IPR&D SPARK NEWSLETTER

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IPR&D Spark Newsletter aims to spark your creativity, ignite your curiosity, and keep you informed on industry trends, legal updates, and insightful analyses. Dive in and explore the fascinating world of IP and R&D with us! This newsletter isn't just about staying informed; it's about fostering a community of passionate minds.

Share your ideas at: <u>Iprdsparknewsletter@evalueserve.com</u>, or directly reach out to our Newsletter team members mentioned below and let's navigate the ever-evolving landscape of IP and R&D together.









LEGAL WATCH

Patent Term Adjustment and Obviousness - Type Double Patenting

Contributor: Christy T George

Apr' 2024: The Federal Circuit's decision in In re Cellect, LLC in August 2023 has raised an important question regarding the relationship between the patent term adjustment (PTA) statute, 35 U.S.C. § 154(b), and the doctrine of obviousness-type double patenting (OTDP). Cellect has now filed a petition for an extension of time and intends to seek Supreme Court review. The fundamental issue in Cellect revolves around whether a patentee must give up their PTA term extensions to avoid an OTDP invalidity finding. This situation arises when a patentee has two patents that cover slightly different inventions (<u>Source</u>).



Costa Rica's Vaping Ban Faces Legal Twist: Court Orders Regulation Deadline

Contributor: Hansprabha Mudgal

Jul' 24: Costa Rica's Constitutional Chamber has overturned the Ministry of Health's **ban on vaping devices**, requiring regulation within two months. Minister Mary Munive had imposed the ban due to health risks and aims to finalize regulations by December. Synthetic nicotine and CBD vapes remain banned. The affected company, facing losses, won't seek damages. This ruling is pivotal for Costa Rica's vaping industry, awaiting regulatory updates (<u>Source</u>).

Patent Battle in Pharma: Mayne Pharma Files Lawsuit Against Sun Pharma Over IMVEXXY

Contributor: Harjinder Singh

Jul' 24: **Mayne Pharma** has sued **Sun Pharma** in New Jersey for infringing on 20 patents related to IMVEXXY, a vaginal insert for menopause-related pain. Mayne Pharma's action follows Sun Pharma's submission of an ANDA to the FDA for a generic version. Sun Pharma's Paragraph IV certification has triggered a 30-month FDA approval stay. **IMVEXXY**, approved in 2018, is distributed by **TherapeuticsMD** (<u>Source</u>).

Indian Patent Office prefers public health over profits Contributor: Ashmita Bera

Jul' 24: The Office has rejected J&J's patent application for the paediatric formulation of Bedaquiline. This rejection came because of a patent challenge initiated in 2019 by the Delhi Network of Positive People (DNP+) and a Mumbai-based tuberculosis (TB) organization. If the patent had been granted, J&J would have had control over the drug's market for an additional four years. However, the pressure from the pre-grant opposition was effective and J&J would not enforce patents on the drug in 134 low- and middle-income countries, allowing the drug to be supplied to the Global Drug Facility (<u>Source</u>).



INDUSTRY NEWS

USPTO and UKIPO Join Forces to Foster Fairness and Transparency in Standard Essential Patents Contributor: Christy T George

Jun' 24: The US Patent and Trademark Office (USPTO) and the UK Intellectual Property Office (UKIPO) have signed a memorandum of understanding (MOU) to collaborate on standard essential patents (SEPs). Under the agreement, the two offices will cooperate on activities to promote a balanced standards ecosystem and exchange information on policy matters related to SEPs. They will also explore ways to educate small and medium-sized enterprises on fair and non-discriminatory terms for implementing technical interoperability standards. Improving transparency in licensing and engaging stakeholders to raise awareness of SEP issues are additional goals. The agreement will be effective for five years and may include discussions on incorporating other jurisdictions. This collaboration aims to benefit businesses, including SMEs and new market entrants, in both countries (Source).

