

PATENT & TRADEMARK POLICY REPORT OCTOBER 6, 2017



I. Congressional Developments:

- Senator Orrin Hatch (R-UT) - the Senate Finance Committee Chairman, and the Chairman of the Senate Republican High Tech Task Force – wrote a [post](#) about patent policy on *Medium* this week. Notably, Hatch writes that Congress may need to provide further guidance on patent venue, even despite the *TC Heartland* Supreme Court ruling. He also writes that inter partes review “clearly... warrants Congress’s attention,” but does not indicate his own views on the matter. Finally, Hatch states that Congress may have to take action on the issue of patentable subject matter, given that the *Mayo*, *Myriad*, and *Alice* Supreme Court decisions have “caused considerable uncertainty for technology and life sciences companies.”
- Senator Claire McCaskill (D-MO) has introduced [legislation](#) intended to prevent companies like Allergan from avoiding inter partes review proceedings by transferring their patents to Native American tribes, which can assert sovereign immunity. The bill (S. 1948) states that “an Indian tribe may not assert sovereign immunity as a defense in” inter partes review proceedings, according to [text](#) obtained by *IP Watchdog* (read Gene Quinn’s analysis [here](#)). In a statement, the Saint Regis Mohawk Tribe, which recently engaged in the controversial maneuver with Allergan, said the bill “specifically targets Indian tribes, yet exempts state universities and other sovereign governments engaged in the very same IPR process.” Read more [here](#). McCaskill also [sent a letter](#) to the Pharmaceutical Research and Manufacturers of America (PhRMA) on Tuesday, questioning whether Allergan’s maneuver is “consistent with the mission of your organization,” and urging “strong action by PhRMA” to “discourage other pharmaceutical actors from employing similar tactics.”

Headlines and Highlights:

- Sen. Hatch outlines patent reform priorities.
- Sen. McCaskill introduces legislation to address Allergan-Saint Regis Mohawk Tribe controversy.
- House OGR asks Allergan for relevant documents.
- Senators discuss taxation of foreign IP assets at Finance Committee hearing.
- FDA announces new measures to promote generic competition.
- AIPLA, IPO, INTA send letter to Sec. Ross expressing concern about PTO & DOC shared services.
- EU drafting patent licensing fee guidelines.

- The House Oversight & Government Reform (OGR) Committee is investigating the Allergan-Saint Regis Mohawk Tribe arrangement, having sent a [letter](#) to Allergan on Tuesday suggesting that the arrangement “may impair competition across the pharmaceutical industry and ultimately dissuade companies from pursuing less-costly generic alternatives to brand drugs.” The letter, signed by Chairman Trey Gowdy (R-SC), Ranking Member Elijah Cummings (D-MD), Rep. Dennis Ross (R-FL), and Rep. Peter Welch (D-VT), asks the company to provide the committee with a range of documents related to the deal. Allergan has said that it will comply with the committee’s requests. Read more [here](#).
- At a Tuesday Senate Finance Committee [hearing](#) on international tax issues, Chairman Orrin Hatch (R-UT) said he is unsure whether the Committee will support a new minimum tax on corporations’ foreign earnings, although he pledged to allow members of the Committee “to move in that direction” if they want. Senator Rob Portman (R-OH) said that the minimum tax is aimed at keeping “people from taking intangible income, like, say, royalty income or patent income and taking it to [the] Cayman Islands.” However, Portman, who used [much of his time](#) during the hearing to discuss international intellectual property taxation, did not indicate whether he supports the minimum tax proposal itself. Read more [here](#) and [here](#).
- Rep. Marsha Blackburn (R-TN), the vice-chair of the House Energy & Commerce Committee, announced on Thursday that she will run for the Senate seat of retiring Senator Bob Corker (R-TN). Read more [here](#).
- *Bloomberg* reports that Senator Jerry Moran (R-KS), the chairman of the Senate Commerce Committee’s Subcommittee on Consumer Protection, “is considering ways to streamline the FTC in light of the business community’s concerns that some of the agency’s practices are too burdensome.” In particular, Moran is “studying” the FTC’s merger review process. Senator Moran has submitted questions to four witnesses at a recent subcommittee hearing, asking them whether Congress should “take action to ensure that” the FTC and Department of Justice “follow the same procedures.” *Bloomberg* suggests that Moran’s line of questioning “is the latest signal that Republicans...could be gearing up to pressure the [FTC] to make changes or ask future nominees about the issues.” Read more [here](#).

