

DEVELOPING AND IMPLEMENTING A WINNING PATENT STRATEGY

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Patent strategy is typically used to describe the plan to develop patents with strategic value in complex competitive relationships. At the corporate level, patent strategy involves many aspects of organizational policy and business strategy. The following questions, for example, will depend on an overall corporate strategy:

- How is the intellectual property going to be acquired? (in-development vs. licensing/purchasing)
- What will the competitive emphasis be? (offensive vs. defensive)
- What type/size of budget impact is expected? (net costs or net profits)
- What organization drives the patent strategy? (R&D or legal)
- What impact will IP have on your research strategy? (discovery driven or IP driven).
- What policies and procedures are in place to preserve IP rights? (e.g., agreements to assign, recordkeeping, invention disclosures, joint-development agreements, etc.)
- How closely integrated are overall corporate strategy and patent strategy?

This article reviews various elements to consider when building and developing your patent strategy, including patent search tools. Importantly, R&D and product development personnel, business developers and patent agents/lawyers should collaborate to optimize patent protection.

To patent or not ?

Deciding whether or not to seek registration for a patent as opposed to maintaining a trade secret is always an important question to address. Patent protection is not always the most appropriate course of action. Often times trade secret protection is the right choice, in particular in the following situations:

- Trade secrets are the better choice when the life of your product is substantially shorter than the 20-year life of a patent. If you expect to make the most money from your product in a year or two, then by the time your patent issues (usually in two to three years), the product's value will be near zero, and your patent will be essentially worthless.
- Trade secrets may be the only choice when you don't have sufficient funds per invention to pursue patent registration. It doesn't make much sense to say that patents are the better choice if you don't have the money to pursue them.

The below table focuses on the advantages and disadvantages of adopting strategies that favor either patent protection or trade secret protection for your company's inventions.

Questions	Patents	Trade Secrets
What is being protected?	Inventions.	Anything you wouldn't want your competitors to know.
What's the heart of the matter?	The invention must be new, useful, and non-obvious.	The trade secret must, in fact, be kept secret and have commercial value.
How long does protection last?	20 years from filing date.	As long as it remains secret
How much does it cost?	Approximately Thai Baht 50,000 – 100,000 per invention to register in Thailand	Establishing procedures and keeping key employees.
How long does it take to secure rights?	Two to three years.	As long as it takes to establish and maintain internal company procedures.
How can my competitors defeat my rights?	Invent and file first. Challenge the validity of my patent. Design around my patent. Invent and publish.	Hire away key employees. Reverse-engineer my product. Patent my trade secret.
How can I make money from it?	By making and using products protected by the patent. By licensing, which is common. By selling the company. By enforcing it against infringers	By making and using products protected by the trade secret. By licensing, but trade secret licensing is less common (and likely more complex) than patent licensing. By selling the company, but be sure that the secrets convey. By enforcing it against infringers

If you are thinking outside of the box, you will also need to look at what your competitors are doing and when appropriate try to defeat their patent or trade secret strategies. For instance, if your client is pro-patent, you should actively try to publish (perhaps in a related patent's abstract) ideas that you don't want your competitors to patent.

Patent or utility model ?

The Thai Patent Act provides protection for two types of patent: patent for invention and utility model. Utility models are considered particularly suited for inventors that make 'minor' improvements and adaptations of, existing products or process and are primarily used for medical devices, kits etc. Utility models are also cheaper to obtain

and to maintain than patents and the registration process is significantly simpler and faster than patents for invention, taking, on average, 14 months. When an application for a utility model is filed, it can be granted without the conduct of a substantive examination unlike patent for invention. That's why utility model is usually presented as a weaker title in comparison to patent for invention. However, the reality is less severe for petty patents than it first appears. Usually a defence to an infringement action consists in filing a counterclaim for revocation of a patent for invention on one or more invalidity grounds. With patents for invention, one of the grounds is almost always a lack of inventive step. Since the inventive step is not required in a utility model, the chances of success in a revocation counterclaim

are significantly reduced when enforcing a utility model, which contribute to make utility model in some aspects a stronger title than patent for invention.

Prosecution phases

Product patent & process patent

Under the Thai patent Act, both product patent (i.e. "a polyamide conforming to the following structure...") and process patent (i.e. "process for synthesizing a compound...") can be registered as patent and petty patent. Product patents provides for absolute protection of the product, whereas process patents provides protection and prevents one from practicing a specific series of steps in the process as defined in the patents. Protection for process patents would not prevent the manufacture of patented products where a different process or method from that which has been invented and patented is used. This is an important element to consider, in some cases the filing of product and process patent is recommended.

