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
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I. Congressional Update:

- Next week, the House Judiciary Committee will likely hold a markup on the PRO Codes Act, among several other unrelated bills. The markup was initially supposed to occur on March 21st but was postponed.

- On Wednesday, April 9, the House Judiciary Committee Intellectual Property Subcommittee held a hearing titled, "Artificial Intelligence and Intellectual Property: Part III – IP Protection for AI-Assisted Inventions and Creative Works." The hearing examined the standards and policy considerations for granting intellectual property (IP) rights to inventions (patents) and creative works (copyrights) made with the help of artificial intelligence (AI). This includes considering whether current or proposed rules on inventorship and authorship need to be changed. The witnesses provided insights into the copyrightability and inventorship of AI-generated works, with differing opinions on whether copyright protection should be extended to works wholly or partially created by AI. Overall, the witnesses expressed reluctance to immediate legislative action. The discussion delved into the challenges of balancing innovation incentives with the protection of human creativity, the implications of AI on patentability and copyright infringement, and the potential impact of AI on various industries, including biotechnology. During the question-and-answer session, committee members probed the witnesses on issues ranging from the fair use doctrine and patent examination processes to international competitiveness and the

Headlines and Highlights:

role of AI in derivative works. While consensus was not reached, the hearing shed light on the complexities surrounding AI and IP law and the need for further deliberation on regulatory frameworks to address this emerging technology. A full summary from ACG can be provided upon request.

- On Wednesday, Senate Minority Leader Mitch McConnell introduced legislation targeting patent and bankruptcy suits, diverging from guidance issued by the federal judiciary's policymaking body. McConnell's bill aims to curb the practice of "judge shopping," which involves seeking out specific judges for favorable rulings in complex cases. By tightening rules for establishing venue in patent and bankruptcy suits, the bill seeks to ensure fairness and integrity in the judicial system. Specifically, the legislation would make it harder for patent litigants to keep cases in certain districts known for favorable rulings and restrict companies from steering bankruptcy filings to preferred venues through affiliates. Although the bill is unlikely to pass in the closely divided Senate, it highlights bipartisan concerns about the politicization of the judiciary. Read more here.

II. USPTO Updates:

- On Wednesday, April 10, the USPTO published additional guidance in the Federal Register for practitioners and the public to inform them of the important issues that patent and trademark professionals, innovators, and entrepreneurs must navigate while using artificial intelligence (AI) in matters before the USPTO. According to the press release, the guidance reminds individuals involved in proceedings before the USPTO of the pertinent rules and policies, helps inform those same individuals of the risks associated with the use of AI, and provides suggestions to mitigate those risks. "Today's notice is part of our work shaping AI policy and encourages the safe and responsible use of AI to benefit the IP and innovation ecosystem," said Kathi Vidal, Under Secretary of Commerce for Intellectual Property and Director of the USPTO. "The requirements in existing USPTO rules serve to protect the integrity of our proceedings and to avoid delay and unnecessary cost, and they apply regardless of how a submission is generated. We will continue to listen to stakeholders on this policy and on all our measures to use AI responsibly and safely to democratize and scale U.S. innovation, creativity, and entrepreneurship." The full text of the guidance is available in the Federal Register and on the USPTO's Artificial Intelligence webpage.

- The USPTO is currently seeking applicants for the position of Chief Public Engagement Officer (CPEO). Reporting directly to the USPTO Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director for USPTO, this executive leadership role involves shaping the Office of Public Engagement (OPE) and driving strategic initiatives to enhance public engagement. The CPEO will lead stakeholder outreach, manage regional and community offices, and design customer experience programs. Apply by April 15th to be considered. More information can be found here.

III. Judicial Update

- On Thursday, in an opinion by Judge Lourie, a split Federal Circuit upheld a district court's determination regarding Salix's claims for using 550 mg of rifaximin three times a day to treat irritable bowel syndrome (IBS), affirming that these claims would have been obvious. Salix contended that the district court erred by concluding that a skilled artisan would have had a reasonable expectation of success in utilizing its claimed dosage. The Federal Circuit, however, disagreed with Salix's argument, primarily relying on a clinical trial protocol assessing the efficacy of rifaximin in treating IBS at various dosages, including 250 mg, 550 mg, and 1,100 mg administered twice a day, and a journal article recommending the use of 400 mg of rifaximin three times a day for IBS treatment while suggesting that a higher dosage might be optimal. Ultimately, the Federal Circuit determined that a skilled artisan would have combined these references and concluded that the 550 mg dose from the protocol represented the optimal dosage, surpassing the 400 mg threshold cited in the journal article. However, Judge Cunningham dissented in part, contending that the court exceeded the bounds of the claimed dosage of 1,650 mg/day, as the protocol only disclosed a dosage of 550 mg twice a day, and the article's assessment of an optimal dosage was vague.