

“Ever-greening” Patent Applications of Pharmaceuticals in Thailand and Their Impact

Maleewong U., Kessomboon N., Kijtiwatchakul K., Eksaengsri A., Atsawintarangkun S.

Introduction

The amendments to the Patent Act of Thailand from process patent to product patent, due to pressure from the United States since 1992, have been an important obstacle to the development of the local pharmaceutical industry. Pharmaceutical expenditure increased significantly due to the high price of monopoly patented medicines. The Ministry of Health reported that the 2011 market share of imported medicines had increased to 77% leaving local manufacturers with only 23% market share. The total market size of pharmaceuticals in 2011 was approximately 144,000 million baht (US\$ 4.8 billion). To extend the period of monopoly in the pharmaceutical market, patent holders filed numerous patent applications on minor incremental developments of the known active ingredients, known as ‘ever-greening patents’.

Objectives

- 1) To develop a pharmaceutical patent examination guideline;
- 2) To explore the situation of ‘ever-greening’ of pharmaceutical patent applications in Thailand between 2000-2010; and
- 3) To estimate the impact of ‘ever-greening’ of pharmaceutical patent applications on pharmaceutical expenditure and access to medicines.

Methods

To meet objectives 1 and 2, pharmaceutical patent applications filed between 2000-2010 were re-examined using the new guidelines for the examination of pharmaceutical patents in Thailand which was developed from the guidelines elaborated by ICTSD, UNCTAD, and WHO 2007 and adopted following focus group discussion among academics, DIP officers, PReMA and TPMA. The patent application examiners were also standardized until reaching the almost perfect agreement among the examiners (kappa coefficient = 0.89). The 59-selected items of pharmaceuticals, which were examined as ever-greening, were then calculated the impact on pharmaceutical expenditures and accessibility. The impact on pharmaceutical expenditure was estimated based upon the price and quantity costing between innovative drugs and their generics plus some parameters found from their competitive behavior. Thereafter, we simulated the 18-year potential additional expense on the 2010 unit price of the patented and monopolized non-patented medicines. We also selected three high cost medicines for three diseases, AIDS, breast cancer, and

osteoporosis, to calculate the incremental cost per quality-adjusted life year gained for original versus generic medicines and calculate access to medicine during 10-year treatment.

Results

1) Situation of Ever-greening Patents

Of the 2,188 patent applications filed during 2000-2010, 1,839 (84.0%) were categorized as 'ever-greening' applications. The 'ever-greening' ranged from Markush claim (34.5%), formulations (23.1%), new use of known substance (18.8%), and combinations (11.5%). Top three of the patent application holders (57.1%) in Thailand were US, German, and Swiss. Only 0.5% of patent applications were from Thai patentees.

2) Impact of Ever-greening Patent Applications on Pharmaceutical Expenditures

The patent applications of selected 59 drugs were examined and were found to be ever-greening. It would result in the monopoly market for 32 years during the year 1996-2028. The cumulative market value of the evergreen was approximately 8,477.7 million baht (US\$ 283 million). If we consider only the impact for 14 years monopoly during 1996-2010, the estimated lost from ever-greening was 1,177.6 million baht (US\$ 39 million). Therefore, if the Department of Intellectual Property considers using the new guidelines to examine the patent applications, potential savings will be in the total amount of 8,477.7 million baht (US\$ 283 million).

3) Impact of Ever-greening Patent Applications on Access to Medicines

The cost-effectiveness analysis of the high-cost original chemotherapy substance to treat breast cancer was not cost-effective when compared with the cost-effectiveness threshold recommended by the World Health Organization (1 to 3 GDP per capita in developing countries). However, if the original medicines were substituted by generic medicines to treat all patients, the use of these medicines was found more cost-effective. The 10-year generic substitution treatment in three diseases showed that the model with generic substitution increased the access up to 66.9 percent in patients with osteoporosis, 21.7 percent of HIV/AIDS patients and 9.3 percent in patients with breast cancer, respectively.

Conclusions

This study has presented the problems associated with the pharmaceutical patenting of minor incremental developments. The large number of patents applied for was not a reliable indicator of innovation. It means that patent strategies on pharmaceutical products in Thailand may have a direct negative impact on access to medicines by blocking generic competition. Therefore, rigorous criteria to assess the inventive step of patent applications relating to pharmaceuticals

should be applied so as to ensure the patents are only granted where genuine contributions to the state of the art are made.