



AMERICAN CONTINENTAL GROUP

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## PATENT & TRADEMARK POLICY REPORT MAY 10, 2024



### I. Congressional Update:

- On Wednesday May 1, Senators Chris Coons (D-DE), Thom Tillis (R-NC) along with Representatives Darrell Issa (R-CA) and Jake Auchincloss (D-MA) sent a letter to the Government Accountability Office (GAO) requesting a study on the potential impact of the National Institute of Standards and Technology's (NIST) proposed framework for exercising march-in rights under the Bayh-Dole Act. The proposed framework, which includes considering "reasonable pricing" as a factor for exercising march-in rights, has raised concerns about its potential impact on drug prices, U.S. innovation, and national interests. Various stakeholders, including trade associations, advocacy groups, universities, and businesses, have opposed the draft framework, expressing concerns about its potential negative consequences for innovation and the economy. The letter requests the study to assess the economic impact, potential effects, clarity for licensees and investors, and expectations of stakeholders regarding the draft framework saying, "We are concerned that implementing the draft framework is likely to have negative consequences for U.S. innovation and global competitiveness, the public-private partnerships that the Bayh-Dole Act created, and the U.S. economy."
- On Tuesday, May 7, 2024, the House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet held a hearing titled "Intellectual Property: Enforcement Activities by the Executive Branch." The hearing examined enforcement of intellectual property (IP) in the United States, with a focus on agencies and U.S. government entities charged with IP enforcement-

### Headlines and Highlights:

- Congressional Members Send Letter to GAO on Bayh-Dole Enforcement
- HJC Holds IP Enforcement Hearing
- USPTO Proposes National Strategy to Incentivize Inclusive Innovation
- Deadline to Submit Comments to the USPTO on IP and Emerging Tech
- USPTO Proposes New Rule on Terminal Disclaimer Practice
- FTC Continues Aggressive Scrutiny of Pharmaceutical Patents Listed in the Orange Book

### In the Blogs:

- IPWatchdog: [The USPTO Needs to Investigate This Disturbing 'Patent Examiner' Reddit Thread](#)

related tasks. Overall, the hearing focused on the enforcement of intellectual property laws by the executive branch, with particular concern over the Biden administration's approach and the significant economic losses attributed to inadequate enforcement, especially due to counterfeit goods predominantly originating from China. Witnesses from various agencies discussed their roles in IP enforcement, the challenges posed by e-commerce and small package shipments, and the importance of international cooperation and resource allocation to combat IP theft effectively. A full summary from ACG can be provided upon request.

- On Wednesday May 8, the House Committee on Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies held a budget hearing to discuss the Department of Commerce's proposed budget for FY25, totaling \$11.4 billion in discretionary funding and \$4 billion in mandatory funding. This request represents a 6% increase over the previous year. The budget allocates resources to various initiatives, including trade enforcement, manufacturing technology innovation, and economic development. Overall, the discussion covered a wide range of topics, including national security, workforce development, technology, trade, and infrastructure. Secretary Gina Raimondo and committee members engaged in detailed discussions on various aspects of the Department's budget proposal and its implications for American competitiveness and security. Of note, many Representatives raised concerns about AI-related issues, including content authenticity and watermarking, deepfakes, and the protection of intellectual property. A full summary from ACG can be provided upon request.

