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PATENT & TRADEMARK POLICY REPORT NOVEMBER 10, 2023



I. Congressional Developments:

- On Wednesday, the Senate IP Subcommittee held a hearing on “Reforming the Patent Trial and Appeal Board – The PREVAIL Act and Proposals to Promote U.S. Innovation Leadership.” Members of the subcommittee heard testimony from Michelle Armond (Armond Wilson, LLP), Joseph Matal (Clear IP, LLC), Joe Kiani (Masimo Corp.), and former Congressman Lamar Smith (Akin Gump). Overall, the hearing examined the Leahy-Smith America Invents Act (AIA) and its centerpiece reform, the Inter Partes Review (IPR) System as well as the recently introduced PREVAIL Act, which aims to respond to these criticisms and prevent the IPR system from being used as a tool for litigation gamesmanship. The witness panel was a diverse group with some advocating for major changes to the Patent Trial and Appeal Board (PTAB), while others argued that it is working well but may need to be updated slightly. A full summary from ACG can be provided upon request.
- On Wednesday, the House Committee on Oversight and Accountability Subcommittee on Cybersecurity, Information Technology, and Government Innovation held a hearing titled “Advances in Deepfake Technology.” The hearing discussed the potential benefits and dangers of artificial intelligence (AI) and deepfake technology. Chair Nancy Mace (R-SC) highlighted the misuse of AI in creating harmful content, while Ranking Member Gerry Connolly (D-VA) emphasized the need for AI imagedetecting tools and collaboration to combat deepfakes. Witnesses discussed

Headlines and Highlights:

- Senate Judiciary Committee Holds PREVAIL Act Hearing
- House Oversight Examine Deepfake Technology
- FTC Challenges More Than 100 Patents as Improperly Listed in the FDA’s Orange Book
- USPTO Proposes Changes to PTAB Decision Review Procedures
- USPTO Postpones Transition to Patent Center System
- Global Innovation Policy Center (GIPC) and USPTO Host Annual Attaché Roundtable
- Supreme Court Denies Certiorari in HIP, Inc. Case on Joint Inventorship
- Federal Circuit Dismisses Allgenesis’s Appeal in Patent Dispute
- Nike Files Patent Infringement Lawsuits

the rapid development of deepfake technology, its potential misuse, and the need for legislation and regulation. The panel also discussed the need for transparency and authenticity in digital content and the potential for deepfake technology to disproportionately impact women and communities of color. A full summary from ACG can be provided upon request.

II. Administration Updates:

- On Tuesday, the FTC raised concerns by sending letters to several medical device and drug companies, including AbbVie, AstraZeneca, and Teva, disputing the accuracy and relevance of 110 patents listed in the FDA's Orange Book. These patents, many of which pertain to devices like asthma inhalers and epinephrine autoinjectors, could potentially cause delays in the introduction of generic competition, impacting drug prices and fair competition. The FTC Chair, Lina Khan, expressed that wrongfully listed Orange Book patents can raise drug costs, harm competition, and delay the availability of more affordable medications, especially in cases like asthma inhalers, which can still be expensive for patients despite being on the market for years. The FTC's action is part of its ongoing efforts to address issues related to patent listings in the Orange Book and ensure compliance with FDA regulations. Read more [here](#) and [here](#).

III. USPTO Updates:

- On Monday, the USPTO announced important updates to the internal decision circulation and review procedures within the Patent Trial and Appeal Board (PTAB). These changes, introduced through a Notice of Proposed Rulemaking (NPRM) issued on October 6, 2023, address the pre-issuance internal decision circulation and review processes at PTAB. Simultaneously, the PTAB released a new Standing Operating Procedure (SOP) that encompasses both pre-issuance and post-issuance decision reviews, as well as updated and renumbered its existing SOP that pertains to handling remands from the Federal Circuit. To provide insights into these developments, a PTAB Boardside Chat webinar, scheduled for Thursday, November 16, from noon to 1 p.m. Eastern Time, will feature a discussion led by PTAB's Vice Chief Judge, Melissa Haapala, focusing on the NPRM and the revised SOPs, shedding light on their potential implications and significance within the PTAB decision review framework. Read more [here](#).
- On Tuesday, the USPTO announced an update regarding the transition to the Patent Center system, which is set to replace the long-standing electronic filing and application management systems, EFS-Web and Private Patent Application Information Retrieval (Private PAIR), used by Patents customers. Originally scheduled for November 8, 2023, the transition date has been postponed to November 15, 2023, to accommodate additional feedback from stakeholders and improve the system's usability, particularly for sponsored accounts with a large number of customer accounts. The USPTO is also enhancing support through the Electronic Business Center to provide real-time assistance during the transition. This shift to the Patent Center system is part of the USPTO's modernization efforts to offer more versatile technology and functionality, ensuring they stay current with the latest digital capabilities and continue delivering excellent customer service. Read more [here](#).

