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Tai Fills Dance Card with Vaccine Manufacturers

As member countries of the World Trade Organization (WTO) continue to debate a temporary IP waiver for COVID-19 vaccines, U.S. Trade Representative (USTR) Katherine Tai met with leaders of all the major vaccine manufacturers and Bill Gates to discuss “increasing vaccine production, global health issues and the proposed waiver,” the USTR’s office said in a series of readouts.

At a formal meeting of the WTO Council on Trade-Related Aspects of IP Rights (TRIPS) April 30, like the informal meeting a week earlier, members still could not reach consensus on a proposal for the waiver (see **WTTL**, April 26, page 2). Proposal cosponsors said they will review the text initially submitted in October 2020 “in an effort to reconcile positions,” a Geneva trade official said.

In addition to Gates, Tai’s meetings held April 26-30 included: Dr. Ruud Dobber, head of U.S. business at AstraZeneca; Pfizer Chairman and CEO Dr. Albert Bourla; John Trizzino, executive VP, chief commercial officer and chief business officer of Novavax; Moderna CEO Stéphane Bancel; and Johnson & Johnson Vice Chairman Joaquin Duato.

With Dobber, Tai said the U.S. “was examining options to share AstraZeneca vaccine doses with other countries as they become available,” a USTR readout noted. She “also emphasized her commitment to working with WTO members on a global pandemic response, including the role of developing countries in any effective solution that addresses critical gaps in global production and distribution of vaccines,” the agency added.

SAP Pays \$8 Million to Settle Export Violations

In the first resolution under a two-year-old Justice policy on voluntary self-disclosures (VSDs), German software manufacturer SAP SE agreed April 29 to pay more than \$8 million in combined penalties as part of a global settlement with Justice, the Bureau of

Industry and Security (BIS) and Treasury's Office of Foreign Assets Control (OFAC). The company settled charges of exporting SAP products, including software, upgrades and patches, to end-users in sanctioned countries, including Iran, without the required export licenses from December 2009 through September 2019. The U.S.-origin software was designated Export Control Classification Number (ECCN) 5D002.c.1 and EAR99, the BIS order noted.

"SAP and SAP Partners, located in Turkey, United Arab Emirates, Germany, and Malaysia, sold SAP software licenses and maintenance agreements to 14 foreign-registered pass-through entities. These pass-through entities were shell corporations located outside of Iran that conducted business in Iran and were directly affiliated with Iranian companies," it added.

"End users in Iran utilized the pass-through entities to make 24,634 downloads of SAP software products, upgrades, and patches from SAP's servers and Company A's servers," BIS noted. The company agreed to pay BIS a \$3.29 million civil penalty and will disgorge \$5.14 million under a non-prosecution agreement (NPA) with Justice.

"Additional apparent violations occurred when SAP's cloud business group (CBG) subsidiaries in the United States sold cloud-based software subscription services to customers that enabled access to employees or customers in Iran. These exports occurred partly as a result of a failure to timely integrate the CBG subsidiaries into SAP's broader compliance structure," OFAC noted.

Justice revised its voluntary self-disclosure (VSD) policy for export control and sanctions cases in December 2019 (see **WTTL**, Dec. 16, 2019, page 5). "When a company (1) voluntarily self-discloses export control or sanctions violations to CES, (2) fully cooperates, and (3) timely and appropriately remediates ... there is a presumption that the company will receive a non-prosecution agreement and will not pay a fine, absent aggravating factors," the department wrote at the time.

"SAP conducted a thorough and extensive investigation into historical export controls and economic sanctions violations. We accept full responsibility for past conduct, and we have enhanced our internal controls to ensure compliance with applicable laws," the company said in a statement. "Our significant remediation efforts, combined with our full and proactive cooperation with U.S. authorities, have led to a mutually agreeable resolution of the Iran investigation without the imposition of an external monitor," it added.

SAP agreed in February 2016 to pay disgorgement of \$3.7 million in profits to settle Securities and Exchange Commission (SEC) charges of violating the Foreign Corrupt Practices Act (FCPA) to win business in Panama (see **WTTL**, Feb. 8, 2016, page 8).

Just in Time, EU Parliament Blesses Brexit Trade Deal

At the same time that the European Parliament formally ratified Brexit, or the Trade and Cooperation Agreement (TCA), the deal cost Northern Ireland First Minister Arlene

Foster her job. Foster was just the latest in the line of United Kingdom leaders who resigned or were fired over Brexit and the preceding years of acrimony with the European Union (EU).

