



AMERICAN CONTINENTAL GROUP

1800 M Street NW | 5th Floor | Washington D.C. 20036
Tel: (202) 327-8100 | Fax: (202) 327-8101

PATENT & TRADEMARK POLICY REPORT FEBRUARY 2, 2024



I. Congressional Developments:

- On Monday, Senator Tammy Baldwin (D-WI) wrote a letter urging the four major inhaler manufacturers—AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline (GSK), and Teva—to cease the allegedly improper listing of patents in the Food and Drug Administration (FDA) database. This practice, highlighted in letters sent by Baldwin, can obstruct the entry of lower-cost generic inhalers into the market. The letters specifically call for the removal of inaccurately listed patents from the FDA's Orange Book, a database containing patent and exclusivity information for FDA-approved drugs. When a pharmaceutical company lists a patent in the Orange Book, it can delay the approval of competing products for up to 30 months, providing an incentive for companies to list numerous associated patents to protect exclusivity. Baldwin's action follows a Federal Trade Commission (FTC) challenge to 10 pharmaceutical companies, including those mentioned in her letter, for improperly listing over 100 asthma inhaler patents in the Orange Book. Despite the FTC's warning, Baldwin notes that the companies have not yet removed all inaccurately listed patents, emphasizing the potential negative impact on competition, generic drug development, and consumer prices. This move aligns with Baldwin's previous collaboration with Senator Bernie Sanders (I-Vt.) and other Senate Democrats in investigating the high costs of asthma inhalers produced by these four companies, which have been accused of exploiting the regulatory system to hinder competition from generics. The senators point out the stark price difference between inhalers sold in the U.S. and those in other countries,

Headlines and Highlights:

- Sen. Baldwin Urges Drug Companies to Stop Gaming Patents for Asthma Inhalers
- House Administration Committee Holds AI Hearing
- House Judiciary IP Subcommittee Holds LA Field Hearing on AI and IP
- USPTO Releases Report to Congress on Success of Patent Pro Bono Programs
- Biden Admin and Chamber Clash Over IRA Drug Pricing Impact
- Tobacco Giants Philip Morris and BAT Resolve Patent Disputes

exemplifying concerns about affordability and competition within the pharmaceutical industry.

- On Tuesday, the House Administration Committee held a hearing titled “[Artificial Intelligence \(AI\): Innovations within the Legislative Branch](#).” The hearing focused on the potential risks and rewards of artificial intelligence (AI) in legislative branch operations. Chair Bryan Steil (R-WI) and Ranking Member Joe Morelle (D-NY) emphasized the need for AI governance plans and transparency. Witnesses from the U.S. Government Publishing Office (GPO), Library of Congress, House of Representatives, and Government Accountability Office (GAO) discussed their respective uses of AI and the importance of data governance. The panel also addressed concerns about AI misuse, the need for human oversight, and the potential for AI to improve efficiency and accessibility. The hearing concluded with a discussion on the importance of leveraging AI benefits while managing its risks. A full summary from ACG can be provided upon request.
- On Wednesday, the Senate Judiciary Committee held a hearing titled “[Big Tech and the Online Child Sexual Exploitation Crisis](#),” which addressed the escalating crisis of online child sexual exploitation in America. CEOs from Meta, TikTok, Discord, Snap, and X Corp (formerly Twitter) testified before the full committee. Despite the tech CEOs facing harsh scrutiny, Chairs Graham and Durbin announced their plans to take the CSAM bills to the Senate floor in the coming weeks, seeking unanimous consent (UC) on a daily basis for their passage. It's important to note that X Corp. and Discord stood out by supporting the Kids Online Safety Act (KOSA). The five CSAM bills that Senators Durbin and Graham are pushing for include: (1) STOP CSAM Act, which aims to support victims and enhance accountability and transparency for online platforms; (2) EARN IT Act, which introduces targeted exceptions to Section 230 of the Communications Decency Act of 1996, removing blanket immunity from civil and criminal liability under child sexual abuse material laws and establishing a National Commission on Online Child Sexual Exploitation Prevention; (3) SHIELD Act, addressing federal prosecutors' tools for privacy violations; (4) Project Safe Childhood Act, modernizing the investigation and prosecution of online child exploitation crimes; and (5) the REPORT Act, designed to combat the rise in online child sexual exploitation by reinforcing measures to strengthen reporting of these crimes to the CyberTipline. A full summary from ACG can be provided upon request.
- On Friday, the House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet held a field hearing in Los Angeles, California. The hearing, "Artificial Intelligence and Intellectual Property: Part II – Identity in the Age of AI" examined how Congress can support responsible innovation in applications of artificial intelligence (AI) technology and address growing concerns about the misuse of AI technology, especially with respect to the likeness, voice, and other identifying characteristics of individuals. The Subcommittee heard the perspective of artists and creators for whom their likeness, voice, etc., are critical to their livelihoods, as well as that of innovators leading the AI revolution. A full summary from ACG can be provided upon request.