## II. USPTO Updates:

- On Wednesday May 1, the USPTO announced a "[National Strategy for Inclusive Innovation](#)" in advance of a [World IP Day event being held on Capitol Hill](#). The Strategy was developed with support from the Council for Inclusive Innovation (CI<sup>2</sup>) and, according to a USPTO press release, "aims to lift communities, grow the economy, create quality jobs, and address global challenges by increasing participation in STEM, inventorship and innovation among youth and those from historically underrepresented and under resourced communities." According to *IPWatchdog*, the strategy focuses on four key "cornerstones": 1) Inspiring new generations of innovators; 2) Educating and empowering innovators; 3) Advancing inclusive innovation across government and other areas; and 4) Bringing innovation to market. USPTO Director Kathi Vidal said in a statement that the strategy "provides a call to action and roadmap to achieve innovative success." Read more from *IPWatchdog* [here](#).
- On Thursday May 2, the United States Patent and Trademark Office (USPTO) issued a final rule updating its regulations concerning patent application disclosures containing nucleotide and/or amino acid sequences. The updated regulations reflect the adoption by the World Intellectual Property Organization (WIPO) of version 1.7 of its Standard ST.26. The final rule will be effective Monday, July 1, 2024. You can find the full text of the [final rule in the Federal Register](#) and on the USPTO's [Patent-Related Notices webpage](#).
- Back in March, the USPTO, with support from the National Oceanic and Atmospheric Administration (NOAA), the National Institute of Standards and Technology (NIST), and the National Science Foundation (NSF), published a [request for comments](#), seeking input on ways the Office could accelerate and incentivize commercialization of innovation through

intellectual property, with particular attention to green, critical, and emerging technologies. Comments are due May 14.

- On Wednesday, May 8, the USPTO announced *Guidance on Use of Artificial Intelligence-Based Tools in Practice Before the United States Patent and Trademark Office* in the Federal Register on April 11, 2024. On May 15, the USPTO will be hosting a webinar where they will provide an overview of the guidance and answer questions related to the guidance. Questions MUST be submitted in advance to [aipartnership@uspto.gov](mailto:aipartnership@uspto.gov) by May 12 and MUST be related to the guidance linked above to be considered for the event. Click [here](#) to register.
- The USPTO and Patent Trial and Appeal Board (PTAB) published a press release offering the public to join the next Boardside Chat webinar on Thursday, May 16, for an overview of two recently published notices of proposed rulemaking before the PTAB. The PTAB will discuss the proposed rules governing Director Review of PTAB decisions. According to the press release, the PTAB also will walk through the proposed rules related to briefing discretionary denial issues, § 325(d) considerations, instituting parallel and serial petitions, and termination due to settlement agreement. The proposed rules are currently open for public comment, which are due in mid-June 2024. For more information about the proposed rules, check out the Federal Register notices: (1) [Notice of Proposed Rulemaking on Rules Governing Director Review of Patent Trial and Appeal Board Decisions](#) (April 16, 2024) (2) [Notice of Proposed Rulemaking on Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325\(d\) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement](#) (April 19, 2024). A question-and-answer session will follow the presentation. Please send questions in advance or during the webinar to [PTABBoardsideChat@USPTO.gov](mailto:PTABBoardsideChat@USPTO.gov). To register for the event, click [here](#).
- On Thursday May 9, the USPTO issued a notice of proposed rulemaking (NPRM) to add a new requirement for terminal disclaimers filed to overcome nonstatutory double patenting. According to the press release, under U.S. law, an inventor, patent owner or joint researchers may obtain more than one patent with claims that vary in only minor (patentably indistinct) ways from each other. The USPTO will reject such claims under “obviousness-type double patenting” (also known as “nonstatutory double patenting”) and will allow claims to issue only as long as the practice of obtaining similar claims across patents isn’t used to extend the patent exclusivity term or allow multiple parties to harass an alleged infringer. “The proposed rule responds to public feedback and proposes to add a third condition that would further promote innovation and competition by reducing the cost of separately challenging each patent in a group of multiple patents directed to indistinct variations of a single invention. Under the proposed rule, to overcome double patenting the patentee would need to agree that the patent with the terminal disclaimer will be enforceable only if the patent is not tied and has never been tied through one or more terminal disclaimers to a patent in which any claim has been finally held unpatentable or invalid over prior art. In addition to reducing costs, the proposed rule is expected to streamline and expedite patent disputes, narrow validity issues, and provide greater certainty to competitors and to the public. The proposed rule is prospective in nature and would apply to terminal disclaimers filed on or after the effective date of any final rule.” The full text of the notice is available at the [Federal Register](#) and on

the USPTO's [Patent Related Notices webpage](#). You must submit comments on the NPRM by July 9, through the [Federal eRulemaking Portal](#), to ensure consideration.

