

## PATENT & TRADEMARK POLICY REPORT SEPTEMBER 29, 2017



### I. Congressional Developments:

- On Wednesday, the Senate confirmed Makan Delrahim to lead the Department of Justice (DOJ) Antitrust Division by a [vote](#) of 73-21. In a [statement](#), Senator Orrin Hatch (R-UT) said that “amid the rising controversy over competition law in the 21<sup>st</sup> century,” Makan Delrahim “is precisely who we need at the helm.” Last Friday, *Reuters* [reported](#) that Senator Elizabeth Warren (D-MA) had lifted the hold she had placed on Delrahim’s nomination.
- The newly-formed [ACTION for Trade](#) coalition, which seeks to ensure that U.S. trade policy and trade agreements advance a “pro-creativity and innovation agenda,” held its official launch event Tuesday on Capitol Hill. Senator Orrin Hatch (R-UT) delivered remarks at the event, and, [according](#) to *Politico*, indicated that he would fight for 12 years of data protections for biologics in a renegotiated North American Free Trade Agreement (NAFTA), and expressed his approval that the administration has said it will push for stronger intellectual property protections in NAFTA. He also said that strong intellectual property language in a renegotiated NAFTA should be used in future trade agreements. The event also featured remarks from Reps. Doug Collins (R-GA) and Scott Peters (D-CA).
- Senators Maggie Hassan (D-NH), Sherrod Brown (D-OH), Bob Casey (D-PA), and Richard Blumenthal (D-CT) have written a [letter](#) to Senate Judiciary Chairman Chuck Grassley (R-IA) and Ranking Member Dianne Feinstein (D-CA) criticizing Allergan’s move to transfer its patents on the drug Restasis to the Saint Regis Mohawk Tribe. The Senators call the move a “blatantly anti-competitive attempt to shield [the] patents from review and keep drug prices high.” The letter states that Allergan

### Headlines and Highlights:

- Senate confirms Delrahim to lead DOJ Antitrust Division.
- Hatch seeks biologics protections in renegotiated NAFTA.
- Senators request Judiciary Committee action on patent arrangement between Allergan and Saint Regis Mohawk Tribe.
- Hatch delivers a second floor speech on antitrust policy.
- Energy & Commerce Subcommittee to hold hearing on access to experimental treatments.
- Rep. Blackburn considering Senate run.
- Tessera files a range of patent infringement legal proceedings against Samsung.

will “license its patents back from the Tribe and continue to sell Restasis,” with the arrangement allowing Allergan to “circumvent” an inter partes review (IPR) of the drug’s patents by having the Tribe assert its sovereign immunity. Notably, the Senators ask the Judiciary Committee to take action. They write that the Committee should investigate Allergan’s arrangement with the Tribe, “examine its implications on pharmaceutical competition and the high cost of prescription drugs, and shine a spotlight to ensure ‘innovation’ in the pharmaceutical industry is not about seeking new legal loopholes but instead about improving the lives of patients.” Responding to the senators’ letter, Allergan said that “experts across the legal, biopharmaceutical and business communities have called on Congress to fix the issues inherent within IPR. Congress has failed to protect innovation, and the matter is now before the United States Supreme Court [in the *Oil States* case].” Read more [here](#).

