to ensure the collection of 70-75% of the equivalent number of bottles and cans introduced into the market annually.

Earlier this year, Coca Cola's ardent competitor, PepsiCo also conveyed that it was highly unlikely to accomplish its 2025 goal of re-designing its entire packaging to be biodegradable, reusable compostable and recyclable ([Source](#)).

P&G Overhauls its Supply Chain for its Gillette Razors with Sourcing from India

Contributor: Apoorv Nayal

Dec' 24: Gillette has strategically decided to source its Steel for Razors from India. It is expected to procure the same from Jindal Stainless. The move is expected to help the company counter the possible US tariffs.

Jindal's Steel is generally more affordable as compared to its Japanese and Swedish alternatives. This move is also speculated to boost company's margins and profits. Jindal Stainless has been manufacturing the material for almost two decades for multiple Indian Clients.

Interestingly, Grooming is P&G's smallest business by revenue and has struggled for years. And sales of the product had declined during the pandemic as men had a behavioral shift. They grew beards and shaved comparatively less times a month when compared to earlier years ([Source](#)).

Rajasthan-based New D2C Brand, Little Indian Spice on Track to 10x its Revenues in a Year

Contributor: Saumya Jaithlia

Nov' 24: Picklepreneur, Sonu Saini worked with the State Bank of India for a decade while noticing and realizing that many of her colleagues and friends craved for the authentic taste of homemade pickles.

She capitalized on the opportunity with the help of iStart Rajasthan, a state led program helping local entrepreneurs with funding, infrastructure, mentorship and networking opportunities. The Brand was launched in August 2023 and delivered INR 15 Lakhs of revenue in FY24. It is all set to cross INR 1.5Cr in the current Financial Year.

The D2C Brand has a portfolio of 17 SKUs with the help of a workforce of women belonging to six different states of India. It offers desi flavors in the form of regional specialties from Bihar, Rajasthan, Punjab, Gujarat, Maharashtra and Madhya Pradesh ([Source](#)).



High-Flying Hazards: Health Risks of Aircraft Engine Emissions

Contributor: Akshay Jawale

Nov' 24: Aircraft engine emissions (AEE) are complex mixtures from burning kerosene, containing various chemicals and fine particles. A Dutch National Institute for Public Health and the Environment (RIVM) report raises concerns about the mutagenic and carcinogenic potential of AEE, particularly for airport workers. The report identifies 21 substances within AEE classified as mutagenic and/or carcinogenic under European legislation. Although AEE itself is not currently classified as such, the Health Council of the Netherlands is evaluating its properties to advise on potential classification and protective measures for workers ([Source](#)).

FDA Approves First Gene Therapy for Rare AADC Deficiency - A Treatment Milestone

Contributor: Megha Walia

Nov' 24: The US FDA has approved Kebilidi (eladocagene exuparvovec-tneq), the first gene therapy for aromatic L-amino acid decarboxylase (AADC) deficiency in adults and children. This treatment targets a rare genetic disorder that disrupts neurotransmitter production and leads to severe motor and cognitive delays. Administered through four infusions in a specialized surgical setting, Kebilidi has shown significant improvements in gross motor function during clinical trials. The FDA's approval under the Accelerated Approval pathway reflects its commitment to treating rare diseases. A study of 13 pediatric patients demonstrated safety and effectiveness, with improvements noted in 8 of the 12 treated individuals ([Source](#)).

FDA Greenlights J&J's Revolutionary VARIPULSE™ Platform for AFib Treatment

Contributor: Sakshi Kumari

Nov' 24: J&J's MedTech announced FDA approval of the VARIPULSE™ Platform for treating drug-refractory paroxysmal Atrial Fibrillation (AFib). The platform integrates PFA therapy with the CARTO™ 3 System, enhancing ablation accuracy, safety, and efficiency. Supported by the admIRE study, the platform achieved high procedural success and minimal adverse events. This approval offers a comprehensive solution for AFib treatment, benefiting millions affected by the condition ([Source](#)).

LMU Researchers Identify Key Protein Interaction Driving Melanoma Growth and Metastasis

Contributor: Ganesh B

Nov' 24: LMU researchers have uncovered how the interaction between the ion channel TPC2 and the protein Rab7a promotes melanoma growth and metastasis. Mutations enhancing TPC2 activity are linked to increased melanoma risk, while its loss reduces tumor development. Using advanced techniques, the team demonstrated that Rab7a amplifies TPC2 activity, destabilizing proteins essential for tumor regulation. In mouse models, the absence of Rab7a or TPC2 significantly reduced tumor size and spread. This discovery offers a potential therapeutic target for combating melanoma by disrupting these molecular pathways ([Source](#)).



