IP and Other Legal Issues
Relevant to Biotech Entrepreneurs in Thailand

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In order to create a supportive infrastructure for biotechnology industry development, the Thai government has been actively seeking to improve the laws governing the industry. Of particular is its focus on upgrading laws to provide a more favorable environment for the protection and enforcement of intellectual property, a vital element for the growth of biotechnology.

On April 30, 2007, the annual Special 301 report by the Office of the United States Trade Representative (USTR) was issued. The report is the result of a Congressional mandate to assess the adequacy and effectiveness of intellectual property protection in selected countries worldwide. The Special 301 report places countries in one of several categories based on their lack of effectiveness in fighting intellectual property theft. Those designated as Priority Foreign Countries, the worst offenders, are vulnerable to immediate sanctions under the amended Trade Act of 1974. Countries not ripe for designation as Priority Foreign Countries are placed on one of two “watch lists.” Placement on the Priority Watch List or the Watch List sends a message that the U.S. government is closely monitoring the country’s progress in intellectual property protection. The announcement places 12 countries on the Priority Watch List and 30 on the Watch List. Among the countries on the Priority Watch List with book publishing markets are China, Russia, India, Thailand, Egypt and Turkey. The annual Special Report coincides with the decisions taken by the Thai government to issue a so called “compulsory licensing” allowing the use of generic versions of Abbot’s Kaletra AIDS drug and blood thinner Plavix of Sanofi-Aventis SA.

There are five forms of intellectual property protection relevant to the biotech industry in Thailand namely patents, trade secrets, plant variety, trade marks and copyright although the most used and relevant protection for biotechnology industry is patent.

Patent for Invention
Obtaining an appropriate patent portfolio is an important instrument in attracting investment and assuring investors that when products and services are finally marketed, exclusivity will be assured to the company. The patent provides an exclusive right to the patentee empowering him/her to prevent another from using, making, selling
or offering for sale, importing or exporting the invention claimed in a patent. The right is territorial and limited to the country where the patent is granted.

Biotechnological inventions are generally protected through patents, which can include composition of matter claims for instance isolated nucleotide or amino acid sequences. It is not permissible to claim methods of medical treatment of humans and animals, or methods of diagnosis in relation to humans or animals. However, a method for preventing a disease can be patented.

The Patent Act does not allow for patents on plants, animals and patents for micro-organism are only granted if the organisms are modified such as modified bacteria to kill mosquito larvae or infect the mosquitoes themselves for fight malaria. It furthermore excludes patents on plant varieties, which are protected under the Plant Variety Protection. The law protects pharmaceutical products through patent. Methods for the production of transgenic animals, plants and microorganisms can also be patented as can the organisms themselves as long as a discernable new function or trait can be documented. For example, modified Bt gene, isolated strains, purified strains etc.

What is the Test for an Invention to be Capable of Patent Protection? Are They Separate Tests for Biotechnology, Medical Device Inventions?

The answer is no, the test is uniform. In order to obtain a valid patent in Thailand, the subject invention must be novel (that is, not known) and inventive at the date of filing the patent application. A further requirement for a valid patent is that the invention must be capable of industrial application or be useful.

The novelty requirement can be troublesome. The invention must not have existed somewhere (in or outside of Thailand) in the form in which it is claimed. In the context of biotechnology, the most obvious concern is the patentability of natural products, which, at first glance, appear to have preexisted. However, if these materials can be claimed in a manner, which distinguishes them from their status as they occur in nature, there is no barrier to patentability in properly constructed claims. For instance, patents have now issued on DNA encoding erythropoietin, pure TPA, DNA encoding TPA, and so forth.

The exclusive rights to the patentee are:
- in case of product patent, the right to manufacture, use, sell, possess for sale, offer for sale or import the patented products;
- in case of a process patent, the right to use the patented process, manufacture, use, sell, possess for sale, offer for sale or import the products which are manufactured by the patented process.