II. USPTO Updates:

- On Tuesday, the US Patent and Trademark Office (USPTO) unveiled the results of a Congress-mandated study assessing the impact of patent pro bono programs, revealing their

success in broadening access to the patent system for financially under-resourced inventors and small businesses. The study, conducted in accordance with the Unleashing American Innovators Act of 2022, disclosed that volunteer patent attorneys and non-attorney advocates donated over \$39.3 million in free legal services from 2015 to 2022. Noteworthy findings include the near doubling of the pro bono budget in 2023 under Director Kathi Vidal's guidance, heightened awareness, and promotion leading to increased inquiries, and the significant role played by non-attorney advocates. Demographic trends in patent pro bono applicants indicate improved representation from historically underserved communities. Despite progress, the study identifies room for enhancing the financial screening threshold and underscores ongoing collaboration between the USPTO and regional programs. The report integrates public feedback from listening sessions and written comments, offering comprehensive insights to support the findings and recommendations. Read more [here](#):

- As previously announced, starting on February 5, 2024, the Assignment Center, our modernized system, will completely supplant the Electronic Patent Assignment System (EPAS) and Electronic Trademark Assignment System (ETAS) for processing patent and trademark reassignment requests. To facilitate a seamless transition, comprehensive how-to guides for utilizing Assignment Center in patent and trademark processes are now accessible, accompanied by step-by-step training videos. The Assignment Center streamlines the submission of patent or trademark assignment orders, enabling users to transfer ownership or modify owner details for pending or granted applications. The user-friendly interface guides stakeholders through each reassignment step, offering a centralized platform to monitor application status. Notably, the location for searching patent and trademark assignments will remain unchanged.

III. Administration Update

- Last week the USTR announced that Ambassador Sarah Bianchi will depart after more than two years of service as Deputy United States Trade Representative. “Ambassador Sarah Bianchi has played an integral role in executing on USTR’s work with our partners in Asia, the Indo-Pacific, and across the African continent, including the launch of the U.S.-Kenya Strategic Trade Partnership, the U.S.-Taiwan Initiative on 21st-Century Trade, and the success of our APEC Host Year,” said Ambassador Katherine Tai. Ambassador Bianchi’s last was January 29, 2024.
- Last week USTR Katherine Tai announced the appointment of Katy Mastman as Acting Assistant U.S. Trade Representative for Labor. “I look forward to working with Katy in this new capacity as we continue to empower workers and strengthen the middle class,” said Ambassador Katherine Tai. “As we welcome Katy into this new role, we must say farewell to Josh Kagan.” Read the full press release [here](#).
- On Monday, the USTR released the findings of its 2023 Review of Notorious Markets for Counterfeiting and Piracy which highlights online and physical markets that reportedly engage in or facilitate substantial trademark counterfeiting or copyright piracy. As a part of the Biden-Harris Administration’s worker-centered trade policy, this year’s Notorious Markets List’s issue focus section examines the potential health and safety risks posed by counterfeit goods. The complete 2023 Notorious Markets List can be found [here](#).

- Friday, the Department of Health and Human Services (HHS) initiated discussions with pharmaceutical companies under the Biden Administration's Inflation Reduction Act of 2022 (IRA), allowing the government to negotiate Medicare drug prices. The U.S. Chamber of Commerce, currently suing the government over the IRA, contends that the negotiation process is not voluntary, as companies refusing participation face excise taxes and potential drug withdrawals, leading to devastating consequences for patients. Despite concerns, HHS Secretary Xavier Becerra sees the IRA program as a milestone for fair drug prices, with the Centers for Medicare & Medicaid Services (CMS) continuing negotiations through August 2024, and agreed-upon prices becoming effective in Medicare from 2026 onwards. However, a report from the U.S. Chamber of Commerce's Global Innovation Policy Center (GIPC) warns of the potential negative impact on patient access to medications, predicting a decrease in new product launches and a decline in U.S. medical innovation. The Chamber's lawsuit alleges that the IRA disguises a mandatory price control regime as a negotiation process, with both preliminary injunction and dismissal motions denied in September 2023. The GIPC report concludes by urging the U.S. government to consider the full ramifications of its policy, stating that imposing price controls on medicines may inevitably reduce patient access to new life sciences products and technologies. The drugs selected for negotiation under the IRA program include Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and Fiasp. Read more [here](#).

IV. Judicial Update

- On Tuesday, Netgear, a computer networking company based in San Jose, California, filed a lawsuit against Huawei in a California federal court, alleging that the Chinese tech giant violated U.S. antitrust laws by refusing to license its patents on reasonable terms. The complaint, lodged on Tuesday, also accuses Huawei of fraud, racketeering, and other offenses, asserting that Huawei withheld patent licenses crucial for Netgear's routers to comply with international Wi-Fi networking standards. Netgear contends that Huawei utilizes patent-infringement lawsuits to elevate licensing rates, compelling other companies into costly litigation or facing exclusion from the market. The complaint highlights similar tactics used against other companies, including Verizon, L3Harris, and T-Mobile. Netgear accuses Huawei of monopolizing standard-essential technology and engaging in racketeering by unlawfully taxing successful standards at anti-competitive rates on a global scale. In response, Huawei has not yet commented on the lawsuit. This legal action follows infringement lawsuits initiated by Huawei against Netgear in Germany and China, adding another layer to the ongoing patent dispute between the two companies.
- On Friday, tobacco giants Philip Morris International (PMI) and British American Tobacco (BAT) announced the resolution of a series of ongoing patent infringement disputes related to their respective cigarette alternatives. The protracted legal battle, which had adversely affected both companies, involved BAT being ordered to pay PMI millions of dollars after losing a case, and PMI facing restrictions on importing its flagship heated tobacco device IQOS into the United States. The non-monetary, worldwide settlement, lasting for eight years, entails the dismissal of all pending patent infringement cases and prevents future claims against current products. Notably, the

agreement includes a provision for the rescinding of the block on IQOS imports into the United States, a significant victory for PMI in its efforts to enter the critical U.S. market. Both CEOs expressed satisfaction with the resolution, with PMI's Jacek Olczak emphasizing the importance of the agreement, and BAT's Tadeu Marroco stating that it allows the company to focus on innovation. The settlement also enables both companies to introduce future iterations of their products, according to separate statements. Read more [here](#).