- On Thursday, May 16, from 9–10:30 a.m. ET, at the University of Central Florida in Orlando the USPTO is hosting an in-person discussion with the U.S. Patent and Trademark Office's intellectual property (IP) attachés on protecting your IP abroad. According to the press release, this program will be an opportunity for businesses in the Central Florida region, especially small and medium-sized enterprises, to hear the attachés' informed viewpoints about: (1) Ways of protecting and enforcing IP internationally, (2) The commercial and export considerations concerning IP-reliant products, and (3) How they can assist you. The USPTO's IP attachés are posted in 12 locations overseas. They work to improve IP systems internationally by directly assisting U.S. stakeholders—such as businesses, legal representatives, and rights holders—and by advocating to improve IP policies, laws, and regulations abroad. This is an in-person program; it will not be webcast. There is no charge to attend, but advance registration is required. For more information and to register, visit the [USPTO website](#).
- Join the Patent Trial and Appeal Board (PTAB) Legal Experience and Advancement Program (LEAP) for an America Invents Act (AIA) oral hearing encore on Friday, May 17, from noon to 1:30 p.m. ET. Practitioners Larissa Bifano of DLA Piper; David Cavanaugh of Wilmer Cutler Pickering Hale and Dorr, LLP; Jeremy Monaldo of Fish & Richardson; and Sangeeta Shah of Brooks Kushman, will present arguments in a mock AIA trial proceeding before a panel of three PTAB judges. After arguments, the practitioners and panel will discuss the effectiveness of the arguments and approaches demonstrated during the mock argument. The event is free and open to all. Captioning service will be provided. More information, including the webinar access information, is available on the [LEAP page](#) of the United States Patent and Trademark Office website. Click [here](#) to register.

### **III. Administration Updates:**

- On Tuesday, May 7, the Office of the United States Trade Representative (USTR) announced that Neil Beck will serve as Acting Assistant U.S. Trade Representative for World Trade Organization (WTO) and Multilateral Affairs. Mr. Beck previously served as Deputy Assistant U.S. Trade Representative in the same office. “Our multilateral work is as crucial as ever as we tackle the shared challenges of today’s global economy and work to ensure our institutions adapt to them,” said United States Trade Representative Katherine Tai. “The U.S. remains steadfast in our commitment to finding collaborative solutions that work for economies of all sizes through multilateral fora. Mr. Beck is an experienced trade professional who is well-equipped to serve the U.S. in this capacity, and I look forward to working with him to further this mission.” According to the press release, the USTR's WTO & Multilateral Affairs (WAMA) office has overall responsibility for trade negotiations and policy coordination regarding matters before the WTO, the Group of Seven (G7), the Group of 20 (G20), and the Organization for Economic Co-operation and Development (OECD). Read more [here](#).
- On Wednesday May 8, *Mayer / Brown* reported that the US Federal Trade Commission (FTC) issued "warning letters" to 10 branded pharmaceutical companies, accusing them of inaccurately listing patents in the FDA's Orange Book. The FTC has submitted patent listing

dispute letters to the FDA challenging the accuracy of over 300 Orange Book patent listings. These challenges mainly target patents associated with drug-device combination products, particularly those claiming devices or device components without disclosing the approved active ingredient. This move follows the FTC's increased scrutiny of Orange Book patent listings, as evidenced by previous policy statements, warning letters, and amicus briefs. Read more [here](#).