The validity period of a patent is 20 years from the application date.
Petty Patent or Utility Model

Many technical creations involve a contribution of minor additions to existing technology and do not comply with the higher criteria of inventiveness required to be patented.

Product and process qualify for utility model protection. Unlike patents for inventions, utility models are not required to meet the inventiveness requirement. Practically, it means that there is no need to prove prominent substantive features and notable progress to existing or prior technology. A product or process is eligible for registration as a utility model if it is new and has industrial applicability. The novelty requirement and industrial applicability are the same as for an invention.

The period of protection for a utility model is six years from the application date, with a possibility of extension for up to four years.

Major Advantages of the Utility Model System

- A lower level of inventiveness is required than for a patent for invention.
- The scope of protectable subject matter is identical to a patent for invention.
- Immediate protection is obtained; there is no substantive examination unlike for patent applications.
- It is suitable protection for products or processes with short life cycles.
- The burden of proof of novelty and industrial applicability is on the utility model’s challenger.

Major Inconveniences of the Utility Model System

- Uncertainty can exist due to the fact that utility models are granted on the applicant’s assumption and at the applicant’s risk.
- Any person can file a claim of invalidity against a utility model if the invention for which the utility model is applied is already patented.
- The lack of substantive examination might result in multiple grants for identical inventions and conflicts between rights owners.

Deciding Whether to Patent or Not?

Companies generally apply for patents:

- To exclude others from using its technology to compete against it in the market place;

- To add value to the product which in turn can lead to higher selling prices and increased profit. A patent should be seen as a financial investment over 20 years;

- To increase the companies’ profits through licensing from royalties paid by third parties. As such patents can be used as a bargaining chip in cross-licensing situations, either in a pro-active manner or as a response to charges of infringement by others;
IP Issues Relating to Biotech for Non-lawyers with Special Considerations for Biotech Research

Government support for scientific entrepreneurs is in place with agencies such as the NSTDA Investment Center (NIC), the Agricultural Research Development Agency Agency (ARDA), the Ministry of Public Health, the Ministry of Agriculture, the Board of Investment (BOI). Several agencies play a leading role such as BIOTEC, Mahidol University, Kasetsart University in biotechnology researches and assistance to biotech entrepreneurs and investors, for instance the Intellectual Property Services (IPS) support unit within BIOTEC.

Researches take generally place through cooperation between the public and private sector, public agencies between themselves or researches conducted inside a company or research institute. They are various IP and IP related legal issues that researches in Thailand must be aware of, the most important ones are listed below:

Inventorship, Ownership and Compensation

It may at first appear a simple matter to decide who the invention is, but this is really so only in those rare cases where one person is involved in the matter from start to finish and can some to the patent office or his agent with a complete working invention and say “all my own work”. Real life situations are usually more complicated than this. Moreover, the ownership of the rights in an invention or creative work is regulated by law and by contract terms, which can eventually overrule the provisions of the law.

Invention Made in Employment

According to the Thai Patent Act, employee's invention are owned by the employer if the invention is made in the course of his employment. It is still important to include appropriate provisions in employment contracts dealing specifically with IP ownership. Employers generally require to own any inventions and developments devised by the employees during the course of their employment and require the employees to take any step required to transfer ownership and/or to assist the employer to protect and enforce its intellectual property rights. Employee-inventors are entitled to compensation where the invention is assigned to the employer and the employer obtains benefits from the commercial exploitation of the invention (e.g. licensing, assignment of the invention etc.).

Commissioned Inventions

Similarly commissioned or contracted inventions will be owned by the person commissioning the work, provided appropriate provisions similar to those noted above in relation to employment contracts are included in a commissioning agreement.
Joint-inventorship and Ownership

It is not unusual for an invention to be co-invented. In that case, more than one person may jointly hold a patent or even trade secret. Intellectual property rights can also be assigned to others (see below Part.3).

Access to Genetic Resources and Bio-prospecting

The access to genetic or natural resources is governed by various laws.

