Biotech, Pharma and Chemical Patent Practice Q&A

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AS FAR AS PHARMACEUTICS AND BIOTECHNOLOGY ARE CONCERNED, WHAT ARE PATENTABLE SUBJECT MATTERS AND WHAT ARE NOT UNDER CHINESE PATENT LAW?

In China, chemical and biochemical products such as pharmaceutical compounds, proteins and nucleic acids are patentable.

The Chinese Patent Law prescribes that patent rights shall not be granted for invention creations that violate the law or social ethics, or harm public interests. It is also prescribed that patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are obtained or used in violation of the provisions of laws and administrative regulations.

In this regard, cloning of human beings, commercial use of human embryos and human embryo stem cells and their preparation are not patentable for ethical reasons as they are considered to contravene social ethics.

The stipulation in the law concerning genetic resource was newly introduced by the Third Amendment of the Patent Law in 2008. According to this stipulation, if one acquires and uses genetic resources by way of violating the relevant stipulations of China's laws and makes an invention by employing the genetic resources, that invention is not patentable. The term "genetic resources" in the law means any materials of human, animal, plant, microbial or other origin containing functional units of heredity and having actual or potential value and the term "inventions that are accomplished by relying on genetic resources" means inventions which are accomplished by exploiting the hereditary function of the genetic resources.

Nevertheless, genes, including human genes, are patentable if they are isolated for the first time, contain a sequence that has not previously been disclosed, and has an established utility in industry.

The Patent Law also prescribes that patent rights shall not be granted for scientific discoveries, rules and methods for intellectual activities, methods for the diagnosis or treatment of diseases, animal or plant varieties and substances obtained by means of nuclear transformation.

In practice, regarded methods of treatment and diagnosis include dosing regimens, methods of determining risk of illness, assays/tests directly leading to diagnosis, gene screening diagnosis, and methods for the prevention of diseases (including immunization). However, first and second medical use inventions are patentable if they are claimed in the socalled Swisstype claim format.

In China, animal and plant varieties are not patentable. Transgenic animals and plants are also not patentable. Furthermore, living materials capable of developing into animals and plants are also considered as animal and plant varieties and are not patentable. However, microorganisms are patentable as long as they are isolated as a pure culture and possess established utility in industry.

WHEN A GENETIC RESOURCE OR A NEW BIOLOGICAL MATERIAL IS INVOLVED IN A PATENT APPLICATION, WHAT SPECIAL FORMALITIES DOES THE PATENT APPLICANT HAVE TO GO THROUGH WHEN FILING IN CHINA?

When a patent application claims an invention that is accomplished by relying on a genetic resource, the applicant shall indicate the direct source and original source of the genetic resource in a special form for disclosure of genetic resource. The form shall be filed together with the application. If the applicant fails to do so, he can make it up prosecution, for example, upon request of the examiner. The direct source must be provided, although the original source can be exempted if it is not known to the applicant. However, the applicant has to give explanations as to the reason why he has no knowledge of the original source.

For a PCT entry case, the applicant may disclose the source of genetic resource at the time of Chinese national entry or during prosecution in the Chinese Patent Office.

When a patent application involves a new biological material that is not available to the public, the applicant shall make deposit of the material in a recognized depositary by the priority date of the application. As China is a party to Budapest Treaty, deposit at a depositary that is recognized internationally under the Treaty will suffice. In addition, the applicant has to furnish a copy of the deposit receipt and the viability report issued by the depositary within 4 months from the filing date or from the date of national entry.

WHEN A PATENT APPLICATION INVOLVES NUCLEOTIDE OR AMINO ACID SEQUENCES, ARE SEPARATE SEQUENCE LISTINGS REQUIRED TO BE SUBMITTED?

Yes. When an application involves a nucleotide sequence of 10 or more nucleotides, or an amino acid sequence of 4 or more amino acids, both a hard copy and a computerreadable form of the sequence listings shall be furnished together with the application. If there are any discrepancies between the two versions, the hard copy prevails.

IS BIOLOGICAL TEST DATA REQUIRED IN CHEMICAL AND BIOTECH PATENT APPLICATIONS? IF SO, IS IT REQUIRED IN THE INITIAL APPLICATION? IS LATER SUPPLEMENT OF DATA POSSIBLE? IS CLINICAL DATA REQUIRED FOR PHARMACEUTICAL INVENTIONS?

When a person skilled in the art would not have been able to predict the alleged effect of the invention based on literal description of the patent application in light of the prior art, test data has to be filed so as to prove that the claimed invention can solve the targeted technical problem or achieve the intended technical effect. This is very often the case with chemical and biotech patent applications. This data is required for the purpose of sufficient disclosure and/or claims being supported from the description and must be provided in the initial application. Any data submitted later for such purposes will not be considered.

In some cases, data is also required to demonstrate inventiveness. Supplement of data for such purpose is possible but only on the condition that the effect shown by the data has been sufficiently disclosed in the original application.

When presenting data, the compounds or materials that were tested must be specified.

There are no strict rules on whether in vitro test or clinical data should be provided as long as the data is convincing to a person skilled in the art that the claimed invention can solve the targeted technical problem or achieve the intended technical effect.

IS IT POSSIBLE TO GET EXTENSION OF PHARMACEUTICAL PATENT, FOR EXAMPLE TO COVER DELAYS IN REGULATORY PROCESS?

No. It is not possible to get any extension of patent term even though there is a delay in the regulatory process.

IS “BOLAR EXEMPTION” APPLICABLE TO PHARMACEUTICAL PATENTS AVAILABLE IN CHINA?

Yes. It was introduced in the Third Amendment of the Patent Law in 2008. According to the current law, manufacture, use and import of a patented drug or patented medical device for the purpose of providing information necessary for regulatory approval is exempted from patent infringement.

GIVEN BOLAR EXEMPTION PROVISION IN THE LAW, WHEN CAN GENERIC VERSIONS OF A DRUG BE ENTERED?

According to Chinese Food and Drug (FDA)'s regulations, an application for generic entry may be filed with the Chinese FDA within two years of the expiry of relevant patent(s). However, the license by the FDA will be granted only upon termination of the patent(s).

IS DATA EXCLUSIVITY AVAILABLE UNDER CHINESE LAW?

Yes. According to Chinese FDA's regulations, data exclusivity is given to a company who produces or sells a drug containing a new chemical entity for six years from granting a license to it.

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