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PATENT & TRADEMARK POLICY REPORT JUNE 16, 2017



I. Congressional Developments:

- On Tuesday, the Subcommittee on Courts, Intellectual Property and the Internet of the House Committee on the Judiciary held a hearing titled “Examining the Supreme Court’s *TC Heartland* Decision.” In his opening remarks, Subcommittee Chairman Darrell Issa (R-CA) stated that the Subcommittee “will hear testimony about the impact of the decision and about what’s left for Congress to do.” Noting that many patent cases are likely to migrate to Delaware and California in the wake of the decision, Chairman Issa said that he “remain[s] concerned that without reform, legitimate businesses in the Eastern District of Texas will now face the patent troll problem more directly,” and that “additional efforts to rein in the abuse of our nation’s patent system will need to happen.” Ranking Member Jerrold Nadler (D-NY) expressed particular concern that “patent trolls will adapt their tactics in light of the decision” and focus on larger retailers with a national presence that have location in the Eastern District of Texas. Finally, Judiciary Committee Ranking Member John Conyers (D-MI) stated that he “continue[s] to support reasonable changes to improve and enhance the patent system, but cannot support any changes, which taken as a whole will undermine our nation’s patent system.”
- On Tuesday, House Judiciary Chairman Bob Goodlatte (R-VA) announced that Rep. John Rutherford (R-FL) would be joining the Committee. Read more [here](#).
- On Thursday, the Senate Judiciary Committee unanimously approved, by voice vote, the nomination of Vishal J. Amin to serve as Intellectual Property Enforcement Coordinator (IPEC). Amin’s nomination now heads to the Senate floor for a full Senate vote.

Headlines and Highlights:

- USTR Lighthizer to testify before Senate Finance and Ways and Means on the President’s trade agenda.
- Sens. Cornyn and Cruz pen op-ed on how to modernize NAFTA.
- Rep. John Rutherford (R-FL) announced as new addition to House Judiciary Committee.
- Senate Judiciary approves nomination of Vishal Amin to serve as IPEC.
- PTAB will hold judicial conference on June 29.
- House Judiciary holds hearing on *TC Heartland* decision.
- White House is reportedly developing an executive order on drug pricing.

- *Politico* has obtained a letter written by Rep. Zoe Lofgren (D-CA) on June 8th to Rep. Jerry Nadler (D-NY) about who would become the ranking member on House Judiciary Committee should Rep. John Conyers (D-MI) decide to retire. “While noting that Conyers has not said what his intentions are for the 116th Congress, Lofgren pointed out ‘that the top Committee position ‘need not follow seniority.’” Read more [here](#).
- On Tuesday, Sens. Cornyn and Cruz, Republicans of Texas, published an op-ed in *The Dallas Morning News* titled “It’s time to modernize the North American Free Trade Agreement (NAFTA) and Texas knows how.” Sens. Cornyn and Cruz underlined the importance of NAFTA to the Texas economy, writing that “more than 380,000 Texas jobs hinge on free trade with Mexico...” However, they also stressed how much has changed in the world since 1994, when the agreement went into effect. “The past 20 years has introduced the internet into our everyday lives, which in turn has developed industries like information technology and digital trade,” the Senators wrote, adding that, despite the vast reach of the digital economy, “there are no clear and enforceable rules on cross-border data flows or intellectual property rights, something a renegotiated NAFTA should address.” Read more [here](#).
- The Senate Foreign Relations Subcommittee on East Asia, the Pacific, and International Cybersecurity held a hearing on Tuesday about state-sponsored cyber threats. Witness Samantha Ravich (Foundation for Defense of Democracies) warned that there is anecdotal evidence that Chinese hackers have resumed largescale efforts to steal intellectual property from American companies. Ravich further warned that the U.S. government is currently “inadequately structured” to protect the private sector from these attacks. Another witness, Eric Rosenbach (Harvard University), argued that the Chinese “are [now] better at doing what they were doing before.” Read more [here](#).

II. Administration Updates:

- On Wednesday, June 21st at 10 a.m. the United States Trade Representative (USTR) Robert Lighthizer will testify before the Senate Finance Committee in a hearing on “The President’s Trade Policy Agenda and Fiscal Year 2018 Budget.” In a [press release](#) announcing the hearing, Senate Finance Chairman Hatch (R-UT) said the United States’ focus “should be on opening new markets for our exporters and protecting intellectual property rights to help maintain the United States’ competitiveness abroad.” Lighthizer will also testify before the House Ways and Means Committee on Thursday, June 22nd at 10 a.m. on the “U.S. Trade Policy Agenda.”
- The White House is reportedly developing an executive order on drug pricing, which could be signed by the President “within weeks.” A second drug pricing executive order could follow later on. This Friday, Office of Management and Budget (OMB) Director Mick Mulvaney will lead a meeting on drug pricing that will include Health & Human Services (HHS) Secretary Tom Price, Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma, and Food and Drug Administration (FDA) Commissioner Scott Gottlieb. Treasury Secretary Steve Mnuchin is also expected to attend. *Bloomberg* reports that the order may support “value-based agreements” in which payments for a drug are based on the drug’s results. Read more [here](#).

