

PUBLICATION

Effective IP Management of Biotechnology in China through Good Business Practices

August 14, 2008

Various research and development services are available through research and development (R&D) centers in China.¹ These R&D centers are sometimes referred to as contract research organizations or CROs. Intellectual property used or created in a contract R&D situation should be protected by good business practices.

A. Due Diligence

Research and development services are available in China through various scientific organizations. An example is a laboratory that provides contract clinical testing to support a regulatory filing. Other examples are wholly foreign- owned enterprises (WFOE), government- sponsored R&D organizations, and strictly private enterprises. "China's more than 300 CROs form an integrated service chain, addressing everything from pharmacogenomics to clinical trials, new drug applications, new drug transfers and exporting. The majority of Chinese CROs are small and simply provide regulatory consultation, drug application and clinical trial assistance to overseas pharma firms. Of these, more than 100 are capable of conducting R&D."²

In any instance, the CRO should be examined. Before selecting a CRO, the prospective service provider should be carefully investigated to verify respect for intellectual property and contractual obligations. One provider of clearance services is PAC-US.

B. Terms for a CRO contract

Certain terms should be considered for a service contract in China. First, the service contract defines the services contracted for and the payment provision. Also, the contract should set out the obligation to assign intellectual property developed by the service provider while providing the service. The service provider should provide a statement of inventory of intellectual property ownership prior to the effective date of the contract. A warranty statement should be provided in the contract that the service provider is not currently providing a similar service to another company in the same field. The service provider should warrant that it will not provide the same service for another company in the same field if the contract is terminated for a period of "X" years. The definition of "same service" should be defined; e.g., animal toxicity for a small molecule analog of a cell receptor (for the treatment of disease "A").

The specific level of performance should be defined. This may include an acceptance provision and performance warranties. In addition, the service provider should provide representations (1) that the R&D activities will be conducted in a manner so as to not infringe any intellectual property, and (2) it will not develop a product that infringes on other's intellectual property rights. In many cases, these clauses are limited to actual knowledge and will have territorial limitations such as the U.S. and China. The service provider must agree to keep the service confidential and not to use the results of the service. For example, an important provision in the service contract is the representation that the service provider will not file a patent or trademark application on the technology provided to it or developed as part of the service contract.

C. Audit Rights

For either a WFOE or an independent service provider, it is critical to have audit rights to frequently inspect the facility and electronic data. In many WFOEs, an employee of the parent is part of the management team in China. This employee is tasked with intellectual property compliance.

D. Enforcement

The key to protecting intellectual property in China is enforcement. The fastest way to enforce intellectual property rights is through an injunction. An injunction is an equitable remedy that consists of an order by civil authorities preventing a person or an entity from doing something. In China, an injunction can be ordered by either a civil court or an administrative court. New rules are scheduled to take effect in 2008 in the State Intellectual Property Office (SIPO) of the People's Republic of China.³

¹ Zhou, *Contract Research Drives China's Pharma Sector*, Pharma Manufacturing.com (Aug. 2006)

² <http://pac-us.tv/about.html>

³ <http://news.sina.cn/012007-10-09/094812693529.shtml>