IP Alert: BIO’s China Summit Highlights Trends in BioPharma Market

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By Pei Wu

In June, the Biotechnology Innovation Organization celebrated its 25th anniversary in Boston. The BIO International Convention drew more than 16,000 attendees from more than 5,000 companies, including the world’s leading biotechnology and pharmaceutical companies, setting a Guinness World Record for the largest business-partnering meeting.

A Prominent International Presence

One-third of BIO attendees were international, hailing from about 75 countries, including Canada, United Kingdom, Germany, France, Australia, South Korea, Japan, China, Taiwan, India, Brazil, Mexico, and Russia. Global leaders highlighted cutting-edge technology developments, shared ideas that covered a broad spectrum of biotechnology innovations relating to disease fighting, population growth and increased energy demand, as well as exchanged insights and experiences with respect to trade, investment and intellectual property (IP) for the development and commercialization of biotechnology.

China Summit at BIO International

In the spotlight was the China Summit, held on the first day of BIO. Distinguished industry leaders and experts presented various topics that characterized the regulatory, policy, and industrial reforms happening in present day China. Joe Damond, Executive Vice President for International Affairs of BIO, and Victor Shi, Chairman of BayHelix Group and Founding President of Asia Pacific QIAGEN, gave the Summit's opening remarks on the opportunities and challenges concerning the world's largest pharmaceutical market. The ensuing four sessions featured keynote presentations as well as panel discussions that shed significant light on the trends in China's biopharmaceutical market.

The first session featured a Fireside Chat with Ge Yanfeng, Director-General of the Research Department of Social Development, Development Research Center of the State Council, who presented on a "Blueprint for China's Healthcare Reform."

The second session featured a panel of speakers on regulatory policy, intellectual property (IP) landscape and innovation horizon of China. The panelists included the U.S. government, Chinese legal, and international pharmaceutical company representatives.

The third session's panel discussed the issues and challenges facing biopharmaceutical companies seeking to expand to China and Asia. The panelists included both U.S. and Chinese corporate biotechnology leaders.

The last panel discussed trends in financing, capital markets, and cross border business development. The panelists included international corporate finance and investment leaders.

The Summit identified promising growth for the biopharmaceutical market in China. This has been attributed to recent improvements in regulatory, IP, and cross-border strategies in China. For example, since 2015, the China Food and Drug Administration (CFDA) has introduced regulatory reforms, including the CFDA drug reform initiative aimed at reducing the drug approval backlog and increasing the number of reviews at the Center for Drug Evaluation (CDE). In addition, the National Reimbursement Drug List has been updated for the first time since 2009, offering new opportunities for U.S. pharmaceutical companies seeking market expansion for their drugs in China. Furthermore, clinical trials for imported drugs can be conducted in China at the same time as trials in other countries, setting the stage for more globally integrated clinical trials and marketing in China. Together, these drug reforms have shortened the time for review and approval of innovative pharmaceutical products in China.

On the IP front, China is moving to strengthen IP protection and to encourage innovation, particularly in pharmaceutical and medical device fields. Notably, China's top policy-making body proposed to explore a new patent linkage system. For example, under China's old framework, drug approval process lacks association with patent protection. As such, only a simple non-infringement statement is required for the granting of drug approval, which makes it hard to hold the applicant liable for the authenticity or accuracy of that statement. The patent linkage system appears to mirror the U.S. system in certain aspects. Specifically, a drug applicant is required to disclose

relevant patent information when filing an application for drug registration and notify the patentee with 20 days if the applicant is willing to challenge the original patent holder's rights. A five-year maximum patent extension was also proposed so that new drugs can be introduced into China at the same time as in other countries. Further, draft rules that arguably extend regulatory data exclusivity periods based on the types of drugs—10 to 12 years for new therapeutic biologics, and six years each for new small molecule drugs, orphan drugs, and pediatric drugs—have also been proposed. Many clinical stage companies seeking to enter China through partnerships have indicated a preference for licensing involving less investment and the least control in business over direct entry, such as joint ventures or mergers.

Favorable policies and China's growing market size have led to an increase in the number of U.S. and European Union biotechnology and pharmaceutical companies that are interested in expanding to China. Of note is the recent rollout of the pilot Marketing Authorization Holder (MAH) scheme, which enabled research & development organizations to become a MAH in China without having domestic manufacturing capability. Companies that currently do not have large-scale infrastructural investments in China can rely on Clinical Research Organizations (CROs) under the MAH scheme. CROs offer expertise, capacity and resources that can help companies navigate a complex, emerging market. The CRO market in China has been growing at twice the global average rate over the past five years.

The Summit also identified obstacles despite the positive trends. For example, administrative hurdles are still in place that hinder effective and robust implementation of China's proposed pro-innovation policies. Of relevance to IP, the newly proposed patent linkage system is hampered by Chinese Patent Law, which needs to be amended to ensure early resolution of patent disputes prior to market entry of follow-on products. Additional market impediments include the restrictions on the collection and exportation of bio-samples, which not only hamper cross-border transport of materials needed for clinical studies, but also raise potential issues on intellectual property rights, for example, over-protectionist regime may unfairly favor large corporations who can accumulate pools of cross-licensed patents and create entry barriers for small- and medium-sized firms. Furthermore, while the CFDA recently proposed 12 years of data exclusivity for therapeutic biologics, geographic and disclosure requirements on applicants may prevent innovative biomedical companies from bringing life-saving therapies to patients in China.

Another major reform is the listing of HKEX. Early this year, HKEX broadened its listing regime to allow pre-revenue biotechnology companies to list on the Hong Kong Main Board. This change mostly benefits pre-revenue companies developing small molecule drugs, biologics and biosimilars, diagnostics and medical devices that have passed early stage clinical testing under the regulations of the U.S. Food and Drug Administration (FDA), CFDA, or European Medicines Agency (EMA). HKEX will allocate at least HKD 2 billion in market capitalization for qualified companies and at least HKD 500 million revenue at the time of IPO. This has attracted an increasing number of Chinese and foreign biotechnology company applicants for listing in Hong Kong. Encouraged by the HKEX reform, many China-based life science investors are investing in U.S. biotechnology companies that have a strong market potential in China. Since the beginning of the first quarter of 2018, China's venture capital funds have poured more than $1.4 billion into U.S. biotechnology

firms, accounting for nearly 40 percent of total biotechnology venture capital investment in the United States. To these Chinese investors, a Hong Kong listing appears to be an attractive exit option for these U.S. biotechnology companies' China affiliates as the Hong Kong stock exchange offers better liquidity, less restrictions on controlling shareholder sell downs after lock-up periods, and higher transparency.

The Summit highlighted an evolving competitive biopharmaceutical landscape in China and provided models for cross-border strategies and alliances, blazing a trail toward biotechnology innovation and development in China.

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