FDA Proposes Ending Use of Oral Phenylephrine as OTC Nasal Decongestant: What's Next for Consumers?

Contributor: Sakshi Kumari

Nov' 24: The FDA proposes removing oral phenylephrine from OTC monograph drugs for nasal congestion, citing ineffectiveness based on a comprehensive review and unanimous advisory committee conclusion. This proposal does not affect phenylephrine's safety profile or its use in nasal sprays. Public comments are invited before finalizing the order, after which manufacturers will need to reformulate or remove affected products ([Source](#)).

FFDA Drops New Roadmap for Oligonucleotide-Based Therapeutics: Next-Gen Safety Protocols

Contributor: Basharat Ahmad Sofi

Nov' 24: The FDA has released draft guidance on nonclinical safety assessments for oligonucleotide-based therapeutics (ONTs), addressing unique challenges in their evaluation. It applies to single- and double-stranded ONTs, such as antisense, RNA, and aptamer therapies, while excluding vaccine-related products. The guidance outlines two key safety approaches: assessing on-target effects, including pharmacological activity risks, and off-target hybridization effects, where ONTs may bind unintended RNA or DNA sequences, potentially causing adverse effects. Recommendations include *in silico* and *in vitro* methods, alongside broader evaluations of pharmacology, toxicity, and carcinogenicity. This guidance provides a comprehensive framework, reflecting ONTs' distinct complexities and the FDA's evolving regulatory approach ([Source](#)).

Human Fertility at Risk: How Everyday Pollution Affects Reproductive Health

Contributor: Mayank Kakkar

Oct' 24: Environmental pollutants disrupt reproductive health by affecting hormonal balance and fertility. Research links higher pollution levels to increased infertility risks, with noise pollution especially impacting women over 35. Mitigating these challenges requires awareness, education, and proactive lifestyle changes to protect reproductive well-being ([Source](#)).

Veratrine Passes EPA Safety Review

Contributor: Hansrabha Mudgal

Oct' 2024: The EPA's Health Effects Division has completed its evaluation of veratrine, a new insecticide ingredient, finding no significant human health risks for its proposed uses despite observed toxicological effects like body weight changes and locomotor issues. An addendum also updated spray drift risk estimates, reinforcing the EPA's commitment to safety and efficacy. This marks a key step toward veratrine's potential approval, offering a promising new option for effective, sustainable pest management ([Source 1](#); [Source 2](#)).



Hyundai Motors Unveils New Hydrogen Car in Bet on Clean Fuel's Future

Contributor: Nitesh Kumar

Oct' 2024: Hyundai Motor Co. unveiled the Initium, a new hydrogen-powered vehicle with a target range of over 650 kilometers, set for release in the first half of next year. The Initium surpasses the Nexō's 609-kilometer range and can connect to a household's electricity supply as a backup power source. Despite challenges in hydrogen production and storage, Hyundai is committed to advancing this carbon-free fuel alternative ([Source](#)).

Viasat Joins 5G Automotive Association to Support Satellite-Enabled Autonomous Vehicles

Contributor: Nitesh Kumar

Nov' 2024: Viasat, Inc. has joined the 5GAA to enable connected transport applications like autonomous vehicles and predictive safety. The 5GAA unites automotive and technology companies to create a unified connectivity ecosystem, known as C-V2X, allowing real-time interaction between vehicles and their surroundings. Viasat is developing a direct-to-device ecosystem to complement its global satellite network, enhancing travel, reducing pollution, and increasing road safety through advanced connectivity solutions ([Source](#)).

LG's Innovative Vehicle AR Technology Recognized at 2024 Technology Patent Awards

Contributor: Nitesh Kumar

Nov' 2024: LG Electronics won the "King Sejong Award" at the 2024 Technology Patent Awards for its pioneering augmented reality (AR) technology for vehicles. This AR system, patented in 2022, enhances driving by providing 3D graphics for vehicle information and navigation on in-vehicle displays. It integrates data from various sensors and external sources to predict hazards and improve safety. LG aims to develop future mobility solutions and generate royalty-based revenue from this technology ([Source](#)).