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Industry News

Technology sharing for "standards-related activities" no longer subject to US export controls

Contributor: Mudit Mittal

Jul' 24: The US Commerce Department's Bureau of Industry and Security (BIS) has issued amendments to the Export Administration Regulations (EAR) that redefine the scope of "standards-related activities" subject to US export controls jurisdiction to ensure that US export controls do not impede the participation of US companies in legitimate standards related activities. The interim final rule amended the EAR to authorize the release of specified items subject to the EAR for standards-related activities. BIS has requested public comments on the amendments (<u>Source</u>).

India and UK Launch 'Technology Security Initiative' to Strengthen Partnership in Critical and Emerging Technologies Contributor: Mukesh Kumar

May' 24: India and the UK are launching a 'Technology Security Initiative' (TSI) to enhance their strategic partnership. The TSI will focus on collaboration in critical and emerging technologies across priority sectors, building on existing mechanisms and establishing new ones. The initiative will be coordinated by the National Security Advisors of both countries, with regular reviews at the Deputy NSA level. The TSI aims to strengthen partnerships, promote trade, and address licensing and regulatory issues. It will cover areas such as telecoms, critical minerals, semiconductors, artificial intelligence, quantum, biotechnology, and advanced materials (<u>Source</u>).

UK Implements Border Target Operating Model (BTOM) Requiring Health Certificates for EU Imports of Medium- and High-Risk Products Contributor: Kanika Banga

Feb' 24: UK implements Border Target Operating Model (BTOM) requiring health certificates on imported on imported medium- and high-risk products from EU such as meat, dairy, fruit, vegetables, and plants, raising concerns about disruptions and reduced product choices. The added costs of border checks and certification requirements could lead to reduced product choices for consumers. However, some believe the regulations will help UK farmers be more competitive (<u>Source</u>).

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Techno-Spotlight



Material that Can Transform Sunlight and Water into Clean Energy **Contributor: Rachna Gupta**

Jul' 24: Oregon State University researchers have developed a new photocatalyst that efficiently produces hydrogen from sunlight and water, offering a sustainable and potentially costeffective alternative to traditional fossil fuel-based hydrogen production methods.

This catalyst, developed through a combination of metal-organic frameworks and metal oxides, represents a significant advancement in the production of clean energy. It holds promise for reducing greenhouse gas emissions and climate change. The photocatalyst structure is based on MOF-derived metal oxide heterojunction (<u>Source</u>).

Key M&A/Strategic Alliances **Contributor: Rachna Gupta**

Aug' 24 (<u>Source 1</u>):

• BP expands its offering in European gas, power and integrated energy solutions with the acquisition of GETEC ENERGIE GmbH

Jul' 24 (<u>Source 2; Source 3; Source 4</u>):

- · Audi and bp are in a new strategic partnership in Formula 1. As Audi prepares to enter the pinnacle of motor racing in 2026, bp and Castrol will develop sustainable fuel and lubricants for Audi's V6 turbo engine and EV fluids for the electric motor and battery.
- UPM Raflatac has acquired Grafityp, a Belgianbased company to further accelerate its growth in graphics.
- · Unilever partners with Samsung to explore the future of laundry with more speed and agility than ever before.

Toxic Compounds – Disrupting Vital Human proteins

Contributor: Rachna Gupta

Jul' 24: Nanoplastics and per- and polyfluoroalkyl substances (PFAS) present in everyday products significantly alter proteins essential for human development, potentially leading to developmental defects and other health issues. While nanoplastics originate primarily as a result of the degradation of larger plastic materials, like water bottles and food packaging, forever chemicals are found in various products like cookware and clothing (Source).

Dark Oxygen – What if it could solve all of our energy problems? **Contributor: Rachna Gupta**

Jul' 24: 4,000 meters below sea level, scientists have found the spectacular 'Dark Oxygen. Scattered across an abyssal plain known as the Clarion-Clipperton Zone (CCZ) are polymetallic nodules which can produce "dark oxygen" acting as a "geobattery" by separating hydrogen and oxygen via seawater electrolysis where light cannot reach. These nodules are also referred as "battery in a rock." by mining companies (<u>Source</u>).



