WILMERHALE

US-China Trade and Investment: 2014 JCCT Yields Significant Market Access Commitments by China

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The 25th US-China Joint Commission on Commerce and Trade (JCCT)—an annual, high-level economic summit[1]—took place December 16-17, 2014 in Chicago, with US and joint China-US "Fact Sheets" released afterwards listing China's commitments.[2] Coming on the heels of several bilateral accords reached during President Obama's November 2014 visit to Beijing, the 2014 JCCT yielded several additional commitments by China that have the potential to further ease market access barriers for a wide range of US companies, including those in the high-tech, pharmaceuticals, medical devices and biotechnology sectors. As always, companies whose business interests are potentially affected should closely monitor China's implementation of these commitments and get involved in preparations for future US-China bilateral summits.

Outcomes of the 2014 JCCT

US officials cited "dozens" of JCCT outcomes that would enhance US companies' access to China's market.[3] Among these are the five categories of outcomes discussed below, pertaining to technology localization requirements, pharmaceuticals and medical devices approvals, trade secrets, the Anti-Monopoly Law (AML), and agricultural biotechnology approvals.

- **Technology Localization Requirements**: China has made the receipt of certain tax preferences and other benefits contingent on the transfer of technology to a Chinese company. For example, the High and New Technology Enterprise (HNTE) program offers qualified companies a 15% corporate income tax rate (versus the standard 25% rate), provided they either own IP rights to core technology in China, or provide an exclusive global license for such IP to a Chinese entity for at least five years. In addition, as the Administration has noted, US and other foreign companies operating in China sometimes face pressure to relocate R&D activities to China.

  Through the 2014 JCCT, China committed to "treat intellectual property rights owned or developed in other countries the same as domestically owned or developed intellectual property rights. Enterprises are free to base technology transfer decisions on business and market considerations, and are free to independently negotiate and decide whether

and under what circumstances to assign or license intellectual property rights to affiliated or unaffiliated enterprises." This apparently broad market access commitment should go a long way in resolving concerns regarding technology localization requirements although much, as always, will depend on how the commitments are implemented on the ground, and continued vigilance—as well as future action within the JCCT and other bilateral summits, such as the annual US-China Strategic & Economic Dialogue (S&ED)—will be key.

- **Pharmaceuticals and Medical Devices Approvals**: China maintains a number of regulatory requirements for pharmaceuticals and medical devices that limit US companies' market access. For example, China's clinical trial approval process typically takes 12-18 months, versus 30-60 days in the United States. In addition, China requires local clinical trials for new pharmaceutical products and variants of existing pharmaceutical products, even though global clinical trial data can provide a sufficient scientific basis to ensure product safety for the Chinese public.

  Through the 2014 JCCT, with respect to pharmaceuticals, China addressed such concerns by committing to: (i) "make great efforts to eliminate the drug application backlog within 2-3 years," (ii) grant clinical trial waivers for companies that use multi-regional clinical trial (MRCT) data that includes data from China, in order to prevent duplicative testing—provided that applications comply with technical review requirements; and (iii) implement measures that allow simultaneous clinical trials in China and other countries.[4] In addition, with respect to medical devices, China committed to "expand the scope of medical devices that can be exempted from conducting clinical trials in China."[5,6] In principle, these commitments should ease market access barriers for both pharmaceuticals and medical devices. However, it remains unclear to what extent China will reduce the drug application backlog within the stipulated timeframe of 2-3 years, and also whether China will take further steps to embrace the MRCT paradigm.

- **Trade Secrets**: Many US businesses are concerned about the level of protection afforded to trade secrets in China. One particular area of concern is the adequacy of legal safeguards for trade secrets handled by government officials, who often have access to companies' trade secrets and proprietary information in connection with regulatory, administrative and judicial proceedings.

  In the 2014 JCCT, China committed that "trade secrets submitted to the government in administrative or regulatory proceedings are to be protected from improper disclosure to the public and only disclosed to government officials in connection with their official duties in accordance with law." China also agreed to study how to "optimize . . . relevant administrative and regulatory procedures . . . including by strengthening confidentiality protection measures, limiting the scope of government personnel having access to trade secrets, limiting the information required from companies to include only information reasonably necessary for satisfying regulatory purposes, and stipulating that any

requirements on government agencies to publicly disclose information appropriately allow for the withholding of trade secrets."[7] These commitments present a further development beyond what was agreed to in the July 2014 S&ED. Much, however, will depend on China's actual implementation.

- **Anti-Monopoly Law**: Foreign industry has voiced concern that China's enforcement of the AML—China's first comprehensive competition law—functions as a market access barrier. This is because Anti-Monopoly Enforcement Agency (AMEA) investigations (including both abuse of market dominance investigations and merger reviews)[8] arguably focus disproportionately on foreign companies, leading to outcomes that sometimes appear linked to industrial policy objectives such as encouraging the growth and consolidation of domestic industry. In addition, foreign industry has complained that due process deficiencies—*e.g.*, lack of access to counsel and the absence of written penalty decisions for abuse of dominance investigations—aggravate the AML's market-restricting effects. The industries affected by China's enforcement of the AML include high-tech, agriculture, mining, medical devices, pharmaceuticals and automobiles, among others.