- On December 6th, the Global Innovation Policy Center (GIPC) and the USPTO will host the 17th Annual Attaché Roundtable, providing an opportunity for assembled attachés to engage in a discussion about recent trends and challenges in IP protection and enforcement around the world. For additional information and to register to attend, please click [here](#).

V. Judiciary Update

- On Monday, the U.S. Supreme Court declined to grant certiorari in a case brought by HIP, Inc., which sought a review of the U.S. Court of Appeals for the Federal Circuit's (CAFC) standard for determining joint inventorship. The petition, filed in August, aimed to address what HIP, Inc. considered a conflict between Section 116(a) of Title 35 and the requirements imposed by the Federal Circuit since the 1984 amendments. The CAFC had previously reversed a district court's decision, concluding that inventor David Howard's contribution to Hormel Foods Corp.'s patent did not meet the Pannu v. Iolab Corp. test's criteria for joint inventorship. HIP, Inc. argued that this case had significant practical implications and could impact the validity of numerous patents, while Hormel defended the CAFC's decision and the applicability of the Pannu test. The Supreme Court's denial of certiorari leaves the CAFC's joint inventorship standard intact. Read more [here](#).
- On Tuesday, in the case of Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC (docket number 22-1706), the Federal Circuit, in an opinion authored by Chief Judge Moore, dismissed Allgenesis's appeal of an inter partes review decision upholding Cloudbreak's patent claims for treating pterygium. Allgenesis's arguments that it faced potential infringement liability and that the USPTO's priority determination created an injury in fact were rejected. The court found that Allgenesis had not demonstrated concrete, non-speculative plans for future infringement, such as pursuing Phase III trials or seeking FDA approval. Additionally, the claims regarding the preclusive effect of the USPTO's determination and its impact on other patents and applications lacked the necessary specificity to establish injury in fact.
- On Tuesday, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued a significant ruling in Actelion Pharmaceuticals Ltd. v. Mylan Pharmaceuticals Inc., overturning an infringement judgment against Mylan in the Northern District of West Virginia. The case hinged on the interpretation of the claim term "a pH of 13 or higher" in cardiovascular treatment patents. Actelion and Mylan had differing interpretations, with Actelion allowing rounding from 12.5, and Mylan excluding anything under 13. The district court sided with Actelion but didn't consider extrinsic evidence like chemistry textbooks. The CAFC ruled that extrinsic evidence was necessary for a proper interpretation. The case was remanded for a reevaluation of the evidence and the claimed pH range's precision, highlighting the importance of extrinsic evidence in patent claim construction. Read more [here](#).

VI. Industry Update

- On Monday, Nike filed federal lawsuits against rival companies New Balance and Skechers, alleging patent infringement related to Nike's technology for creating the upper portions of sneakers. The lawsuits specifically claim that several athletic shoes from New Balance and sneakers from Skechers misuse Nike's patented "Flyknit" technology, which is utilized in running, soccer, and basketball shoes. Nike has previously initiated similar patent infringement lawsuits against Adidas, Puma, and Lululemon for violations of its

Flyknit patents, with Adidas and Puma reaching settlements, while the case against Lululemon remains ongoing. New Balance stated that it respects competitors' intellectual property rights but emphasized that Nike does not possess exclusive rights to design and produce footwear through traditional manufacturing methods used for decades in the industry. Nike's legal action seeks unspecified monetary damages and permanent court orders prohibiting New Balance and Skechers from infringing the patents. Read more [here](#).

VII: International Update

- According to a report released on Sunday, Chinese companies, including Huawei and Tencent, have significantly increased their global patent holdings in the cybersecurity technology sector. These firms now account for six of the top 10 global patent holders in this sector as of August. This surge in patent filings reflects China's commitment to self-reliance in science and technology amid escalating tensions with the United States. The report highlights the growing importance of intellectual property protection in the battle for advanced technology and data security. Read more [here](#).