Industry-academia Collaborations to Shape **Future** Contributor: Rani Holani

Jul' 24: Industry-academia collaboration is crucial for innovation, a competitive edge, diversity, and developing a high-growth ecosystem. The Berlin Center for Gene and Cell Therapies, a joint initiative by Bayer AG and Charité - Universitätsmedizin Berlin aims to accelerate the development of innovative treatments for diseases (Source 1).

Danaher launched Beacon Research Collaboration with Stanford University aiming to build next generation of smart microscopes for cancer drug screening (<u>Source 2</u>).

University of Oxford and Apollo Therapeutics entered into drug discovery and development collaboration for cancer and autoimmune diseases (Source 3).

Antidote for Cobra Bites Discovered Using **CRISPR** Technology

Contributor: Mahima Gupta

Jul' 24: Current antivenom treatment is expensive and does not effectively treat the necrosis of the flesh where the bite occurs. Researchers from the University of Sydney and Liverpool School of Tropical Medicine have discovered that heparin, a widely used blood thinner, can be repurposed as a cost-effective antidote for cobra venom. Using CRISPR gene-editing technology to identify ways to block cobra venom, the team successfully repurposed heparin (a common blood thinner) and related drugs and showed they can stop the necrosis caused by cobra bites (<u>Source</u>).

One Drop Unlocks a Wealth of Health **Secrets**

Contributor: Aparajita Basu

Jul' 24: A team of scientists at Ludwig-MaximiliansUniversität München (LMU) and the Max Planck Institute of Quantum Optics (MPQ) in collaboration with Helmholtz Zentrum München, has created a new health screening tool using a combination of infrared light and machine learning. This innovative tool, developed, can detect multiple health conditions with just a single measurement. It analyzes blood to create a unique "fingerprint." By analyzing the infrared fingerprint combined with machine learning, of the blood plasma samples, to simultaneously detect commonly occurring chronic conditions and noncommunicable diseases (Source).

Root Cause of Lupus Contributor: Pranjal Gupta

Jul' 24: The study led by researchers at Northwestern University and Brigham & Women's Hospital have conducted a study to understand the underlying mechanisms of lupus and identify a way to potentially treat the autoimmune disease. A protein called interferon is main cause for the T-cell imbalance. Too much interferon blocks protein called the aryl hydrocarbon receptor, which helps regulate how the body responds to bacteria or environmental pollutants, that likely leads to the disease. The study received grant funding from Merck Sharp & Dohme and Janssen Research & Development (Source).



Oppo and Ericsson Sign a 5G Patent Cross-Licensing Deal Contributor: Mukesh Kumar

Jul' 24: Oppo and Ericsson have signed a global cooperation agreement on 5G patent crosslicensing. Under the multiyear deal, Oppo will pay royalties to use Ericsson's 5G technology in its future devices.

The partnership also includes cooperation on device testing and marketing activities. The agreement allows Oppo to establish a healthy intellectual property portfolio, and both companies aim to resolve any IP disputes through friendly negotiation.

Ericsson sees the deal as an opportunity to further invest in fundamental communications technologies. This announcement follows Oppo's settlement of a 5G patent dispute with Nokia, and it aligns with the trend of resigning existing partnership deals in the industry (<u>Source</u>).

Global IT Infrastructure Paralyzed: The Fallout of CrowdStrike's Faulty Software Update Contributor: Christy T George

Jul' 24: A faulty software update from cybersecurity company CrowdStrike caused widespread disruption, affecting 8.5 million devices worldwide. The incident, labeled as one of the most severe IT failures in history, impacted businesses, governments, and individuals. The comparison was made to a car's engine, where bad fuel can cause cascading issues throughout the system. Similarly, CrowdStrike's software operates at a deep level within Windows, and a problem with their update had far-reaching consequences (<u>Source</u>).

Meta Turns to an Old Strategy to Boost New Al Business Contributor: Subin Khullar

Jul' 24: Meta, formerly Facebook, has released Llama 3.1, an open-source AI model. By making it freely available, Meta aims to foster an ecosystem of developers and users while potentially disrupting competitors closed-source models. While there may be long-term financial benefits, Meta has incurred significant costs in developing Llama (<u>Source</u>).