Foster, leader of the Democratic Unionist Party (DUP), was a staunch opponent of the Northern Ireland Protocol. “The Protocol being foisted upon Northern Ireland against the will of unionists has served to destabilize Northern Ireland in more recent times,” she said in a statement announcing her resignation April 28. In February, she tweeted: “It’s time for the Government to step up & protect this part of the United Kingdom with permanent solutions, not sticking plasters” (see **WTTL**, Feb. 15, page 5).

Under the Protocol, goods coming from Britain must undergo EU checks. This angered the Irish and forced the EU to initiate legal action, accusing Prime Minister Boris Johnson of breaching the Northern Ireland trade agreement as well as international law.

In anger, weeks leading up to ratification, members of the EU Parliament had threatened not to sign the agreement by the April 30 deadline, if Johnson failed to resolve the issue. It appears, it was a bluff. In the end, Parliament ratified the deal April 27 in a 660-5 vote, with 23 abstentions. As was true before ratification, the TCA only covers goods, not services: financial services (the UK’s comparative advantage), student exchanges, foreign policy and the EU courts are all off limits. Johnson credits the deal with providing “stability” to “close allies and sovereign equals.”

While the EU’s chief negotiator Michel Barnier has referred to Brexit as “a failure,” he celebrated the ratification vote, calling it a “big green light” for the TCA. “My thanks to all MEPs [members of Parliament] for the excellent cooperation over the past years. It is the EU & UK’s joint responsibility now to ensure that their respective commitments are respected - today & in the future,” he tweeted after the vote.

No side likes the increased costs, paperwork and long lines at border crossings. In addition, French fishermen are displeased with the UK request for fishing licenses and the rate at which they are granted, while the UK is frustrated at the EU ban on shellfish. As of February 2021, the UK imports more than it exports to the EU, by more than £5 billion.

Appeals Court Opens Door to Online Gun Blueprints

The Ninth Circuit Court of Appeals April 27 opened the door to online gun blueprints, reversing a lower court’s injunction against moving 3D-printed firearms from State to Commerce jurisdiction. In a 2-1 mixed vote, the appeals court cited a seemingly technical issue, that Congress expressly blocked courts from reviewing regulatory actions in the Arms Export Control Act.

In March 2020, a Seattle U.S. District Court judge issued a preliminary injunction on 3D printing software moving to Commerce jurisdiction from the U.S. Munitions List (USML),

granting the motion of 22 states and the District of Columbia to enjoin State's final rule. A week before the appeals court decision, a group of Senate Democrats urged President Biden to immediately restore oversight to State and Congress and to reverse the transfers (see **WTTL**, April 26, page 1).

“Congress expressly barred judicial review of designations and undesignations of defense articles under the Control Act and of any functions exercised under the Reform Act. Accordingly, the district court erred in reviewing the [State] and Commerce Final Rules, and its injunction is therefore contrary to law,” the majority wrote. The panel remanded with instructions to dismiss.

In his dissent, Judge Robert Whaley cited the difference between designations and removals, disagreeing “with the majority’s holding which allows this new regulatory system to escape appropriate oversight,” he wrote. “The lack of judicial oversight over designations means that the President’s decision over which weapons to regulate is wholly discretionary, and thus individual complainants cannot avoid regulation through litigation. In contrast, judicial review over the removal of items from the Munitions Lists would prevent deregulation that is arbitrary or otherwise unlawful,” he added.

The National Shooting Sports Foundation (NSSF) welcomed the decision. “NSSF intervened in this case to protect the rules transferring export licensing authority of commercial and sporting firearms and ammunition products to commerce. We argued correctly that the antigun attorneys general had no standing to sue in part because the rules were not judicially reviewable,” NSSF VP and General Counsel Lawrence Keane told **WTTL**.

Lawmakers and human rights organizations denounced the ruling. “America is already facing a gun violence crisis fueled by weapons that are far too easy to access, but the 9th Circuit just threw gas on the fire. I will be asking the Biden administration to prevent the online posting of blueprints for 3D-printed guns,” Sen. Ed Markey (D-Mass.) tweeted.

Industry Rejects Broad, Overbearing ICT Licensing Process

Industry sent Commerce back to the drawing board over a licensing process for entities seeking pre-approval before engaging in or continuing to engage in transactions involving information and communications technology and services (ICTS). The 18 comments were almost unanimous in urging the administration to rethink the whole idea.

In March, Commerce served subpoenas on “multiple Chinese companies that provide” ICTS in the U.S. (see **WTTL**, March 22, page 3). In an interim final rule published the day before President Biden’s inauguration, the department created a process where it could provide referrals on certain transactions, specifically those involving six types of technology and six countries identified as “foreign adversaries.”

