

PATENT & TRADEMARK POLICY REPORT OCTOBER 13, 2017



I. Congressional Developments:

- Ten healthcare organizations have written a [letter](#) to House Speaker Paul Ryan (R-WI), House Minority Leader Nancy Pelosi (D-CA), Senate Majority Leader Mitch McConnell (R-KY), and Senate Minority Leader Chuck Schumer (D-NY) calling Allergan's use of the Saint Regis Mohawk Tribe's sovereign immunity to avoid Inter Partes Review (IPR) challenges to its patents a "brazen attempt to circumvent U.S. law and engineer a mechanism to maintain monopolistic high drug prices." The letter's signatories - including the BlueCross BlueShield Association, the American Hospital Association, and the Alliance of Community Health Plans – urge Congress to "apply [its] oversight authority to shine a light on the possible effects" of Allergan's maneuver "and its implications for U.S. health care spending, intellectual property law, and access to affordable medicines." Additionally, the letter argues that Allergan's agreement threatens competition from generic and biosimilar alternatives.
- In an [op-ed](#) in the *Wall Street Journal* on Sunday, Allergan CEO Brent Saunders remained defiant about his company's arrangement with the Saint Regis Mohawk Tribe. Saunders argues that the IPR process itself is to blame, not his company's maneuver, which is merely "a way of protecting the [company's] intellectual property from unfair challenges" in IPR. He writes that "the IPR process is stacked against biopharmaceutical patents" and "expressly undermines the legitimacy of approved patents."
- Speaking to the *Financial Times* this week, former Representative Henry Waxman, well-known as an author of the 1984 Hatch-Waxman Act, criticized Allergan's maneuver, saying it would have the effect of "blocking competition that

Headlines and Highlights:

- Allergan CEO defends Native American tribe maneuver, criticizes IPR process.
- Ten healthcare organizations urge Congress to investigate Allergan deal.
- USTR holds hearing on China Section 301 investigation.
- Stakeholders concerned that NAFTA renegotiations might break down.
- Supreme Court to hear oral arguments in *Oil States* and *SAS* cases on November 27.
- Antonio Campinos elected President of European Patent Office.
- AIPLA to hold 2017 Annual Meeting next week, will honor Sens. Hatch and Leahy.

would create price competition and provide patients with a choice.” Waxman said Allergan entered into the agreement “with the intention of extending [its] drug’s monopoly,” and warned that “now we are seeing efforts that are throwing off the balance we achieved” in the Hatch-Waxman Act between promoting competition and providing incentives for manufacturers. In response, Allergan said that Waxman “is not appreciating the facts” of the agreement, which the company entered into to avoid the “fatally flawed IPR process.” Read more [here](#).