Product-by-process patent

A product-by-process claim defines a compound in terms of the method (manipulative steps) used to manufacture that compound. It is like the product claim, as it covers the compound, but it describes the compound in terms of what steps are conducted to make that compound. An example of a product-by-process claim could be "a polyamide made by the amidification reaction of a poly fatty acid and a polyamine conforming to the following structures...". Although this type of patent provides a narrower protection than product patent it can still be valuable in the case of polymeric structures, where the specific structure of the product might, for instance, be ambiguous.

What to patent ?

One basic issue is what to patent. Not all biotech related inventions qualify for the grant of a patent for invention or utility model. The Thai Patent Act specifically excludes several subjects from patentability.

i) Naturally occurring micro-organisms, their components, animal, plant or animal and plant extract are exempted from patentability. However, plant transformation and DNA fingerprinting and molecular diagnosis of plant diseases can be patentable. For instance, the following hybrid and transgenic plants have been patented in Thailand:

- A method of producing hybrid plants which involves inducing cross-pollination of self-pollinating species by selecting a female plant and a male plant having different genotypes (for an English translation of the Thai patent you can refer to US priority patent 6,066,785).

- Grain aroma is the most attractive characteristic of high quality rice increasingly demanded all over the world. The aromatic compound 2-acetyl-1-pyrroline is the major potent flavor component of all aromatic rice. The invention provides transgenic rice plants in which 2-acetyl-pyrroline is synthesized at a level greater than in naturally occurring non-aromatic varieties. The transgenic plants have reduced expression of the Os2AP gene and protein, resulting in an aromatic phenotype. (for an English translation of the Thai patent you can refer to US corresponding patent 7,319 181).

ii) Methods of diagnosis, treatment or cure of human and animal diseases are also exempted from patentability. For instance the following invention made by a team of Thai inventors is not patentable under the current Thai patent legislation and practice:

- Methods of determining risk of developing Dengue Hemorrhagic Fever/Dengue Shock Syndrome (DHF/DSS) in an individual infected with dengue virus (DV). This invention is registered in USA (US 7,629,117) where medical treatments methods are patentable.

The following medical invention is however patentable under the Thai Patent Act:

- A skin cleansing product which includes a soap which comprises sericin protein from Thai silk, as a main ingredient. The soap helps to nourish the skin so as to smooth and soften the skin when used. This Thai invention which belongs to the Foundation for the Promotion of Supplementary Occupations and Related Techniques of Her Majesty Queen Sirikit is protected in several countries including Thailand, Japan and USA (US patent no. 7,314,851). A medical device or medical substance such as the one referred in the above invention is a product and is not considered a method of treatment.

One way of getting around the medical method claims issue is to rewrite them as "Swiss claims"

such as "use of substance X in the manufacture of a medicament for the treatment of condition Y." It is permissible under the current Thai patent practice so long as the method of treatment is not a "pure" treatment method, for instance the method of using a scalpel during surgery.

iii) Computer software. While it is not possible to obtain a patent on software per se, patents may be granted for inventions requiring the use of software to achieve their purpose. This, however, is conditional on the software having a "technical effect" when the programme is run. Such effect may, for example, be found in the control of an industrial process or in the internal functioning of the computer itself.

iv) The Thai Patent Act does not explicitly exclude business methods from patentability and it is debatable whether business methods are patentable under the Act. Arguably, Thai patents for pure business methods would not be granted because they cannot satisfy the meaning of invention under the Act. According to Section 3 of the Act, invention means any innovation or invention, which creates a new product or process, or any improvement of a known product or process. Furthermore, the Act defines "process" as "any method, art or process of producing, maintaining or improving the quality of a product, including the application of such process". A pure business method is neither a product nor a process of producing, maintaining, or improving the quality of a product under the meaning of Section 3.

Under the current practice of the Thai Patent Office, a method or model for doing business, standing alone, no matter how innovative, is considered to lack the crucial component of an inventive step, according to Section 5 of the Patent Act.

How and where to file patents ?

There are three main options for seeking patent protection in Thailand. A combination of some options may suit depending on the chosen patenting strategy (i.e. non convention national filing followed by a PCT application).

i) Non convention national filing

Applicants, including foreign applicants subject to specific conditions of country of origin or domicile, who wish to file their patents in Thailand can file a patent directly in this country. It takes a period ranging 3-5 years from the date of filing for the acquisition of patent for invention up to

the registration. The period is shorter for utility model.

ii) Convention application

Thailand is a member of the Paris Convention. Under the Paris Convention, it is possible to file a patent application in Thailand within 12 months of the filing date of the priority or first patent application filed in another member country of the Paris Convention.

iii) The International Patent Application - PCT

Thailand has deposited its instruments of accession with WIPO on 24 September 2009, thus became the 142nd contracting state of the Patent Cooperation Treaty. The treaty has become effective in Thailand from 24 December 2009.

