Radeemada Mungkarndee
Consultant & Patent Agent
radeemada.m@tillekeandgibbins.com

The "Evergreening" Euphemism: A Threat to Technological Innovation

"Everything that can be invented has been invented" was the mythic pronouncement of the Commissioner of the United States Patent and Trademark Office, Charles H. Duell, in 1899. Nonetheless, in the 110 years since these words were purportedly spoken, inventors have continued to develop innovative new technologies that benefit humanity. Threatening technological innovation, however, include those with the mindset encapsulated in Duell's remark who utilize the euphemistic term "evergreening" to unduly label as a strategy of prolongments what may in fact be patentable improvements to patents. Evergreening is prevalent in modifications covering different aspects of the same product, particularly in the pharmaceutical industry. These modifications may facilitate the use of a known medication and lead to patient compliance, optimize bioavailability, improve stability, or minimize toxicology and side effects.

As a WTO member, Thailand has obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide patent rights without discrimination as to the field of technology. However, there are debates from many parties, such as NGOs, the Food and Drug Administration, and the Government Pharmaceutical Organization, concerning drug prices based on patent exclusivity and public health interests. For example, there have been several attempts to cancel or oppose AIDS drug patents and patent applications based on the ground that the patent lacks novelty and inventiveness. This has led to a number of disputes among the pharmaceutical industry, patient groups, and patent practitioners regarding the standard of examination in the quality of the invention.

The level of examination is not defined by the TRIPS Agreement, and thus patentability criteria vary on a country-by-country basis. No provision under the Thai Patent Act is specifically directed towards evergreening issues. In contrast, the Indian Patent Law addresses issues relating to evergreening in Section 3(d) (see inset box).

In the absence of specific legal provisions to prevent evergreening patents, Thai patent examiners treat patent applications of modified drugs by taking a long period for exhaustive examination to ensure that they demonstrate "surprising results." The term "surprising results," as stated in the Thai *Manual of Patent Examination*, is likely more open compared to Section 3(d) of the Indian Patent Law because it is not restricted only to the efficacy, but could also refer to chemical improvement and practical benefits, including better yield, dissolution rate, bioavailability, and stability of pharmaceutical product patents. This criterion is evaluated in relation to the state of the art—whether or not it enables one of ordinary skill in the art, at the time of the invention, to predict the results with a reasonable expectation of the invention's success.

In this view, two scientist lecturers who specialize in organic synthesis, Assist. Prof. Paitoon Rashatasakhon, Ph.D., and Sumrit Wacharasindhu, Ph.D., from Chulalongkorn University (formerly researchers in the United States at Schering-Plough Research Institute and Wyeth Research, respectively), have provided important commentary on this issue. Their position is that advanced synthesis and separation techniques make it possible to design reactions to selectively obtain or certain form or characteristic of substances. Despite this, Assist. Prof. Paitoon Rashatasakhon further opined that a new complex or polymorphic form may increase stability and solubility of the same drug, and insome situations a single enantiomer may be destroyed during the biological transformation process or can have interaction with target receptors in a specific way. Therefore, it would not be possible to predict whether modified forms of a certain substance would have better properties, present activity, and none of its toxicity compared to the existing product. In other words, the advances provided by these modifications may not be foreseeable at the time the original substances are invented. It should be noted that chemical test data, clinical test, or bioequivalent results showing the benefits of the modified drug may be submitted later, provided that no new matter is inserted into the patent application.

> "in the absence of specific legal provisions to prevent evergreening patents, Thai patent examiners treat patent applications of modified drugs by taking a long period for exhaustive examination to ensure that they demonstrate 'surprising results'"

The developer of the modified product is not always the same entity as the originator. Who would benefit if pharmaceutical patents are granted only to new drugs? Foreign companies which have the resources and investment capabilities to discover new drugs? Or companies in the domestic pharmaceutical sector which have the opportunity to modify existing drugs and obtain an "evergreen patent" on the modification of the basic patent belonging to others, no matter when the basic patent expires? When the basic patent expires, the protection ends; even if there is a patent on a modified version, people can still use the old version, and the patent for the new version cannot preclude a generic competitor from selling products defined in that expired patent. Granting incremental patents offers incentives for companies which cannot engage in new drug discovery and development to undertake their effort and investment in modifying better drugs.

Indian Patent Law – Section 3 (d)

[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be same substance, unless they differ significantly in properties with regard to efficacy.