

PATENT & TRADEMARK POLICY REPORT May 7, 2021



I. Congressional Developments:

- On Tuesday, the House Energy and Commerce Subcommittee on Health held a hearing titled "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs." Democratic members pushed their drug pricing legislation, H.R.3, saying it was essential to lowering Americans' pharmacy expenses. Meanwhile, Republican lawmakers endorsed H.R.19, which includes a series of reforms including an out-of-pocket cost cap for seniors on Medicare Part D. Representatives David McKinley (R-WV), Markwayne Mullin (R-OK), and McMorris Rodgers (R-WA) questioned how H.R. 3 would impact the discovery of new medications, including for rare diseases. Many Republicans, including Representative Rodgers, argued that allowing Medicare to negotiate would stifle private innovation. The hearing comes as Democrats are pressing for the inclusion of their legislation to grant Medicare power to negotiate for lower drug prices in a massive infrastructure package. Watch the full hearing here.
- On Wednesday, May 12th, at 9:30 a.m. ET, the Senate Finance Committee will hold a hearing on "The President's 2021 Trade Policy Agenda," featuring testimony from United States Trade Representative (USTR) Katherine C. Tai. More info. here.
- On Thursday, May 13th, at 10:00 a.m. ET, USTR Tai will testify before the House Ways & Means Committee at a hearing on the Biden Administration's 2021 trade policy agenda. More info. here.

Headlines and Highlights:

- Biden Administration announces its intention to support a WTO proposal to waive protections for COVID-19 vaccines.
- USTR Tai to testify before Senate Finance Committee next week.
- House Energy & Commerce Subcommittee on Health considers legislation to lower the cost of prescription drugs at hearing.
- Washington Post Editorial
 Board cautions that waiving
 IP protections for the
 COVID-19 vaccine is not
 the best way to ensure
 equitable access.
- WSJ Editorial Board warns that Biden's decision to support WTO IP waiver may be "the single worst presidential economic decision since Nixon's wage-and-price controls."

• After the Biden Administration announced its intention to support the WTO IP waiver, congressional republicans quickly criticized the decision. Senators Tillis (R-NC) and Cotton (R-AR), members of the Senate Judiciary Committee, issued a joint press release calling the decision "disastrous" and that it will "do little to end the COVID-19 pandemic and help developing nations." Rep. Kevin Brady (R-TX), Ranking Member of the House Ways and Means Committee, said "it is dangerous for America to "consent to strip away patents on lifesaving COVID vaccines now that cost businesses billions of dollars to develop at a historic pace." "The better solution to help our global neighbors is to solve the very real logistical hurdles slowing access to these vaccines, not undermine the incentives to develop them."

II. Administration Updates:

• On Wednesday, United States Trade Representative (USTR) Katherine Tai announced that the Biden Administration will support a World Trade Organization proposal to waive IP protections for COVID-19 vaccines. "The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines," the statement from Tai reads. "We will actively participate in text-based negotiations at the World Trade Organization needed to make that happen." It remains unclear how broad the scope of the final waiver will be, but the current iteration includes patents, copyrights, and trade secrets. India and South Africa, the countries leading the waiver, agreed on Wednesday to revise their proposal and will present it to members for a meeting tentatively scheduled for the second half of May. Read more here.