  Through the 2014 JCCT, China made several commitments which, in principle, should ease foreign industry concerns:

  - *Access to Counsel*: China will allow local counsel to participate in meetings with AMEAs without restrictions. In addition, China will allow qualified international counsel to participate subject to approval by the relevant AMEA, "which shall be granted as normal practice."
  - *More Transparent Penalty Procedures*: China committed that before imposing penalties, AMEAs will "notify the parties of the facts, grounds, and basis according to which the administrative penalties are to be decided, notify the parties of the rights that they enjoy in accordance with the law, and provide the parties with the right to state their cases and to defend themselves." In addition, China committed that all penalty decisions "will be provided in writing to the party and include the facts, reasons, and evidence on which the decision is based."
  - *Competition-Oriented Remedies*: China committed that AML remedies would "address the harm to competition" rather than "impose enforcement measures designed to promote individual competitors or industries."[9]

- **Agricultural Biotechnology Approvals**: For several years China has delayed, and in some cases denied, approval for certain US genetically modified crop exports. The result is that China's very large market has effectively been closed to a range of US biotech agricultural products.

  Through the 2014 JCCT, China partially addressed these concerns by agreeing to grant three pending approvals of biotechnology products in 2014.[10] In addition, China and the United States agreed to conduct an annual Strategic Agricultural Innovation Dialogue,

which could pave the way for faster approvals and greater market access. This dialogue has the potential to lead to a comprehensive framework agreement for ensuring timely approvals of all pending applications for US genetically modified crop exports, which the US biotech industry had called for in advance of the JCCT.[11] However, it remains to be seen whether and how quickly pending and future applications will be approved.

Other 2014 JCCT commitments by China relate to issues such as geographical indications; inventor remuneration; sale of IP-intensive goods and services; online infringement; government procurement regulations; treatment of IP in standards setting; bad faith patent litigation; illegal, unreported or unregulated fishing; legal services; and a range of cooperative activities.12 The full English-language 2014 JCCT Fact Sheets are available at http://www.commerce.gov/news/fact-sheets/2014/12.

Next Steps

The 2014 JCCT outcome potentially represents a significant step forward in a number of areas that are of key concern to US and other non-Chinese companies in particular. Companies and other stakeholders should actively monitor implementation and, to the extent they may be affected, get involved in preparations for future bilateral summits such as the 2015 S&ED and JCCT to ensure that their concerns are taken on board and placed as high on the bilateral agenda as possible.

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[1] The 2014 JCCT was co-chaired by US Secretary of Commerce Penny Pritzker, US Trade Representative Michael Froman, and Chinese Vice Premier Wang Yang.

[2] The US Fact Sheet was initially released December 18, 2014, and the Joint US-China Fact Sheet was released December 29, 2014. See http://www.commerce.gov/news/fact-sheets/2014/12.

[3] Inside U.S. Trade, "U.S. Officials Announce JCCT Progress On AML, GMO Approvals, GIs" (Dec. 18, 2014).

[4] In addition, with respect to the supplementation of data submitted for pharmaceutical product patent applications, China and the United States "affirm[ed] that continued exchanges and engagement exchanges and engagement on specific cases are beneficial."

[5] The September 2014 *Regulations on Supervisory Management of Medical Devices* requires clinical trials for all Class II and Class III medical devices unless specifically exempted. This requirement has the potential to significantly restrict medical devices' market access in China. However, China's 2014 JCCT commitments regarding medical devices suggest that China will grant exemptions to mitigate restrictions on market access.

[6] In addition, with respect to both pharmaceuticals and medical devices, China committed that "for all draft . . . rules and regulations where notifications are required under the relevant WTO rules, a

comment period will be provided that will be no less than 60 days."

[7] The 2014 JCCT Fact Sheet also contains the following commitments: “Government officials who illegally disclose companies’ trade secrets are to be subject to administrative or legal liability according to law. The United States and China agree to exchange information on the scope of protection of trade secrets and confidential business information under their respective legal systems. China acknowledges that it is to conduct a legislative study of a revised law on trade secrets.”

[8] Investigations of abuse of market dominance are carried out by the National Development and Reform Commission (NDRC) (in the case of price-based investigations) and the State Administration for Industry and Commerce (SAIC) (in the case of non-price-based investigations), while merger reviews are performed by the Ministry of Commerce (MOFCOM). These are the three Anti-Monopoly Enforcement Agencies (AMEAs). Each AMEA’s regional counterparts also participate in AML enforcement.

[9] China made a similar commitment at the 2014 S&ED “that the objective of competition policy is to promote consumer welfare and economic efficiency rather than promote individual competitors or industries.” US Department of the Treasury, Press Release, “UPDATED: U.S.-China Joint Fact Sheet Sixth Meeting of the Strategic and Economic Dialogue” (July 11, 2014), *available at*http://www.treasury.gov/press-center/press-releases/Pages/jl2561.aspx.

[10] The products were genetically modified varieties of soybeans and corn. *See* Inside U.S. Trade, “U.S. Officials Announce JCCT Progress On AML, GMO Approvals, GIs” (Dec. 18, 2014).

[11] *See* Letter from U.S. Biotech Crops Alliance to US Trade Representative Michael Froman, US Secretary of Commerce Penny Pritzker, and US Secretary of Agriculture Tom Vilsack (Dec. 10, 2014).

[12] The US-China Bilateral Investment Treaty was not cited in the 2014 JCCT, even though it was cited in the 2014 S&ED Joint Fact Sheet http://www.treasury.gov/press-center/press-releases/Pages/jl2561.aspx. The reason for this omission is unclear.

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