II. Administration Updates:

- On Monday, Food and Drug Administration (FDA) Commissioner Scott Gottlieb [announced](#) “a major new set of policies to advance” the agency’s goal related to reducing drug prices by fostering generic competition. In particular, the FDA is issuing two sets of draft guidance to assist abbreviated new drug application (ANDA) applicants. Furthermore, the agency will “soon release other important policies aimed at spurring competition to complex drugs.” Those policies will be in the area of generic drug development, and the FDA will hold a series of workshops intended “to speed product development, reduce development costs, and improve access to these products.” The FDA will team up with the Federal Trade Commission (FTC) to host a [workshop](#) titled ‘Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics’ on November 8. Read more [here](#).
- The Office of the United States Trade Representative (USTR) held a [hearing](#) this week on China’s compliance with World Trade Organization commitments, ahead of USTR’s annual report to Congress on that subject. *Reuters* reports that at the hearing U.S. business groups

complained about “increasing threats from Chinese investment rules, industrial policies, subsidies to state-owned enterprises, excess manufacturing capacity, cybersecurity regulations and forced technology transfers.” Organizations that testified at the hearing include the Information Technology Industry Council (ITI) and the U.S. Chamber of Commerce. Read more [here](#).

- On Tuesday, October 10, USTR will hold a hearing in connection with its Section 301 investigation into China’s practices related to intellectual property and technology transfer. Read the Federal Register notice from August [here](#).
- The Department of Justice (DOJ) and Federal Trade Commission (FTC) have released their FY 2016 Hart-Scott Rodino (HSR) Report, which provides data on the HSR Premerger Notification Program and summarizes the agencies’ merger enforcement activities. Read more [here](#).

III. USPTO Updates:

- The American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO), and the International Trademark Association (INTA) sent a [letter](#) to Commerce Secretary Wilbur Ross on Monday expressing concern about the Department’s shared services initiative, and pointing out that “the Department has failed to provide adequate, concrete evidence of the expected benefits and disregarded the potential negative impacts of this arrangement on fee-paying users of the USPTO.” The organizations note that Senate Judiciary Committee Chairman Charles Grassley (R-IA) and Senator Chris Coons (D-DE) sent Ross a letter on the matter in July, and say they “are particularly eager to hear your response because we understand that the USPTO has been asked to begin contributing millions of dollars to fund the initiative’s startup costs.”
- Last Friday, the House Budget Committee released a FY 2018 budget blueprint that proposes “establish[ing] the U.S. Patent and Trademark Office as an independent agency.” However, the actual [House budget resolution](#) itself, which passed the House on Thursday, does not contain any language to that effect. Read the blueprint [here](#) (see page 50).
- This week, the USPTO’s Chief Economist held the 2017 PatentsView Workshop on Engaging User Communities. The goals of the workshop were to launch new services and features to the Community Site and Data Visualization components of PatentsView; present new patent data fields to users; and collect feedback on patent data services and analytics from the user community to set priorities for future PatentsView data products. Speakers from the PTO provided a roadmap for the future of patent data and innovative services in the PTO’s pipeline. The agency argues that open data will lead to better informed applications, which will facilitate breakthroughs in innovation and new commerce.

IV. Judicial Updates:

- On Wednesday, the Federal Circuit ruled in *Aqua Products v. Matal* that in inter partes review proceedings, the petitioner must shoulder the burden of proving the unpatentability of

amended claims. Read more [here](#), and see a collection of industry reactions [here](#).

- The Patent Trial and Appeal Board (PTAB) has rejected a challenge to a patent covering Eli Lilly's Alimta, a drug used to treat lung cancer and mesothelioma. PTAB ruled that the petitioners failed to demonstrate that it was more likely than not that the claims underlying the patent in question could not be patented. Alimta accounted for \$2.28 billion of Eli Lilly's total revenue last year, and has received multiple patentability challenges. Read more [here](#).

V. International Updates:

- *Reuters* reports that the European Commission is "drawing up guidelines on how much patent holders should charge for their technologies." The guidelines, which would not be legally binding, would address whether the rate charged can vary based on the value the underlying technology adds to the licensee's product. In a May filing to the Commission, Apple argued that "it is not reasonable to charge more for use of the very same component in a Mercedes versus a Hyundai or a car versus a bicycle." The Commission intends to finalize the guidelines by the end of this year. Read more [here](#).
- The European Union has ordered Amazon to pay Luxembourg approximately \$295 million in back taxes after Amazon allegedly moved profits to a holding company that was not subject to tax. European Union Competition Commissioner Margrethe Vestager said that Luxembourg had given Amazon "illegal tax benefits" such that "almost three quarters of Amazon's profits were not taxed." Amazon maintains that it "did not receive any special treatment from Luxembourg," and is considering appealing the decision. Read more [here](#).

VI. Industry Updates:

- In an *IP Watchdog* op-ed, Joseph Allen, a former Judiciary Committee staffer for Senator Birch Bayh (D-IN), argues that "policy makers should place a heavy burden of proof on those wanting to alter the Bayh-Dole system," noting that China, having recognized the system's benefits, "is adapting their own Bayh-Dole model" with the goal of "surpass[ing] us." Allen warns that, "like seven-year locusts, we're again seeing instant experts buzzing around state and national leaders with cries that the current tech transfer system is failing." These critics are arguing for reforms such as a greater role for the government in increasing commercialization rates, and the use of metrics such as a university's revenue per patent. Read more [here](#).