#### **IV. Judicial Updates:**

- On Monday, May 6, *Reuters* reported that Activision Blizzard owes \$23.4 million in damages for violating patents related to multiplayer features of its hit games "World of Warcraft," "Call of Duty: Black Ops III" and "Call of Duty: Advanced Warfare." According to the article, the two patents at issue in the trial covered communications technology related to the "simultaneous sharing of information" between multiple "widely distributed" computers. The Delaware jury agreed with patent holder Acceleration Bay that aspects of the games' online multiplayer networking technology infringe two of its patents. "While we are disappointed, we believe there is a strong basis for appeal," an Activision spokesperson said in a statement on Monday. "We have never used the patented technologies at issue in our games." Acceleration Bay president Joe Ward said in a statement that the company was "delighted" with the outcome. Read more [here](#).

#### **V. Industry Updates:**

- Last Friday, May 3, *POLITICO* reported that former Senator Richard Burr (R-NC) has been selected to co-chair the Business Alliance to Stop Innovation Confiscation (BASIC) Coalition, a coalition formed by the U.S. Chamber of Commerce to oppose the Biden administration's proposal to exercise march-in rights to lower drug prices. The coalition aims to counteract the administration's determination that the government can seize patents of certain high-priced drugs developed using taxpayer funds. Burr, alongside retired judge Paul Michel, will lead efforts to safeguard private property rights and defend free enterprise principles. "This mission, which is to safeguard private property rights from unwarranted government seizure and to staunchly defend the principles of free enterprise, resonates deeply with me," Burr said in a statement, calling "the proposed misuse of march-in rights" a "matter of grave concern."
- On Monday, May 6, *POLITICO* reported that new polling shows Americans favor AI data regulation. A recent poll conducted by the Artificial Intelligence Policy Institute indicates a growing concern among Americans regarding the training practices of AI companies and their energy consumption. The majority of respondents expressed the view that AI firms should not have unrestricted access to public data and should compensate data creators. Additionally, a significant portion of respondents favored regulations on the use of public data for training AI models. There was also support for the idea of imposing a special tax on electricity for AI companies to support the upgrade of electrical grid infrastructure. Furthermore, opinions on the Biden administration's proposed funding for the AI Safety Institute showed a partisan divide, with Democrats more supportive than Republicans. The

poll also revealed shifts in attitudes toward AI's impact on employment, particularly after exposure to generative AI music. College-educated respondents, in particular, showed an increase in concern about AI's potential to replace human jobs. Read more [here](#).

- On Tuesday, May 7, the Special Competitive Studies Project (SCSP) and the Council for Innovation Promotion (C4IP) co-hosted a Fireside Chat titled *AI and IP: Can AI Generated Creations and Inventions be Protected?* Shira Perlmutter, Register of Copyrights and Director of the U.S. Copyright Office, alongside Andrei Iancu, Partner at Sullivan & Cromwell and former USPTO Director, spoke about the implications of AI on patents and copyrights and on U.S. innovation and competitiveness. The discussion was moderated by Rama Elluru, Senior Director for Society & Intellectual Property at SCSP. For additional information click [here](#).
- On May 7, it was announced that veteran intellectual property (IP) protection and enforcement executives Steve Francis and Jan van Voorn have launched IP House, “a private sector company founded to support organizations in combating IP theft and defending their innovations from illicit trade.” Backed by a U.S.-based investment firm, IP House incorporates the best-in-class investigative teams and is supported by proprietary tech platforms, which enable it “to deliver proactive, end-to-end intellectual property protection at scale, addressing threats more completely than the industry’s patchwork of vendors can do.” Francis is serving as Executive Chairman of IP House following a 25-year career in federal law enforcement leadership positions; and van Voorn is the organization’s CEO following leading global content protection for the Motion Picture Association (MPA).
- On Wednesday, May 8, USPTO Director Kathi Vidal spoke at the AI Expo on what the USPTO is doing to incentivize the responsible and safe development and use of AI models and implement the USPTO requirements in the White House's Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI. She mentioned that the USPTO hopes to issue the next examiner guidance on patentability of AI inventions by July which would address two categories of applications. (1) AI assisted inventions, and (2) Inventions in AI machines/tools.