Regulation of the Office of the Prime Minister on Conservation and Use of Biological Resources

This Regulation was passed by the Cabinet on 17 January 2000 and has principles, conditions and instructions for drafting access contracts to ensure fair and equitable benefit sharing when genetic resources are used commercially. Under this regulation, a government agency, Thailand Biodiversity Center – TBC – has been established under the umbrella of the National Science and Technology Development Agency (NSTDA) and is in charge of enforcing the Regulation.

Access, collect or use of genetic resources must be disclosed to and considered by the Royal Forest Department (RFD), Biodiversity Committee before it is approved by the RFD’s General Director. The collector must disclose its intention to the RFD and the concerned local administration for consideration and approval.

Where the collector or its principal is a foreign legal or natural person, the agreement must stipulate that scientists who are Thai citizens and who work in the accredited Thai institutions shall be actively involved in the research and collection process. Foreign collectors or their principals must obtain from the National Research Council of Thailand a certificate to permit work or research before hand.

If a commercial product is derived from biological or genetic resources endemic to Thailand, fair and equitable benefit sharing must be negotiated and included in the agreement.

Importation of Transgenic Plants

Based on the Cabinet’s decision on April 3, 2001, and the Plant Quarantine Act B.E. 2507 amended, importation of transgenic plants is strictly regulated. The Department of Agriculture (DOA) has issued a ministerial declaration under the Plant Quarantine Act that all transgenic plants are prohibited, unless permission is granted by the Director General of the DOA, and only for experimental purposes,
from entering the country for commercial purpose and field trials with the exception of: (1) processed food and (2) imports or sales of soybeans and corn for feed use, human consumption, and industrial use.

**Exploitation and Commercialization of Resources**

**Bio-safety Guidelines**


Thailand is one of the few countries in the world that is not a signing member of the Rio Janeiro Agreement on the Convention of Biological Diversity (CBD). However, it has adopted the Biosafety guidelines in 1992 for laboratory research, field Work and planned release of genetically improved organism (GIOs) into the environment. Additional guidelines for the field trials of transgenic plants have also been developed and recommended for use by the Department of Agriculture (DOA) under the Ministry of Agriculture and Cooperatives (MOAC). In June 2001, the NBC Subcommittee on Food also issued Guidelines in Safety Assessment of Genetically Modified Foods, which has been recommended for use by all concerned parties.

The adoption of the guidelines is not mandatory. However, there are several laws that could be referred to in the regulation of laboratory modified organisms in the country which could be used in such a way that they could compliment the enforcement of the biosafety guidelines whenever necessary.

There are also few guidelines on laboratory research. The Thai government does not place any restrictions on embryonic stem cell. Nothing beyond a MTA is required for the transfer of human DNA and Thailand has no regulation regarding the treatment of laboratory animals although there are national guidelines for the humane treatment of animals. Most universities have committees that set local regulations on the above matters.

As a non party to the CBD, Thailand has to comply itself with Article 24 (Non-parties) of the Cartagena Protocol on Biosafety to the CBD which states that:

1. Trans-boundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral and arrangements with non-Parties regarding such trans-boundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to
contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved or out of, areas within their national jurisdictions.

Field Tests

With increasing number of applications for introducing transgenic plant into the country and for biosafety field tests in Thailand, each private company who applies for approval has to build their own contained environment (greenhouse or netted house). Thailand allows research only at the greenhouse level and not open field at the time being unlike in the past.

The management of field-testing is achieved through cooperation with various research institutes. The IBC is responsible for research work at its own institute, in consultation with the NBC. The NBC acts as the Ministry of Agriculture and Cooperatives’ (MOAC) Technical Advisory Committee with BIOTEC as its secretariat. Application for field-testing are sent to the Director General of the Department of Agriculture (DOA), MOAC, with a copy to the NBC. The NBC will, after consideration of the proposal, provide its recommendation to the DOA for final consideration and approval.

There have been only a few cases in the past of open field-testing of transgenic plants in Thailand in the past. These are Flavr Savr Tomato, Monsanto Bt Cotton, Bt Corn.