- The Allergan-Saint Regis Mohawk deal has received significant scrutiny from Congress in recent weeks. Senator Claire McCaskill (D-MO) has introduced a [bill](#) (S. 1948) to ban such maneuvers, and the House Oversight & Government Reform Committee is [investigating](#) Allergan. Four Senators have also [asked](#) the Senate Judiciary Committee to investigate the issue. With limited to no support apparent on Capitol Hill for Allergan’s deal, the policy debate appears to be headed towards how, not whether, Congress should act to prevent companies from using Native American tribes’ sovereign immunity to avoid Inter Partes Review challenges.
- On Wednesday, the International Trademark Association (INTA), the U.S. Chamber of Commerce Global Intellectual Property Center (GIPC), and the Congressional Trademark Caucus held a briefing on Capitol Hill titled ‘The Intersection of Trademarks and Brands: A Dialogue with Famous Brands and Law Enforcement.’ The event featured remarks from Senator Chris Coons (D-DE), Senate Judiciary Committee Chairman Chuck Grassley (R-IA), Rep. John Ratcliffe (R-TX), and Rep. Ted Deutch (D-FL), the co-chairs of the Congressional Trademark Caucus. In addition to trademark issues, the event featured broader discussion about the importance of protecting intellectual property.
- The House Energy & Commerce Subcommittee on Oversight and Investigations held a [hearing](#) on Wednesday about the 340B drug pricing program. The hearing covered issues such as transparency and accountability in the program, the spending practices of covered entities, hospitals’ buyouts of private clinics, and the provision of drugs to rural areas. Read more [here](#) and [here](#).
- On Wednesday, Rep. Keith Ellison (D-MN) sent a letter to Acting Federal Trade Commission (FTC) Chair Maureen Ohlhausen requesting that the agency make public its reports “documenting the complete findings and analysis in the [FTC’s] Google antitrust investigation that concluded in 2013.” The letter argues that “given the impact Google has on small businesses, the flow of information, and that Google controls an outsize portion of the market for online search and online advertising, the public has a right to know what the Federal Trade Commission found in its investigation into Google.” Read the letter [here](#).
- *Bloomberg* reports that Google, Facebook, and Twitter are “scrambl[ing] to hold Washington at bay” in light of recent controversy over issues such as election interference, fake news, online sex trafficking, and potential antitrust violations. In September, Google “summoned about 200 staff from around the world for an annual policy meeting,” where “one agenda item” was “how to deal with the sudden drumbeat of calls in the U.S. to regulate the company for being too big.” Meanwhile, Facebook has hired two “crisis PR firms,” and its “top executives, including Chief Executive Officer Mark Zuckerberg, are phoning members of Congress directly.” Read more [here](#).

- On Tuesday, October 17, the Senate Committee on Health, Education, Labor, and Pensions (HELP) will hold a [hearing](#) titled ‘The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay.’
- On Wednesday, October 18, the Senate Foreign Relations Committee will hold a [hearing](#) on the nomination of Manisha Singh to be Assistant Secretary of State for Economic and Business Affairs. Singh was most recently Chief Counsel and Senior Policy Advisor to Senator Dan Sullivan (R-AK).

II. Administration Updates:

- On Tuesday, the Office of the United States Trade Representative (USTR) held a public hearing about its Section 301 [investigation](#) into Chinese government acts, policies, and practices related to technology transfer, intellectual property, and innovation. The hearing featured testimony from organizations such as the Commission on Theft of American Intellectual Property; the Information Technology and Innovation Foundation; the American Bar Association Intellectual Property Law Section; and the Center for Strategic & International Studies. While organizations representing American companies described an array of challenges they face doing business in China, representatives from Chinese industry said they are “greatly concerned about the investigation,” and warned that any penalties the Trump administration might levy “may trigger a trade war.” Read more [here](#) and [here](#).
- *Axios* and other publications have reported this week that members of Congress and their staff are concerned that the Trump Administration’s proposals in NAFTA renegotiations are too extreme for Canada and Mexico to accept, and may even be designed to “give Trump the justification he’s been searching for to withdraw.” The potentially controversial proposals are about issues such as automobile rules of origin, Investor State Dispute Settlement, and a five-year sunset on the deal. Read more [here](#) and [here](#).
- On Wednesday, the leaders of the International AntiCounterfeiting Coalition (IACC), the Biotechnology Innovation Organization (BIO), the Motion Picture Association of America (MPAA), the Recording Industry Association of America (RIAA), and the Pharmaceutical Research and Manufacturers of America (PhRMA) wrote an op-ed in *The Hill* arguing that in NAFTA renegotiations, “U.S. negotiators ought to insist on trade policies that respect innovation and creativity, and ensure strong protections for IP and creative content.” In one passage, the authors state that “many U.S. trading partners, including Canada and South Korea, impose draconian price cuts on innovative U.S. medicines – severely undervaluing U.S. innovation.” Read more [here](#).