Samsung's Patent Reveals Horizontally Rollable Tablet with Dynamic Resizing Display Contributor: Mukesh Kumar

Jul' 24: Samsung's patent filing reveals a horizontally rollable tablet with a dynamically resizing display. The device can extend its screen using rolling actuators, adjusting its size based on user interactions and connected peripherals. The tablet's dedicated processor enables it to detect peripheral devices and expand the flexible display accordingly (<u>Source</u>).



Scandinavian Tobacco to acquire Mac Baren **Contributor: Neha Negi**

Jun' 24: Scandinavian Tobacco Group (STG) has agreed for the acquisition of all the shares of Mac Baren Tobacco Co. from Halberg. On a debt and cashfree basis, the transaction is valued at \$76.87 million. Mac Baren is a global smoking tobacco company. The company also produces and sells nicotine pouches with the brands ACE and GRITT (Source).

Zimbabwean Firm to Turn Leaf Waste into **Agrochemicals**

Contributor: Neha Negi

Jul' 24: African Extracts of Zimbabwe is looking to process tobacco scraps into fertilizer and agricultural chemicals. The million-dollar project is set to begin production in August (<u>Source</u>).

KT&G to Release New Heat Not Burn Device "Lil Able 2.0" **Contributor: Neha Negi**

Jun' 24: The new HNB device by the South Korean tobacco company KT&G is equipped with three different types of cigarette sticks, including "Real," "Granule," and "Vapor Stick," and comes with two usage modes, "Balance Mode" and "Classic Mode." Additionally, the device also includes a "Pause" function, allowing users to pause for up to 2 minutes during each use (Source).

rescinds JUUL FDA ban on product applications **Contributor: Neha Negi**

Jun' 24: The Food and Drug Administration (FDA) has rescinded the marketing denial orders (MDOs) for Juul Labs Inc. regarding all of the company's products marketed in the United States. This action is being taken, in part, as a result of the new case law, as well as the FDA's review of information provided by the applicant. Rescission of the MDOs is not an authorization or a denial and does not indicate whether the applications are likely to be authorized or denied (<u>Source</u>).

R.J. Reynolds Vapor Company expands portfolio with introduction of SENSA, a Zero Nicotine option for adult tobacco and Vapor consumers **Contributor: Neha Negi**

Jun' 24: SENSA products include a locking feature to prevent unintended usage, and adult consumers of the device will have access to Call2Recycle's battery recycling program, which will facilitate the responsible disposal of SENSA batteries. The SENSA portfolio of flavors is intended for adult tobacco and vapor consumers and does not include flavors intended to appeal to the underage. The product will be responsibly marketed to adult tobacco and vapor consumers, consistent with the Reynolds American organization's marketing practices for tobacco and nicotine products (<u>Source</u>).



EU's Supply Chain Reform Contributor: Kanika Banga

Jul' 24: The European Union has introduced a new supply chain law, known as the "Corporate Sustainability Reporting Directive" (CSRD). It aims to increase transparency and accountability in the supply chain by requiring companies to disclose their environmental and social impacts.

This includes information on their supply chain risks, including human rights, labor standards, and environmental concerns.

The CSRD is expected to have a significant impact on UK businesses, particularly retailers and manufacturers that rely on global supply chains. Companies will need to conduct thorough due diligence on their suppliers to ensure compliance with the new regulations.

The CSRD is part of the EU's broader efforts to promote sustainability and combat climate change. The law is expected to be implemented in the UK after Brexit, despite the country's departure from the EU (Source).