Clinical Trials

Thailand has deployed lots of efforts to become an attractive location for the conduct of clinical trials. In order to prove the viability and safety for therapeutic use on patients, clinical trials must be conducted to obtain required regulatory approval. Thailand’s strong medical tertiary care system infrastructure makes Thailand a destination of choice for trials.

The following authorities are involved in the control and authorization of clinical trials:

- The Food and Drug Administration;
- The Department of Medical Services (DMS) of the Ministry of Public Health (MOPH);
- The Department of Communicable Diseases Control (DCDC) of the MOPH;
- Ethical Review Committee for Research in Human Subjects (ERC) of the MOPH;
- National Sub-Committee of HIV Vaccine (NSCHIV) of the MOPH;
- Specific regulations of medical schools and hospitals.

Before a clinical trial can start, there are certain conditions to fulfill, which depend on the type of drug that is being studied.

Genetically Modified Food Labelling

The standard for labelling GM food came into force in May 11, 2003 (Manual for
Labeling Procedures for GMO products according to Ministerial Regulation No. 251 B.E.E 2545 (2002). It requires any food, food ingredient or processing aid produced using gene technology and containing novel DNA or novel protein to be labelled as 'genetically modified.'

The Ministry of Public Health implements the regulation on a post-marketing basis. The product labeling by the producer/importer is voluntary on their judgment, however unlabelled products may be confiscated and the producer/importer will be subject to the penalties applicable if the inspector process that the products are supposed to be GMO labeled.

The products covered by this law are as follows: In the case that the product has any of the 22 listed products as the first three ingredients, labeling will only be required if each ingredient constituting 5% or more of the final product weight and the GMO content by weight in that ingredient is 5% or more.

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Successful entrepreneurs and the companies they represent will take pride in their enterprise if they engage in business with transparency, intentionality, and integrity. To treat customers, clients, employees, and all those affected by a venture with dignity and respect is ethical. In addition, ethical business practices serve the long-term interests of businesses because customers, clients, employees, and society at large will be much more willing to patronize a business and work hard on the business's behalf if that business is perceived as caring about the community it serves. Best Masters Biotechnology Programs in Europe. With Focus on Commercialization, IP/Patenting, Business, Product Development, and Entrepreneurship. European Biotechs Startups with >1M raised/generated and own innovative technology. (Source: labiotech.eu). The one-year MSc Biotechnology and Business programme is designed for life science and chemistry graduates who want to pursue a career in management or entrepreneurship in technology and science-based fields. It's ideal for the folks who are seeking a first job in a biotechnology or biopharmaceutical company, starting your own small business or creating new opportunities in larger companies. Because biotechnology has applications in many industries, professionals can choose to work for a variety of organizations, including government agencies, private companies, regulatory bodies, or clinical laboratories. Biotechnology employers range in size and type from small start-ups to global pharmaceutical leaders to federally-funded organizations such as the Department of Agriculture and National Institutes of Health. Broadbelt emphasizes the extraordinary developments happening in the field, including personalized medicine, gene therapy, industrial disease treatment, and even hazardous w Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs. *Deputy Director, Licensing & Entrepreneurship, Office of Technology Transfer, National Institutes of Health, Rockville, Maryland **President & CEO, Aavishkar Innovations Inc., Bedford, Massachusetts. The federal government's investment in basic biomedical research. For many years the United States has led the world in government funding of nonmilitary research and development (R&D), notably support for basic and clinical research that directly relates to health and human development. The Entrepreneur's Guide is also relevant for non-entrepreneurs with industry experience who want to know how a biotech company gets to where it is and where it can possibly go. Well done. -David Bancroft, PhD, VP Automation & Head of Intellectual Property, GPC Biotech AG. I supplemented what I learned from business books by interviewing attorneys, investors, entrepreneurs, and other professionals (see Acknowledgements). Subsequently, I wrote The Entrepreneur's Guide to a Biotech Startup (the Guide) and published it on Evelexa.com early in 2001.