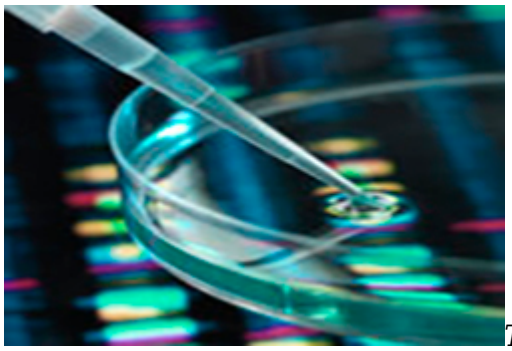
Major Life Sciences Licensing Deal Trends in China in 2023

 *This is the first of two articles focused on 2023 life sciences deals in China. The second article, which is coming soon, looks at trends in M&A.*

In 2023, there were 240 reported life sciences licensing deals in China, an increase of almost 50% compared to 2021.

That includes 70 out-license deals involving Chinese companies licensing drugs and technologies to foreign companies, with a disclosed aggregate deal value surpassing US$35 billion.

It also includes 170 in-license deals involving Chinese companies licensing drugs and technologies from other Chinese companies or from foreign companies. This represents a 32% increase compared to 2021 — and a 58% increase compared to 2022 (more than making up for the 2022 dip in deals).

Read the full alert **here**.

Draft Implementing Rules of China's Human Genetic Resources Regulations as Applied to Foreign Persons

 The Administrative Regulations of the People's Republic of China on Human Genetic Resources (the "Regulations"), promulgated by China's State Council, have been in effect for almost three years. As the administrative department under the State Council with the primary responsibility for the administration and enforcement of the Regulations, China's Ministry of Science and Technology ("MOST") is also responsible for promulgating rules implementing the Regulations. On March 21, 2022, MOST published Draft Implementing Rules for

the Regulations (the “Draft Rules”) for public comment, which must be submitted to MOST by April 21, 2022.

This article is not a comprehensive review of the Draft Rules, but rather focuses on those provisions of the Draft Rules that are specifically related to “foreign organizations and individuals and the entities formed or actually controlled by them” under the Regulations (collectively, “Foreign Persons”), with the exception of the first part on the definition of “human genetic resources information.”

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An Overview of the Latest Human Genetic Resources Regime in China

On July 1, 2019, the Administrative Regulations on Human Genetic Resources (人类遗传资源管理条例) (the “Regulations”) issued by the State Council of the People’s Republic of China (the “PRC”) came into effect. On October 17, 2020, the Standing Committee of the PRC National People’s Congress promulgated the Biosecurity Law (中华人民共和国生物安全法) (the “Biosecurity Law”), which came into effect as of April 15, 2021. Having replaced its predecessor, the Interim Measures for the Administration of HGR (人类遗传资源管理暂行办法), the Regulations now form the basis of PRC’s regime on its human genetic resources, and govern the collection, preservation, use, and external provision of human genetic resources abroad. The Biosecurity Law further reinforces the Regulations by asserting PRC’s sovereignty over its human genetic resources and re-iterating certain key provisions under the Regulations.

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China Closer to Granting Patent Term Extensions?

A new draft amendment to Chinese Patent Law was submitted to the National People's Congress Standing Committee on June 28, 2020. Key provisions include the establishment of patent term adjustment (PTA) caused by delays in the patent office and patent term extension (PTE). Under the new draft amendment, a Patentee could receive up to 5 years of PTE, as long as the overall patent term does not extend beyond 14 years after approval of the drug, similar to PTE available in the United States

The proposed amendments in the draft also address many other weaknesses in biopharma IP protection in China. For example, these changes include litigation reform, including stronger and more efficient patent enforcement, an increase in the statutory limit on damages (up to CNY 5,000,000), and a 6-month grace period for public disclosures made for the benefit of the public during a national emergency.

Notably, the draft also provides for a delay of marketing approval of a new drug, if that new drug is subject to patent dispute. If a lawsuit is filed by an owner of a patent listed in China's "drug patent information registration platform" within 30 days of publication of a marketing approval application, the application is stayed for up to 9 months.

If implemented, these changes would make China a more attractive jurisdiction for life science innovators and biopharmaceutical investment opportunities from around the world.

This new draft is currently available for public comment until August 16, 2020.

Chinese Cross Border Life Sciences Strategic Transactions in the Age of COVID-19

Increasingly in China over the past decade, corporations in the pharmaceutical, biotechnology and medical device sectors have supplemented their own internal research and development and business development efforts by participating in the equity funding of

start-up and early stage Chinese as well as other Asian, U.S. and European companies which have over time been able to provide the corporation's business with potential strategic and sometimes even financial gain. In recent years, regulations in both China and abroad relating to currency controls, foreign investments into sensitive industries and other factors have complicated this strategy, but it has continued to be an important means by which innovation in the sector is advanced in China and more broadly throughout Asia and the world.

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Racing Against COVID-19: An Introduction to China's Regulatory Fast-Track Processes

In response to the outbreak of a pneumonia-like disease caused by coronavirus (COVID-19), Chinese regulatory authorities adopted a few emergency measures under certain "Special Review and Approval Procedures" to fast-track the review and approval process for developing diagnostic kits, vaccines and therapies for combating COVID-19 infections. There are several types of "fast track" procedures available under the current Chinese regulatory framework. The most important three are Special Review and Approval Procedure of 2005, Special Review and Approval Procedure of 2007, and Priority Review and Approval Procedure of 2017, all of which are summarized in this alert.

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