The Telecommunications Industry Association (TIA) cited the more recent supply chain review that President Biden launched in key sectors, including semiconductors. “TIA

urges the administration and Commerce to not implement broad and overbearing regulations on the ICT industry that could adversely affect innovation in the name of supply chain security while undergoing this review,” the organization wrote.

The Information Technology Industry Council (ITI) urged the administration to delay implementing the final rule before establishing a licensing process. commented. “At present, the IFR provides the Secretary broad authority to review practically every single ICTS Transaction with any nexus to an identified “foreign adversary,” and casts a cloud of uncertainty over all other ICTS transactions given the list of named foreign adversaries could change at any time,” the group wrote.

IBM pulled no punches. “This rule remains massively broad in scope, was adopted after disregarding input from industry, and is entirely unclear in defining what [ICTS] constitute an unacceptable national security risk. This approach violates due process for U.S. businesses, which will have no meaningful notice of which transactions may be subject to government intervention. Moreover, given the enormous number of transactions that would be covered by the rule, it simply will not be administrable,” the company wrote.

“Before a workable pre-clearance or licensing process can be established, Commerce should first tailor and clarify the scope of the Rule or elect to take an altogether different approach to effectively meet national security and economic goals,” the National Association of Manufacturers commented.

USTR Upgrades Algeria, UAE in Special 301 Report

Even in the midst of a global pandemic, the USTR’s office kept its focus on old favorites in its annual Special 301 Report released April 30 on intellectual property (IP) rights protection in 100 trading partners. In all, nine countries were listed on the Priority Watch List and 23 on the Watch List, as the report upgraded the status of Algeria and United Arab Emirates (UAE)

The report specifically took on China in the wake of commitments made under the phase-one trade deal, especially measures to address forced technology transfer. “In China, investment and regulatory approvals, market access, government procurement, and the receipt of certain preferences or benefits may be conditioned on a firm’s ability to demonstrate that IP is developed in or transferred to China, or is owned by or licensed to a Chinese party,” it said.

The report also cited concerns with the EU’s aggressive promotion of its exclusionary geographical indications (GI) policies. “The EU GI agenda remains highly concerning, because it significantly undermines the scope of trademarks held by U.S. producers and imposes barriers on market access for U.S.-made goods that rely on the use of common names, such as parmesan or feta,” the report said. The Priority Watch List now includes Argentina, Chile, China, India, Indonesia, Russia, Saudi Arabia, Ukraine and Venezuela. On the

Watch List USTR listed: Algeria, Barbados, Bolivia, Brazil, Canada, Colombia, Dominican Republic, Ecuador, Egypt, Guatemala, Kuwait, Lebanon, Mexico, Pakistan, Paraguay, Peru, Romania, Thailand, Trinidad & Tobago, Turkey, Turkmenistan, Uzbekistan and Vietnam.

Algeria moved from the Priority Watch List to the Watch List. The country “has taken some positive steps to improve the environment for intellectual property (IP) protection and enforcement in recent years. Algerian authorities have increased efforts at IP enforcement, including by disbanding informal markets selling counterfeit merchandise, increasing coordination between customs authorities and law enforcement, and engaging in capacity-building and training efforts for law enforcement, customs officials, judges, and IP protection agencies.”

The USTR’s office removed UAE from the Watch List “due to the Ministry of Health and Prevention resolving concerns with IP protection of pharmaceutical products,” the report said. “The UAE also made progress on long-standing IP enforcement concerns, particularly with Dubai Customs which was a major cause of industry complaints given its role in the global movement of goods, including counterfeit goods,” it added.

BSA | The Software Alliance welcomed the report. “The U.S. software industry supports millions of American jobs and leads the world in technology innovation. Data localization mandates and similar data-related innovation barriers put technological innovation and economic growth at risk by impairing IP rights and undermining market access for persons who rely on IP rights,” BSA Policy Director Joseph Whitlock said in a statement.

*** * * Briefs * * ***

TRADE PEOPLE: President Biden April 27 named former AFL-CIO trade and globalization policy specialist Celeste Drake to be first Made in America director at Office of Management and Budget. Drake “will shape and implement federal procurement and financial management policy to help carry out the president’s vision of a future made in all of America by all of America’s workers, including minority entrepreneurs and small businesses,” White House said. Drake was on Biden’s USTR transition team (see **WTTL**, Nov. 16, page 1).