III. USPTO Updates:

- USPTO is seeking nominations for the 2021 National Medal of Technology and Innovation (NMTI). The NMTI is the nation's highest honor for technological achievement and is presented to recipients by the President of the United States at a White House ceremony. NMTI staff will hold a webinar to answer questions about the award and the nomination process on June 2nd at 12:00 p.m. ET, and nominations are due by July 30th. More info. here.
- On Thursday, May 13th, from 12:00 1:00 p.m. ET, USPTO is hosting a discussion about preparing for an appeal brief for independent inventors, new practitioners, and those interested in learning more about the Patent Trial and Appeal Board (PTAB). Vice Chief Judge Janet Gongola, Lead Judge James Worth, Judge Eric Jeschke, Judge Frances Ippolito, Judge Nina Medlock, and Acting IT Branch Chief Joy Weber are all slated to participate in the discussion. More info. here.
- On Thursday, May 27th, from 1:00 2:00 p.m. ET, USPTO is hosting a conversation about innovation featuring Frances Ligler, National Inventors Hall of Fame inductee and leader in the optical biosensor industry, and Drew Hirshfeld, performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. Ligler will discuss her work as a groundbreaking biochemist and bioengineer and offer lessons learned from her personal journey. Register online here.

IV. Judicial Updates:

• News surfaced this week that Skittles owner Mars Wrigley has filed complaints against Terphogz, the maker of THC-infused candy Zkittlez, on the grounds of trademark infringement. "At Mars Wrigley we take great pride in making fun treats that parents can trust giving to their children and children can enjoy safely. We are deeply disturbed to see our trademarked brands being used illegally to sell THC-infused products, and even more so to hear of children ingesting these products and becoming ill," a Mars company spokesperson said in an email to *CNBC*. The Skittles maker is seeking damages from Terphogz and its resellers and has asked the court to place a permanent injunction on the sale of any products using Zkittlez marks and hand over any products or merchandise using the marks. Read more here.

V. International Updates:

- Late last week, Margrethe Vestager, the European Commission's top antitrust official, said Apple is in breach of competition law because it charges app developers high commission fees and forbids them from advertising cheaper alternatives. "Our preliminary conclusion is that Apple abused its dominant position for the distribution of music streaming apps through its app store, and distorted competition in the music streaming markets," she told reporters during a press conference. Apple will now be offered the opportunity to reply to the Commission in writing and request a hearing. More info here.
- This week, the European Union Intellectual Property Office (EUIPO) released a study titled "Monitoring and analyzing social media in relation to IP infringement." The researchers looked at the role of social media in relation to counterfeiting and piracy. They found that 35% of all conversations on digital content could "possibly" be related to piracy and observed that Reddit was the most used site for piracy-related conversations. Read the report here.
- On Thursday, the European Union said it would consider the Biden Administration's decision to support the WTO IP waiver. In a speech on Thursday, European Commission President Ursula von der Leyen did not endorse the plan and raised questions about whether the bloc would agree to waive patents. Instead, she suggested that the focus should be on getting more vaccines to countries that are in need by following the EU's example in permitting the ample export of doses. The EU would need to approve the waiver in order for it to be enacted since unanimous approval by WTO member countries is required for any proposal to waive patents. Read more here.

VI. Industry Updates:

• On Monday, The Washington Post Editorial Board cautioned that waiving IP protections for the COVID-19 vaccine is not the best way to ensure equitable access. They argued that turning over IP rights on vaccines to other nations "would not quickly result in more shots" becuase vaccine manufacturing is exacting and time-consuming. Instead, the Editorial Board suggests that the U.S. should share its sizable vaccine surplus with the world, beyond those doses already pledged to Canada and Mexico. Furthermore, U.S. manufacturers should be encouraged to strike licensing deals in order to speed production in qualified facilities elsewhere. Read more here. • On Thursday, The Wall Street Journal Editorial Board warned that President Biden's decision to endorse a patent waiver for COVID-19 vaccines and therapies may be "the single worst presidential economic decision since Nixon's wage-and-price controls." The Editorial Board cites that the global vaccine supply is already increasing rapidly due to licensing agreements that vaccine makers have made with manufacturers around the world. Furthermore, they insist that busting patents will not speed up production, since it would take months for countries to set up new facilities. Finally, they raise potential safety concerns if unlicensed producers begin making vaccines. "Waiving IP protections for Covid vaccines and medicines will give away America's crown pharmaceutical jewels and make the U.S. and world more reliant on India and China for pharmaceuticals," the article concludes. Read more here.