- Rep. Marsha Blackburn (R-TN), the Vice-Chair of the House Energy & Commerce Committee, announced on Tuesday that she is considering a run for the Senate seat of retiring senator Bob Corker (R-TN). In a statement, Rep. Blackburn’s campaign spokeswoman said that “over the next week” Rep. Blackburn “will take a look at the Senate race and decide, how, and where, she believes she can best serve her state and her nation.” Read more [here](#).
- On Tuesday, the Senate Commerce Committee held a hearing on Federal Trade Commission (FTC) reform proposals. During the hearing, Senator Richard Blumenthal (D-CT) criticized the FTC for failing to take action against Google for demoting its competitors’ content in search results, saying that the FTC has “a duty to investigate and discipline Google for any illegal actions that may have unfairly disadvantaged competitors and limited consumer choice.” The hearing largely focused on the FTC’s role in privacy and data security in the wake of the recent Equifax breach. Read more [here](#).
- On Monday, Senator Orrin Hatch (R-UT) delivered a [floor speech](#) on antitrust policy, a follow up to a speech he [made in early August](#) notable for its use of the term “hipster antitrust” to describe antitrust policy that seeks a mandate broader than that provided by the consumer welfare standard. In his speech on Monday, Hatch struck the same notes, praising the consumer welfare standard and urging “caution, especially to some of the more zealous advocates for reform, hipster or otherwise.” He said, “I’ll gladly sample the avocado toast. I really will. But nobody should get the idea we’ve moved on from the meat and potatoes.”
- On Thursday, the Senate approved the nomination of former Utah Governor Jon Huntsman to be U.S. Ambassador to Russia by voice vote. Read more [here](#).
- On Tuesday, October 3, the House Energy & Commerce Subcommittee on Health will hold a [hearing](#) titled ‘Examining Patient Access to Investigational Drugs.’ The hearing will cover patient access to investigational drugs, and the Food & Drug Administration’s (FDA) expanded access program. The subcommittee will also discuss HR 1020, the Compassionate Freedom of Choice Act of 2017, which seeks to allow terminally ill patients to use investigational drugs and devices, and S. 204, the Right to Try Act of 2017, which allows terminally ill patients to access experimental drugs, biological products, and medical devices. The latter bill passed the Senate in August.
- On Thursday, October 5, the Senate Finance Committee will hold a [hearing](#) on the nominations of Jeffrey Gerrish to be Deputy U.S. Trade Representative for Asia, Europe, the

Middle East, and Industrial Competitiveness, and Jason Kearns to be a member of the International Trade Commission (ITC).

- On Wednesday, October 4, the Senate Commerce Committee will [vote](#) on the nominations of David Redl to lead the National Telecommunications and Information Administration (NTIA) and Walter Copan to lead the National Institute of Standards and Technology (NIST).

## II. Administration Updates:

- President Trump has [announced](#) his intent to nominate Dennis Devaney and Randolph Stayin to serve on the International Trade Commission (ITC).
- The Food & Drug Administration (FDA) has [issued](#) final guidance titled ‘Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization.’ The guidance “provides recommendations to pharmaceutical companies interested in participating in the FDA’s Emerging Technology Program.” In a statement, FDA Commissioner Scott Gottlieb said, “In recent years, we’ve seen significant advances in modernization of drug manufacturing, including shifts to continuous manufacturing and the first 3D printed drug [...] The FDA is committed to continuing to foster advances in innovative pharmaceutical manufacturing.”
- In an article about copyright policy in NAFTA renegotiations this week, the *Wall Street Journal* cited congressional aides as saying that U.S. Trade Representative Robert Lighthizer is “eager to boost intellectual property provisions in NAFTA.” Read more [here](#).
- White House Chief of Staff John Kelly has moved Peter Navarro and his Office of Trade and Manufacturing Policy (OTMP) into the National Economic Council (NEC), meaning that Navarro will now report to NEC Director Gary Cohn. Read more [here](#).
- Commerce Secretary Wilbur Ross met with Chinese Government officials in Beijing this week. According to a Commerce Department [statement](#), Ross “relayed the ongoing concerns of the U.S. business community at forced technology transfers, data localization, and other intellectual property rights issues.” Ross also “highlighted his intention to lead a senior level trade mission to China in November.” The Commerce Department has issued a [Federal Register notice](#) inviting companies to apply to participate in the mission. President Trump also [plans](#) to visit China in November. Read more [here](#).
- The White House has been engaged in a “comprehensive review of its approach to China,” according to *Politico*. The review has been ongoing “for months,” and is being led by the National Security Council (NSC) and the National Economic Council (NEC). *Politico* reports that the review is focusing on issues such as intellectual property, forced joint ventures, trade secret and scientific research theft, and cybersecurity. The review will result in a report to the President that is “expected to include hundreds of policy options, ranging in severity.” Read more [here](#).
- *Bloomberg* reports that former White House Chief Strategist Steve Bannon, now back at *Breitbart News*, “is preparing a project to sound an alarm about what he views as the primary

economic threat to America: China.” Bannon told *Bloomberg* that “the forced technology transfer of American innovation to China is the single biggest economic and business issue of our time. Until we sort that out, they will continue to appropriate our innovation to their own system and leave us as a colony – our Jamestown to their Great Britain, a tributary state.” He has been consulting with foreign policy experts such as Henry Kissinger, hoping to apply pressure and “tilt Trump toward action.” In particular, Bannon is considering starting a “global conference series” in locales around the world, including East Asia. Read more [here](#).