The PCT Receiving Office of Thailand officially opened at the Department of Intellectual Property of Thailand (DIP) on January 4, 2010.

The PCT is an international patent treaty, administered by the World Intellectual Property Organization (WIPO), between more than 140 Paris Convention countries (See list of all Contracting Parties to the PCT <http://www.wipo.int/pct/en/>). The PCT makes it possible to seek patent protection for an invention simultaneously in each Contracting Party (or countries) by filing a single "international" patent application instead of filing several separate national or regional patent applications. However, the granting of patents remains under the control of the national or regional patent Offices in what is called the "National Phase".

Advantages of the PCT route, as compared to filing individual foreign patent applications, include:

- The applicant has up to 18 months more than would be the case in a procedure outside the PCT, to reflect on the desirability of seeking protection in foreign countries.
- The applicant is assured that, if the international application is in the form of prescribed by the PCT and has met the formal requirements; it cannot be rejected on formal grounds by designated office during the national phase of the processing of the application.
- On the basis of the international search report from the International Search Authority [ISA] or the written opinion, the applicant

can evaluate with reasonable probability the chances of the patentability of the invention in the regions or countries where the patent is sought.

- The search and examination work of national patent offices during the national phase can be considerably reduced or virtually eliminated thanks to the international search report, the written opinion and, where applicable, the international preliminary examination report that accompany the international application, therefore the registration of the patent might be accelerated.
- Since each international application is published together with an international search report, third parties are in a better position to formulate a well-founded opinion about the patentability of their claimed invention.

How to assess inventions ?

i) Patent due diligence

Patent due diligence is the detailed patent investigation of a business (e.g. company to acquire or to obtain a patent license from), the aim being to identify problems within the business, especially those that might result in future liabilities. Due diligence of a biotech's patent portfolio will cover the following issues:

- The biotech's key product candidates and platform technologies will be investigated to determine whether they are adequately covered by patents. The length of each patent's unexpired term will also be investigated.
- Have the biotech's invention been protected in key territories, and are procedures in place to ensure that all renewal fees have been paid for those territories?
- Employment contracts and research contracts will be reviewed to determine how ownership of intellectual property is dealt with in the business.
- The due diligence process will establish whether there have been any challenges or opposition to a biotech's patents, whether the patents actually provide useful protection, and whether they can be circumvented.
- Due diligence reviews will consider whether another party has offered the biotech licenses

to technology, or has threatened to sue. Further investigations may involve relevant third-party patents, and if these exist, may question whether the company has sought infringement and validity advice in respect of those patents.

ii) Patent Landscape Mapping (PLM)

Patent landscape mapping (PLM) is a tool to analyze existing IP to determine the risks and opportunities of participating in a given technology and/or product space. It describes the technologies and alternative solutions that have been applied to a particular product category. PLM identifies competitors based on their issued and filed IP, and outlines their strategies, strengths and problem-solving approaches. PLM enables a company's scientific and commercial management teams to identify the best opportunities for investment in a selected product area, to create a strategy to protect their IP, and to establish differentiation with respect to their competitors.

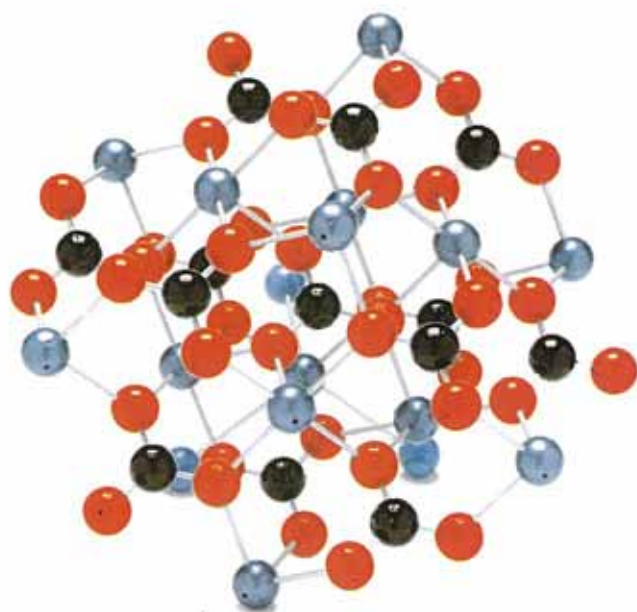
CONCLUSION

Patents play a critical role in driving innovation and protecting advancements in the biotechnology sectors, and the need for strategic management of patents is greater than ever. Because the ultimate purpose of any good patent strategy is to serve the enterprise's overall business objectives, that strategy must be developed concurrently with research, development, and investment strategies. It certainly requires consistent business, technical, and legal collaboration.

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