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China Will Reshape Administrative System for Human Genetic Resources

By Xun Yang

The State Council promulgated the Administrative Regulation for Human Genetic Resources (the “**Genetic Resource Regulation**”) on 28 May 2019, which will become effective on 1 July 2019. The Genetic Resource Regulation will supersede the Provisional Measure on Human Genetic Resources Administration (the “**Genetic Resource Measure**”) which was promulgated by the Ministry of Science and Technology (“**MST**”) and the Ministry of Health (“**MOH**”) and will provide more comprehensive and robust administration for the collection, storage, usage, and export of human genetic resources.

1. A Historical Review

The current Genetic Resource Measure came into effect on 10 June 1998. It was issued in response to a breakthrough in genetic technology at the end of the last century and, in particular, to a wave of collection in China genetic resources for scientific and commercial use. The Genetic Resource Measure provides for some principles on administrations for collection of genetic resources, multi-national cooperation in researches by using genetic resources collected in China, and export

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of genetic resources. In particular, the Genetic Resource Measure imposes a requirement on multi-national cooperation in the genetic area that the parties involved share intellectual property rights fairly, which form a critical foundation for multi-national researches using genetic resources in China.

However, the Genetic Resource Measure was issued on an urgent basis and it has some limitations.

Firstly, the Genetic Resource Measure is only a ministerial rule. It is not a formal source of law per se and does not bind the court or any government agent other than those issued the measure. Consequently, not all government agents enforce the Genetic Resource Measure consistently.

Secondly, the Genetic Resource Measure provides for a limited scope of administration over use of genetic resources. Although the Genetic Resource Measure claims to regulate the collection, aggregation, research, development, purchase, export, and delivery of genetic resources, it only contains detailed rules for multi-national researches using genetic resources and export of genetic resources.

Thirdly, the Genetic Resource Measure itself does not provide for any specific penalty for the violations of provisions in it. Rather, it refers to the judicial system and the customs offices for sanctions, which does not cover all types of violations.

In response to these limitations, the MST commenced the preparation of the Genetic Resource Regulation as early as 2006 and the first draft was released for public consultation in October 2012. The draft was then amended according to the feedbacks into a final draft and was submitted to the State Council for adoption in 2016, thus giving birth to the current version of the Genetic Resource Regulation.

2. Highlights of Genetic Resource Regulation

The Genetic Resource Regulation presents a great improvement in the genetic resource administration. In particular, it is featured by the following highlights.

(1) Reformed Administrative System

Under the Genetic Resource Measure, the collection, use, and export of genetic resources are administered by MST and MOH jointly. However, in practice, the Genetic Administration Office subsidiary to MST leads the administration. In response, the Genetic Resource Regulation reflects such fact and confirms that MST is the primary regulator in the genetic administrative regime.

Additionally, whilst the Genetic Resource Regulation recognizes the wide spread of activities concerning genetic resources, it also recognizes that such activities may affect public interest national-wide. Therefore, under the Genetic Resource Regulation, the core administrative power to

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regulate activities concerning genetic resources vests in MST at the state level and MST is supposed to improve its electronic administrative system to facilitate market players to get access to them remotely.

Moreover, different from the Genetic Resource Measure which only has rules on cross-border cooperation concerning and export of genetic resources, the Genetic Resource Regulation provides for a comprehensive administration over whole research process concerning genetic resources, including, as discussed below, the collection, storage, use, and export of generic resources.

(2) Comprehensive Regulation

The Genetic Resource Regulation provides for rules on all aspects of activities concerning genetic resources. Please see below a chart summarizing these rules.

Activities concerning genetic resources	Legal Requirements
Collection of genetic resources	- The collection of genetic resources from important genetic families, from specific regions or from other resources of which the types and quantities are specified by MST must be subject to an approval requirement; - The person from whom the genetic resources are collected must be informed of the purpose of the collection and potential impact by the collection, and must be granted with the right to consent to or withdraw the consent from the collection of their genetic resources.
Storage of genetic resources	The entity which stores genetic resources must: - be subject to an approval requirement, and - keep proper records of use of genetic resources under its possession.
Sales and purchase of genetic	Not allowed.

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Activities concerning genetic resources	Legal Requirements
resources	
Use of genetic resources	Generally encouraged subject to ethical rules and rules for clinical trials.
Cross-border cooperation concerning genetic resources	- Subject to approvals by MST (except for clinical trials using genetic resources where there is no need to export genetic materials, which is subject to a filing requirement); - IP derived from the research must be shared by the parties fairly.
Export of genetic materials	- Subject to certification requirement by MST.
Sharing of genetic information with foreign persons or entities or organizations controlled thereby	- Security assessment organized by MST if public health, national security or public interest may be affected; - Subject to filing requirement with MST.

(3) Sharing of IP Rights from Genetic Researches

The Genetic Resource Regulation restates the principle established in the Genetic Resource Measures that Chinese and foreign parties must share the IP rights derived from the researches using genetic resources fairly.

Firstly, Chinese researchers must be fully and substantially involved in the research using genetic resources collected in China and must be granted with the access to all data and records generated from the research.

Secondly, both Chinese and foreign parties have the right to use the information developed from genetic resources.

Thirdly, with respect to patent protections for researches using genetic resources collected in China, both Chinese and foreign parties must apply for patent protections jointly and, when patents are granted, both parties must jointly own the patents.

Fourthly, with respect to technological achievements from genetic researches protected other than patents, both Chinese parties and foreign parties may agree on the sharing of such achievements and,

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absent of such agreement, both parties will have co-ownership over the achievements.

These requirements look protective. They, without doubt, are designed to ensure Chinese researchers can be benefited from the researches using genetic resources in China. However, the concept “co-ownership” may create problem because, under the PRC law, coownership in patents means either co-owner may have right to grant third party licenses without consents of the other co-owners and coownership in some other types of IP such as technical secrets means either co-owner must seek co-owners’ consents to grant third party licenses, whilst US laws and EU laws have different provisions. As such, a technical achievement developed from genetic resources which protected as both patents and technical secrets, in China and overseas regions, may face a situation where the licensing rights are not consistent as to the types of protection and the jurisdictions.

(4) Penalties for Violations of Genetic Resource Regulation

The Genetic Resource Regulation sets out serious penalties for violations of different provisions. The amount of administrative fines is up to RMB10 million, and in case that the violator receives an income from the violation above RMB1 million, up to 10 times of the income. Individuals who are responsible for the violations may also be subject to a fine up to RMB500, 000 and, in serious cases, be banned from engaging in the genetic research sector.

3. Practical Suggestions

Obviously, the Genetic Resource Regulation strengthens the administrations over activities involving genetic resources. It is advisable for pharmaceutical companies, CROs, and research institutions to review their own practices from the follow aspects:

- Whether they have established proper ethical rules of conducts;
- Whether they have established a system to ensure that the subjects are informed sufficiently about the collection of their genetic resources and personal data;
- Whether they have established a system to protect genetic resources in their possession.

Additionally, given the strong but general requirement on sharing of IP rights among participants of researches using genetic resources in China, it would be critical important to clearly describe the sharing of IP to detail the legal requirements in agreements among these participants.

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