Stellantis Patents Innovative Multifunction Hood for EVs

Contributor: Nitesh Kumar

Dec' 2024: Stellantis has patented a new multifunction hood design for electric vehicles (EVs), enhancing accessibility and ergonomics for the front cargo compartment, or "frunk." The hood opens at angles of 90° to 120°, providing superior clearance for loading. The design includes various door configurations, such as dual longitudinal, bifold, and roll-up doors, ensuring unobstructed entry. This innovation complements Ram's multifunction tailgate and addresses EV-specific needs, improving user safety and accessibility ([Source](#)).





New SEP Resource Hub - UK Unleashes its Innovative Potential

Contributor: Christy T George

Nov' 24: The UK Intellectual Property Office (UKIPO) launched the Standard Essential Patent (SEP) Resource Hub in 2024 to address complexities in SEP licensing and FRAND terms. The hub aims to improve understanding, transparency, and efficiency in SEP dealings, particularly for SMEs, by providing a centralized 'one-stop shop' for information and guidance on SEPs and FRAND licensing. Initial reactions are positive, with the hub being user-friendly and informative. While it has made strides in demystifying SEP and FRAND licensing, its long-term impact remains to be seen. Continued support from stakeholders is essential for its ongoing development and effectiveness ([Source](#)).

A Glimpse Behind the Curtain Part Three: An Industry Perspective on Commercial Discussion Phase of an SEP Licensing Negotiation

Contributor: Chandandeep Kaur

Nov' 24: The commercial discussion phase of SEP licensing negotiations involves various international guidelines. Under the Huawei v ZTE framework in the EU, the SEP holder must provide a FRAND offer, and the implementer must respond diligently. The European Commission emphasizes strict sequential order. In China, the ACT v Oppo ruling considers factors like disclosure of licensing price calculations. The UKIPO stresses good faith negotiations. Japan's METI guidelines require specific FRAND offers and counteroffers. The US Draft Policy Statement advocates good faith engagement. Challenges include transparency, regional royalty rate differences, patent privateering, and unreasonable terms. Successful negotiations require sincerity and transparency to avoid litigation ([Source](#)).

China Introduces Regulation on Standard Essential Patents

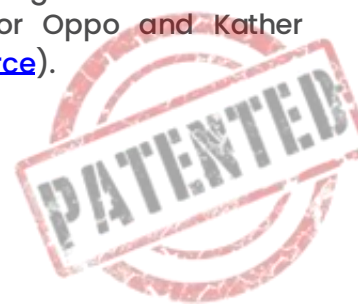
Contributor: Chandandeep Kaur

Nov' 24: China's State Administration for Market Regulation (SAMR) has issued guidelines to prevent the misuse of standard essential patents (SEPs) to restrict competition. The guidelines aim to promote fair market competition and protect innovation by regulating SEP holders' antitrust behavior, encouraging good faith negotiations, and scrutinizing standardization agreements. The guidelines address emerging issues and balance innovation protection with fair competition ([Source](#)).

Oppo Infringed Panasonic SEP says Local Division Mannheim in First FRAND Ruling

Contributor: Chandandeep Kaur

Nov' 24: The UPC's local division in Mannheim has issued its first FRAND ruling, banning Oppo from selling certain 4G-enabled devices in several European countries and ordering provisional damages of €250,000. Despite a pending settlement between Panasonic and Oppo, the court ruled that Oppo infringed Panasonic's SEP and dismissed Oppo's FRAND counterclaim. The detailed 26-page judgment addresses FRAND compliance and rate-setting, referencing the CJEU's Huawei vs ZTE ruling and other relevant cases. This ruling is significant for future FRAND proceedings at the UPC. Oppo can appeal, and Panasonic must deposit a security for the ruling to take effect. The legal teams involved include Vossius & Brinkhof for Oppo and Kather Augenstein for Panasonic ([Source](#)).





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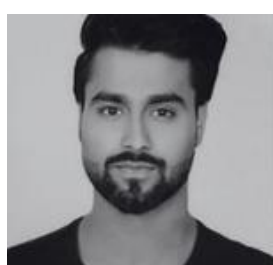
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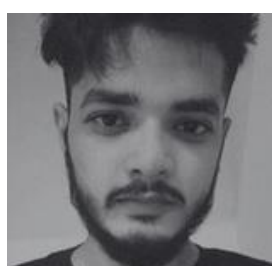
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