

“NO PATENTS ON LIFE”: PATENTABILITY V. MORALITY AND MEDICAL BIOTECHNOLOGY EXAMINATION PRACTICE IN THAILAND

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As a result of the rapid development of innovation in the field of biotechnology, patent-related practitioners face the constant challenge of moving quickly in an attempt to keep pace. The process of discovering and finalizing new pharmaceutical products has become more and more costly in terms of both time and financial investments. This process involves large dollar-value deals for the medical biotechnology industry. Patent protection is a means to secure an adequate return on investment to fund continuing research for the next generation of technologies.

The most significant current trend in medical biotechnology is the development of new technologies to create novel drugs. An example of this process is the discovery of targets (receptor proteins) which act by stimulating or inhibiting, or the discovery of ligands (molecules) which could act on or bind to these targets, as well as the development of research tools including a screening methodology which may be utilized in identifying candidate compounds. The patent offices of Japan, the United States, and Europe (jointly referred to as the “Trilateral Offices”) have combined efforts to better understand and harmonize procedures and activities with respect to patent protection. Some of the aims of the cooperation are to solve problems related to the protection of industrial property rights and to promote the dissemination of the technical information contained in patents. The Trilateral Offices therefore adopted a series of comparative study reports in the field of biotechnology, such as the report of reach-through claims in 2001, the report of DNA with function inferred from homology in 2002, the report on comparative study on protein 3-dimensional (3-D) structure-related claims in

2002, and the report on comparative study on Examination Practice Relating to Single Nucleotide Polymorphisms (SNPs) and Haplotypes in 2003. However, the patentability of biotechnology-related patents in Thailand does not seem to follow the pattern set by these international reports.

Section 9 of the Thai Patent Act 1992 prescribes that the following medical biotechnology-related inventions cannot be protected under the Thai Patent Act 1999:

- naturally existing microorganisms and their components, animals, plants or extracts from animals or plants;
- methods of diagnosis, treatment or cure of human and animal diseases;
- inventions contrary to public order, morality, health or welfare.

Animal/Human Parts

The patentability of inventions which relate to the elements of the human or animal body is an extremely sensitive issue. Microorganisms, plants, and animals per se are not patentable with respect to Section 9. Any action that treats living beings (both human and animal) as non-living beings is considered immoral. However, in the case of advanced and deepened medical biotechnology where research and development is conducted on a molecular level, this work is likely to escape criticism due to the fact that the molecular animal or human parts, such as monoclonal antibodies, can hardly be seen as animals or human beings. Claims that provide acceptable protection should be objectively considered patentable.

Method of Diagnosis/Treatment

There is no additional clarification about the meaning of the terms “treatment” or “diagnosis” defined in the law, regulations, examination

guidelines, or any case law. As a result, any biological method which relates to therapy, surgery, or diagnosis resulting in alleviation of disease or symptoms of pain and suffering in humans or animals which would be of value for the purposes of treatment should be considered excluded from patent protection. Patentability problems arise in the area of biotechnology dealing with biological molecules, such as the method for identification which could be done in an assay. In these cases, the practice is likely to depend on the discretion of the Thai examiners to issue the outstanding office action in order to reject claims on the basis of naturalistic morality and on the grounds that the biotechnologies have usefulness to be shared, not economic value to be monopolized.

It should be highlighted that, unlike many other countries which do not provide protection for methods of treatment, the Thai examination guidelines clearly indicate that claims for methods of prevention are allowable and may be protected. The Thai examination guidelines also indicate that cosmetic methods may be patentable because they do not tend to improve or cure a pathological state. For example, the method of plaque removal from teeth is considered to be a non-therapeutic effect. The applicant may obtain protection for the claims of such a method.

In light of the above, the connection of bioethics and intellectual property rights may seem dubious. Thailand is fully entering into a global level of the debate and discussion. A huge gray area of the patentability and moral assessment for medical biotechnology inventions is still awaiting legal interpretation in Thailand. ❖