MACH: Future-Ready Tech Infrastructure Contributor: Tejasvi Sinha

Jul' 24: The consumer goods industry is undergoing a technological transformation, with companies investing in modern tech infrastructures to stay competitive. The MACH architecture, defined by four key principles (Microservices, API-first, Cloud-native SaaS, and Headless), is gaining traction as a flexible and futureready approach. MACH Alliance, a not-for-profit industry body reports, 40% of consumer goods manufacturers are dedicating a portion of their IT budgets to become more composable. Companies like Kraft Heinz, Reckitt, and Mars have already implemented MACH-based tech stacks, resulting in improved e-commerce capabilities and omnichannel engagement (Source).

PepsiCo & Yara Join Forces Contributor: Simmi Kapoor

Jul' 24: PepsiCo Europe has announced a new partnership with Yara, a leading crop nutrition company, to decarbonize crop production in Europe. The partnership aims to reduce carbon footprint in the agriculture sector by providing farmers with lower-carbon fertilizer products and promoting sustainable farming practices. The collaboration will cover around 1,000 farms and 128,000 hectares across the European Union and the UK, with a focus on potatoes, oats, and corn. The partnership will also support farmers in adopting regenerative agricultural practices, which can help reduce emissions and promote soil health (<u>Source</u>).

Mars Unwraps Eco-Innovation with Seaweed Contributor: Kanika Banga

Jul' 24: Mars is focused on reducing its environmental impact and promoting sustainability. It is exploring the use of seaweed-based biodegradable packaging materials, which can be composted at home, in partnership with Loliware, a seaweed resin company. Additionally, Mars is working with Sea Forest, an environmental technology company to reduce cattle emissions using red seaweed-based feed additives. Mars is also leveraging digital twins to better understand sourcing complexities and reduce the amount of plastics in packaging. The company is prioritizing raw materials sourcing and exploring ways to reduce emissions from dairy, cocoa, and other ingredient (<u>Source</u>).



Is it time to leave Diet Coke and chewing gums behind? Contributor: Akshay Jawale

Jul' 24: Aspartame, a widely used artificial sweetener in food and beverages like diet drinks and chewing gum, faces renewed scrutiny as the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC) classify it as possibly carcinogenic to humans (Group 2B). This follows assessments citing limited evidence of its potential to cause liver cancer in humans and some experimental animals. Despite this classification, the WHO's Joint Expert Committee on Food Additives (JECFA) reaffirmed its safe daily intake limit of 40 mg/kg body weight. Notably, a 12-ounce can of Diet Coke contains about 180 mg of aspartame (Source).

Safeguarding Health and Environment: EPA Proposes Risk Evaluation for High-Priority Chemicals

Contributor: Harjinder Singh

Jul' 24: The U.S. EPA proposed designating five Vinyl chemicals, including Chloride and Acrylonitrile, as High-Priority Substances for risk evaluation under TSCA. This aligns with the Biden-Administration's goals Harris of promoting environmental justice, clean air, and water. The chemicals, linked to cancer and used in plastic production, will be evaluated for safety to protect public health and the environment (Source).

Cannabis During Pregnancy: Risks for Newborns Soar Contributor: Anuradha Sharma

Jun' 24: A study in the Journal of Perinatology found that prenatal cannabis use in New York significantly increases risks for newborns. Despite rising acceptance, about 22% of pregnant women don't view weekly use as risky. Cannabis use nearly doubles the risk of low birth weight and increases fetal death risk sixfold, underscoring the need for informed decisionmaking and public health initiatives (Source).

New Studies Reveal Triclosan's Cancer Risks, IARC Flags Acrylonitrile and Talc Contributor: Raja Chandra and Harjinder Singh

Jul' 24: Triclosan, a widely used antimicrobial, showed potential carcinogenic effects in a mouse study, with increased liver and pancreatic tumors. Meanwhile, the IARC has classified acrylonitrile as carcinogenic (Group 1) due to lung cancer risks and talc as probably carcinogenic (Group 2A), citing limited ovarian cancer evidence and concerns over asbestos contamination. All three chemicals raise significant health concerns (<u>Source 1; Source 2</u>).