III. USPTO Updates:

- On Wednesday, October 18, the U.S. Patent & Trademark Office (USPTO) will host a day-long [roundtable](#) on intellectual property infringement at trade shows. Read the agenda [here](#).
- On Thursday, the USPTO held a [webinar](#) titled ‘Examiners Provide Their Views on Prepared Applications: Application Readiness Survey.’ The webinar featured discussion of the USPTO’s twice-yearly survey of patent examiners, which is part of the agency’s patent

quality initiative. The survey found that examiners reported three areas in particular that applicants should focus on to improve their applications: clear specification of the inventive concept; having independent claims that capture the same inventive concept disclosed in the specification; and having claims that are solely directed at the inventive concept.

- A number of trademark systems, including the Trademark Electronic Application System (TEAS) and the Trademark Status and Document Retrieval (TSDR) system, will undergo maintenance from 8pm on Saturday, October 14 to 5:30am on Monday, October 16, and system availability may be affected. Read more [here](#).

IV. Judicial Updates:

- Last Friday, the Supreme Court released the [calendar](#) for its December sitting, which starts on November 27. The Court will hear oral arguments in two patent cases - *Oil States v. Greene's Energy* and *SAS v. Matal* - on November 27.
- On Thursday, Allergan reached a settlement with InnoPharma, one of the four generic pharmaceutical companies challenging the patents on its drug Restasis in a Texas district court. The remaining three companies are Mylan, Teva, and Akorn. Restasis has been the subject of intense controversy in recent weeks after Allergan transferred its patents on the drug to the Saint Regis Mohawk tribe in order to avoid Inter Partes Review challenges. Read more [here](#).
- Restasis was drawn into further legal difficulties last week when Shire filed a lawsuit in federal court arguing that Allergan has engaged in anticompetitive practices by entering into exclusive contracts for Restasis with Medicare Part D providers, shutting out Shire's competing product called Xiidra. Read more [here](#).

V. International Updates:

- Antonio Campinos has been elected President of the European Patent Office (EPO), with his five-year term beginning in July 2018. Campinos is currently the Executive Director of the European Union Intellectual Property Office (EUIPO). Read more [here](#).
- *Politico* reports that brand-name and generic pharmaceutical companies are fighting in Europe over potential waivers to supplementary protection certificates, which grant branded drug makers an extra five years during which generic rivals cannot produce their versions of branded drugs within the European Union, although they can do so elsewhere. The European Commission is considering waivers that would allow generic companies to produce generic versions of drugs covered by such a certificate within the European Union, although they would only be allowed to sell those drugs outside of the European Union's borders. Read more [here](#).
- Qualcomm has filed lawsuits in China accusing Apple of infringing three patents covering power management and touch-screen technology. *Bloomberg* [reports](#) that Qualcomm is "seeking to ban the sale and manufacture of iPhones in the country," with the suits representing "the chipmaker's biggest shot at Apple...so far in a sprawling and bitter legal

fight.” Separately, on Wednesday Taiwanese authorities fined Qualcomm approximately \$744 million for antitrust violations in the CDMA, WCDMA, and LTE chip markets. Read more [here](#).

- In a speech at the U.S. Chamber of Commerce this week, French Finance Minister Bruno Le Maire said that Europe should make “much faster progress” with regard to increasing taxes on American internet companies such as Google and Amazon. The *Wall Street Journal* reports that Le Maire suggested taxing those companies on their turnover instead of their profits. Read more [here](#).

VI. Industry Updates:

- The Center for the Protection of Intellectual Property (CPIP) at the George Mason University Antonin Scalia Law School held its [2017 Fall Conference](#) on Thursday and Friday. The conference, which sought to “encourage and discuss proposals to make IP work more effectively,” featured panel discussions on topics such as the international IP system and IP in trade agreements, the concept of property in IP, and the relation between antitrust policy and IP.
- The American Intellectual Property Law Association (AIPLA) will hold its [2017 Annual Meeting](#) next week from Tuesday, October 17 to Saturday, October 21. The organization will [honor](#) Senators Orrin Hatch (R-UT) and Patrick Leahy (D-VT) with its Board of Director’s Excellence Award, recognizing their “outstanding contributions fostering intellectual property law.”