III. USPTO Updates:

- USPTO Commissioner for Trademarks Mary Denison has written a guest post on the USPTO Director's Forum Blog about her trip to the TM5 mid-term meeting in May. The TM5 is an organization made up of the trademark offices of the United States, Europe, China, Japan, and Korea, the world's five largest trademark offices. She reports that the group has "continued to make headway this year towards global trademark harmonization." Denison also details the group's current projects, such as the Common Status Descriptors project, the Identification project, and the Indexing of Non-Traditional Marks project. Read more [here](#).
- The USPTO has a new Patent Virtual Assistance Pilot Program. Through this program, WebEx is available at the Broward County Main Library's Patent and Trademark Resource Center in Fort Lauderdale, Fla. The center provides a privately located computer that meets USPTO system requirements for a secure two-way WebEx video conference with USPTO representatives.
- The Patent Trial and Appeal Board (PTAB) will hold its Judicial Conference on June 29 in Alexandria, Virginia. The program is "intended to educate the public about aspects of Board practice and provide a forum to enhance the dialogue between the public and the Board." Read more [here](#).

IV. Judicial Updates:

- On June 12, 2017, the Supreme Court handed down its opinion in [Sandoz Inc. v. Amgen Inc.](#) The case concerns an arcane provision of the [Biologics Price Competition and Innovation Act of 2009](#) (BPCIA), and specifically, the available remedies for violations of section 262(l)(2)(A) of the Act, and the timing of effective notice of commercial marketing. The BPCIA provides an abbreviated process for obtaining FDA approval of biologics (drugs derived from natural, biological sources such as animals or microorganisms), namely by piggybacking off the showing made by another manufacturer (the sponsor) or a previously licensed biologic that constitutes a biosimilar (a drug which is highly similar and has no meaningful differences in terms of safety, purity, and potency). Because the sponsor may hold multiple patents covering the biologic, the BPCIA facilitates litigation during the period preceding FDA approval. To kick off this process, the applicant must provide the sponsor a copy of the application and information about how its biosimilar is manufactured. In this case, Sandoz informed Amgen that it would not provide a copy of the application and manufacturing information for its biosimilar under section 262(l)(2)(A), and informed Amgen that it could sue for infringement immediately under section 262(l)(9)(C) of the BPCIA. After the district court granted Sandoz partial judgment on the pleadings, Amgen appealed to the Federal Circuit, which granted an injunction pending appeal. Regarding the available remedies, the Supreme Court held that "an injunction under federal law is not available to enforce §262(l)(2)(A)," and noted that section 262(l)(9)(C) provides declaratory judgment as a remedy, observing that "[s]ection 262(l)(9)(C) thus vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation." Regarding the second issue, namely the timing of effective notice of commercial marketing, the Court held that "an applicant may provide notice [of commercial marketing] before obtaining a license" from the FDA for its biosimilar, so long as notice is not provided any later than 180 days before the date of the first commercial marketing of the biosimilar. The Court observed that the timing is important because the applicant "wields

substantial control over the timing of the second phase of litigation” under the BPCIA by choosing when to give notice.

- On June 12, 2017, the Supreme Court granted certiorari in [Oil States Energy Services LLC v. Greene’s Energy Group LLC](#). The Court limited its grant to the first [question](#) presented, namely “[w]hether *inter partes* review—an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.”

V. International Updates:

- Germany’s Constitutional Court has requested that the German President refrain from signing a bill necessary for implementation of the European Unified Patent Court (UPC) until the Constitutional Court has considered a case challenging the constitutionality of that legislation. A spokeswoman for the President confirmed that the legislation will not be signed until the Court finishes its review. This development could delay Germany’s ratification of the UPC, according to analysts from law firm Pinsent Masons. The UPC system cannot take effect unless 13 European Union countries, including Germany, France, and the UK, pass ratifying legislation. Read more [here](#).

VI. Industry Updates:

- *Axios*’s Kim Hart has profiled the rising tide of complaints that large technology companies such as Google and Facebook hold too much power. Hart writes that these companies “have become enormous concentrations of wealth and data, drawing the attention of economists and academics who warn they’re growing too powerful.” However, Hart points out that FTC Chair Maureen Ohlhausen “said in a recent speech that the agency has no intention of meddling in the way tech companies use algorithms and data.” Hart also claims that “insiders expect” Makan Delrahim, the nominee to head the Department of Justice Antitrust Division, to “be cautious” when it comes to policing online platforms. Read more [here](#).