FCPA: Donville Inniss, former Barbadian industry minister, was sentenced April 27 in Brooklyn U.S. District Court to two years in prison for his role in scheme to launder \$36,000 in bribes that Insurance Corporation of Barbados Limited (ICBL) paid in exchange for insurance contracts between August 2015 and April 2016. Jury found Inniss guilty of money laundering and conspiracy to commit money laundering in January 2020 after one-week trial (see **WTTL**, Jan. 20, 2020, page 11). In August 2018, Justice declined to prosecute ICBL under its FCPA Corporate Enforcement Policy. In addition to sentence, court also ordered Inniss to pay \$36,536.73 in forfeiture.

VOLUNTEER OPPORTUNITY: BIS is recruiting candidates to serve on one of seven Technical Advisory Committees (TACs) that advise agency “on the technical parameters for export controls applicable to dual-use items (commodities, software, and technology) and on the administration of those controls,” agency said in Federal Register April 28. Individual TACs cover: information

systems, materials, materials processing equipment, sensors and instrumentation, transportation and related equipment, emerging technology, and regulations and procedures. To respond, please send resume to Yvette Springer at Yvette.Springer@bis.doc.gov by Sept. 30.

EXPORT ENFORCEMENT: Shuren Qin, Chinese national residing in Wellesley, Mass., pleaded guilty April 28 in Boston U.S. District Court to conspiring to illegally export U.S.-origin goods, including 78 hydrophones (devices used to detect and monitor sound underwater), to blocked Chinese military research institute. He was arrested in June 2018 (see **WTTL**, June 25, 2018, page 7). Qin allegedly lied to U.S. supplier and caused false shipping information to be filed, according to affidavit filed in court. Sentencing is set for Sept. 8.

SANCTIONS: Dallas-based MoneyGram Payment Systems agreed April 29 to pay OFAC \$34,328.78 civil penalty to settle 359 apparent violations of sanctions programs, including Syria, Congo and Central African Republic, between March 2013 and June 2020. “MoneyGram provided services to blocked individuals incarcerated in U.S. federal prisons without a license from OFAC, processed transactions on behalf of an additional blocked person, and processed transactions for individuals who initiated commercial transactions involving Syria,” agency said. Firm voluntarily self-disclosed violations.

SOMALIA: OFAC in April 28 Federal Register issued final Somalia Sanctions Regulations to replace abbreviated regulations published in May 2010 (see **WTTL**, May 10, 2010, page 4). New regulations include “additional interpretive and definitional guidance, general licenses, statements of licensing policy, and other regulatory provisions that will provide further guidance to the public,” agency said.

NOMINATIONS: President Biden April 29 nominated Jessica Lewis to be assistant secretary of State for political-military affairs, replacing R. Clarke Cooper. Lewis currently serves as Democratic staff director of Senate Foreign Relations Committee (see **WTTL**, April 26, page 4).

POTATOES: Dan Quayle, watch out. Mexican Supreme Court April 28 overturned 2017 lower court decision that prevented Mexican government from implementing regulations to allow imports of fresh U.S. potatoes. Since 2003, Mexico has restricted potato imports to 16-mile area along U.S.-Mexico border. “This ruling is consistent with Mexico’s obligations under the USMCA and the WTO,” Jared Balcom, National Potato Council (NPC) VP of trade affairs, said in statement. Sen. Mike Crapo (R-Idaho) called decision “a positive step forward.”

WTO DISPUTES: At meeting of WTO Dispute Settlement Body (DSB) April 28, Venezuela and U.S. agreed to consult with chair on U.S. measures imposed on Venezuelan goods and trade dealings with certain Venezuelan persons. Previous DSB meeting ended abruptly after diplomatic tussle over Venezuela’s request to establish dispute panel to examine measures (see **WTTL**, March 29, page 4).

CAFC: CAFC April 26 affirmed CIT ruling on Customs’ classification of Janssen’s darunavir ethanolate, active ingredient in HIV treatment, as subject to duty-free treatment. “Because Table 1 covers ‘such products,’ by ‘whatever name [otherwise] known,’ that are ‘described by’ the INN ‘darunavir,’ and darunavir ethanolate is a product described by the INN ‘darunavir,’ it is unnecessary to reach Table 2. Janssen’s entries of darunavir ethanolate are subject to duty-free treatment under Table 1,” Circuit Judge Evan Wallach wrote for three-judge panel in *Janssen Ortho, LLC v. U.S.* “The CIT did not erroneously ‘render’ Table 2 inoperative; Table 2 is simply irrelevant to the classification,” he added.