- On Monday, President Trump signed a [memorandum](#) about increasing access to Science, Technology, Engineering, and Mathematics (STEM) Education. The memorandum directs the Department of Education to “establish a goal of devoting at least \$200 million in grant funds per year to the promotion” of STEM education, and computer science in particular. It also directs the Department of Education to prioritize STEM education, with a particular focus on computer science and the recruitment and training of STEM teachers. In connection with President Trump’s memorandum, a number of technology companies, [including Internet Association members](#) Facebook, Google, Amazon, and Microsoft, have committed to spend \$300 million on computer science education programs over the next five years. Read more [here](#).
- The State Department has named Robert Strayer as Deputy Assistant Secretary for Cyber and International Communications and Information Policy. Strayer formerly worked as a general counsel on Senator Bob Corker’s (R-TN) Foreign Relations Committee staff, and as director of the Bipartisan Policy Center’s Homeland Security project. Read more [here](#).

### III. USPTO Updates:

- The USPTO will hold a Patent Quality Chat webinar on October 12 from 11am to noon EST. The webinar will cover recent USPTO polling of examiners on patent applications that “enhance the ability of examiners to efficiently and effectively do their job.” Read more [here](#).
- The USPTO has extended the After-Final Consideration Pilot 2.0 and the Quick Path IDS pilot until September 30, 2018. Read more [here](#).
- The USPTO is now accepting applications for its ‘Patents for Humanity’ award, which seeks to honor “patent owners and licensees who use game-changing technology to meet humanitarian needs.” Read more [here](#).

### IV. Judicial Updates:

- Tessera Technologies, a subsidiary of Xperi Corporation, has filed 10 legal proceedings against Samsung over the alleged infringement of 24 patents in Samsung’s semiconductor products, Galaxy and Note smartphones, and other technologies. The proceedings were filed in the U.S. International Trade Commission, three U.S. federal district courts, and in Germany and the Netherlands. “Although we always prefer to reach negotiated license agreements, Samsung has left us with no choice but to defend our intellectual property rights through these legal actions,” said Xperi CEO Jon Kirchner. “We are confident in the breadth and quality of the proceedings we initiated today and we strongly believe these actions are in

the best interests of the company, our other licensees, and our shareholders.” Read more [here](#).

- AbbVie has reached a settlement with Amgen under which Amgen will refrain from selling its biosimilar version of AbbVie’s Humira in the United States until 2023. AbbVie remains in litigation with Boehringer Ingelheim over that company’s biosimilar version of Humira. Read more [here](#).
- The *Chicago Tribune* reports that the Chicago Cubs are ramping up efforts to crack down on the sale of counterfeit merchandise. The Cubs are Major League Baseball’s most active user of the Trademark Trial and Appeal Board (TTAB), having opposed 47 trademark applications since the start of their 2016 championship season. The Cubs used the TTAB “about four times as frequently as the runner-up New York Yankees.” Read more [here](#).

## V. International Updates:

- The International Generic and Biosimilar Medicines Association (IGBA) recently held a panel discussion at the World Trade Organization (WTO) on the role of competition policy in promoting access to medicines. *Intellectual Property Watch*’s Catherine Saez writes that panelists discussed topics such as provisions in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement that involve competition policy; generic competition; and the inclusion of ‘TRIPS-plus’ provisions in trade agreements. One panelist cautioned against weakening patents with excessive competition law, noting that it “is inherent in the patent system to license exclusively and benefit from market exclusivity for a period of time.” Read more [here](#).

## VI. Industry Updates:

- On Tuesday, September 26, the Center for Strategic and International Studies (CSIS) hosted a [conference](#) on humanitarian licensing, a new concept in intellectual property (IP) policy concerned with promoting access to goods that improve the quality of life in lower income countries. The program focused on voluntary licensing models that allegedly strike a balance between promoting access to pharmaceutical drugs in developing countries and protecting the rights of patent holders. Panelists largely praised voluntary licensing, arguing that in many cases it allows companies to enter markets that would not otherwise be profitable, and to facilitate the delivery of drugs to low-income individuals. Read more [here](#).
- On Tuesday, October 3, The Atlantic will host an event about how the health care industry can make prescription drugs more affordable. Speakers will include Senator Amy Klobuchar (D-MN), Rep. Patrick Meehan (R-PA), and representatives from organizations such as AARP, PhRMA, and America’s Health Insurance Plans. Read more [here](#).