New Hazard Standards: Class **Safeguarding Chemical Safety Contributor: Mayank Kakkar**

Jul' 24: The European Commission has revised the CLP Regulation to include new hazard classes and criteria for classifying substances and mixtures under REACH in the EU. This update affects active substances in biocidal and plant protection Manufacturers, importers, products. and distributors must comply with the new standards. Member States are required to align their classification and labeling proposals with these updated criteria, which now encompass categories such as endocrine disruption and persistent, bioaccumulative, and toxic properties (<u>Source</u>).

FU Introduces ΑΙ Act: World's First Comprehensive Regulation Artificial on Intelligence

Contributor: Anuradha Sharma

Jun' 24: The EU has adopted the AI Act, the first comprehensive global AI regulation, to ensure safe and transparent AI use. It classifies AI systems by risk levels, banning those with unacceptable risks like behavior manipulation or social scoring. Highrisk AI systems affecting safety or rights must be assessed before market entry and throughout their lifecycle. Generative AI systems will face transparency requirements, and AI-modified content must be labeled. The law also fosters innovation by supporting start-ups and SMEs in AI development. Adopted by the Parliament and approved by the Council, the AI Act will be fully applicable within 24 months (<u>Source 1; Source 2</u>).

The Dawn of Next-Generation Probiotics (NGP): From Simple Dietary Supplements to **Medical Marvels** Contributor: Basharat Ahmad Sofi

Apr' 24: Next-Generation Probiotics (NGPs) are advanced beneficial bacteria for dietary and pharmaceutical use, studied for their potential to modify the gut microbiome and influence disease development. Promising strains like Eubacterium hallii and Akkermansia muciniphila enhance immunity, improve cancer immunotherapy, and reduce chemotherapy complications. Despite limited human research and rare regulatory approval, future studies should address their isolation, mechanisms, safety, and clinical efficacy (<u>Source 1</u>; <u>Source 2</u>).

India's Medical Device Revamp: BIS Standards & Refurbished Devices in Focus Contributor: Harjinder Singh and Basharat Ahmad Sofi

Jul' 24: The DCGI mandates adherence to Bureau of Indian Standards (BIS) for medical devices to enhance safety, efficacy, and quality assurance, aligning with the Medical Devices Rules, 2017. This move aims to streamline regulations, reduce import dependency, and promote domestic manufacturing. India is also considering refurbished medical devices to improve healthcare affordability, requiring a robust regulatory framework to ensure their safety and reliability (<u>Source 1; Source 2</u>).

EU's



Goodbye To Wind Turbines With "Eolic Vibration"

Contributor: Nitesh Kumar

Jun' 2024: Vortex Bladeless is another prospect for wind power generation that is not the same as other well-known turbines. With the help of two key concepts: vibration and resonance, this technology can be identified as an innovative approach to harnessing wind energy distinct from that carried out by blades (<u>Source</u>).

Exicom to Acquire Australia-based Tritium to Expand Global Footprint in EV Charging Contributor: Sachin Patel

Aug' 2024: Exicom Tele-systems Limited, India's largest electric vehicle (EV) charger manufacturer, announced that its subsidiary Exicom Power Solutions B.V. Netherlands and its other step-down subsidiaries have entered into a definitive agreement to acquire the business and assets of the Tritium group of companies. Tritium, a global leader in DC fast chargers based in Australia, has sold over 13,000 DC fast chargers in 47 countries and is recognized for its durable and aesthetically appealing designs (Source).

Bajaj Auto launches world's first CNG bike, Freedom 125 Contributor: Sachin Patel

Jul' 2024: Bajaj Auto, India's third largest motorcycle maker, on Friday launched the world's first compressed natural gas (CNG)-powered twowheeler, Freedom 125, in Pune under a separate brand Bajaj's bi-fuel motorcycle (<u>Source</u>).

DENSO and JERA Partner on High-Efficiency Hydrogen Generation Contributor: Nitesh Kumar

Aug' 2024: DENSO Corporation and JERA has announced that they will jointly develop highefficiency hydrogen generation technology that combines SOEC with waste heat utilization and conduct joint demonstration testing at a JERA thermal power station (<u>Source</u>).



OUR SPARK TEAM

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