AN INTRODUCTION TO ADMINISTRATIVE PROTECTION FOR PHARMACEUTICALS

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This Paper focuses on three primary topics: (1) the origination and major contents of administrative protection for pharmaceuticals; (2) the characteristics of administrative protection for pharmaceuticals; and (3) the implementation of administrative protection for pharmaceuticals.

ORIGINATION AND MAJOR CONTENTS OF ADMINISTRATIVE PROTECTION FOR PHARMACEUTICALS

Administrative protection for pharmaceuticals is a special protection for exclusivity which is different from patents, trademarks, or copyrights. This program was originated from Article 2 of the Memorandum of Understanding Between the Governments of People's Republic of China and the United States of America on Protection for Intellectual Property (MOU), signed on January 17, 1992. The Article provides administrative protection for pharmaceutical products and agrochemical products. (Hereafter, any references are only with regard to administrative protection for pharmaceuticals.)

Provisions on the protection can be summarized as follows. A pharmaceutical product that was granted a product patent in the U.S. during the period of January 1, 1986 and January 1, 1993, that has been approved for marketing in the U.S. by the Food and Drug Administration (FDA), and that has not been sold in the territory of China, is eligible to apply for administrative protection in China after signing a contract for manufacturing or distribution with a Chinese enterprise as legal entity. After examination and approval by the competent authorities of China, the product concerned would be granted an exclusive right of administrative protection for seven and a half years, starting from the date of certificate issuance.

According to Article 2 of the MOU, China enacted the Regula-

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tions on Administrative Protection for Pharmaceuticals (Regulations), which were approved by the State Council and promulgated by the State Pharmaceutical Administration of China. These Regulations came into force on January 1, 1993. Subsequently, China signed bilateral agreements on administrative protection in succession with Switzerland, the European Union, Japan, and Norway. The Regulations are now applied to the above contracting countries as well.

The rights of administrative protection for pharmaceuticals are explicitly specified in the Regulations. For pharmaceutical products under administrative protection, the health authorities of China shall not approve any other entity to manufacture or sell the same without license from the exclusive right holder. Administrative protection is a transitional protection only. In time, fewer drugs will be eligible for administrative protection because the Patent Law of China began to provide protection for drug products on January 1, 1993, while the number of patents issued between January 1, 1986 and January 1, 1993 is fixed. The program of administrative protection will terminate automatically as soon as protection is finished for all these drug products that were both patented and approved for sales.

CHARACTERISTICS OF ADMINISTRATIVE PROTECTION

Comparing patent protection with administrative protection, we can find an apparent difference between them. The major points are demonstrated below.

A. Scope of Protection

To view the conditions for protection, administrative protection covers a specific drug product included in the patent claims issued between January 1, 1986 and January 1, 1993, and at the same time approved for marketing by the health authorities. A patent, on the other hand, protects a range of products defined by the claims.

B. Supply of Products

When applying for administrative protection, the applicant has to submit a copy of contract with a qualified Chinese enterprise as legal entity on manufacture or sales of the drug concerned. This means that a foreign enterprise intending to apply for administrative protection for a pharmaceutical in China has to make the product available to the Chinese market, including manufacturing and sales. However, for a patent application, it is not possible to require supplying the
product covered by the application, because when a patent applica-
tion is filed, the development of the product is still at a very early
stage, and therefore it is not possible to supply the product. Even for
those valid patents that were already granted, it may not be one hun-
dred percent feasible to provide products.

C. Economic Benefits

Drugs seeking administrative protection are patent drugs already
on the market. Some have been selling well on the international
market. Under such conditions, the economic benefit is significant if
the administrative protection is approved and an exclusivity of seven
and a half years on the Chinese market is available. Although these
products have not and could not obtain patent protection in China,
administrative protection will enable the right holders to obtain very
solid economic benefits, perhaps greater benefits than under patent
protection. Administrative protection may be greater, because when
patent protection is filed the technology is not yet mature and it may
take several years or more to develop the products and then make
profit. Furthermore, some patents may not ultimately become a
commercial products.

To conclude the above, providing administrative protection by
China means providing a special exclusive protection for foreign
pharmaceutical manufacturers. This will not only allow a substantial
economic benefit for the right holders, but will also provide a better
environment for investment. We hope that the foreign pharmaceuti-
cal manufacturers can bring their new products and new technologies
under patent protection to China for cooperative production with
Chinese enterprises. However, presently, while a majority of prod-
ucts applied for administrative protection are or will be imported for
marketing in China in the form of finished preparations, only a minor
part are or will be jointly manufactured in China. The latter is mostly
formulating preparations from imported bulk materials or repackag-
ing of finished preparations.

IMPLEMENTATION OF THE REGULATIONS

In order to implement the Regulations, State Pharmaceutical
Administration of China has set up a special office, the Office of
Administrative Protection for Pharmaceuticals (OAPP), authorized
as the receiving and examination organization of application for ad-
ministrative protection for pharmaceuticals. At the same time,
Huake Pharmaceutical Intellectual Property Consultative Center is
designated as the agency for applications for administrative protection.

It has been over four years since January 1, 1993 when the Regulations on Administrative Protection for Pharmaceuticals came into force, OAPP has been strict, serious and fair in executing the Regulations. By July 10, 1997, China had received ninety applications filed by applicants from the USA, Japan, Switzerland, England, Germany, Ireland, Italy, Netherlands, Sweden, Belgium, Finland, and France. Among these eighty-five were accepted, seventy-one approved, eighty-four concluded, while others are under examination.

In order to better implement the Regulations and to make the examination procedures perfect, China has made some corresponding provisions. We are sure these provisions conform with the Regulations and the MOU. Furthermore, we are striving to improve and perfect our work in the future so that the Regulations can be better implemented.