I. Introduction

When a company intends to place a new product or service on the market, it must understand the risk of infringing the third parties' intellectual property. It is a common practice for the company to conduct a Freedom-to-Operate (FTO)[1] search to determine and reduce the risks of potential patent infringement prior to launching a new product or service. The FTO search is performed to find relevant third parties' patents that may cover the new product or service. The FTO is also called "Patent Clearance". If the company completely neglects the FTO search, and then, later on, the product is found to infringe a third parties' patent, it is most likely that the company would be sued by the patentee as an infringement of the patent. As a result of losing the infringement case at the court, the company has to stop selling its product and to compensate the damage that the patentee suffered from. Therefore, the FTO search is indispensable to perform prior to placing the new product or service on the market. Even if the company finds some relevant patents as a result of the FTO search, the company should not necessarily give up marketing the product because the company still has a chance to obtain a license from the patentee. With this licensing-in activity, the company can operate its business freely in the market. Therefore, this activity is called "FTO-licensing".

In part II of this paper, I would like to focus on the FTO-licensing in the pharmaceutical industry. There are many characteristic aspects in this industry that are never seen in other industries, which makes the FTO-licensing in the pharmaceutical industry very special. These characteristic aspects roughly consist of the following four points. First, the economical scale of the market in the pharmaceutical industry is incomparably large, with an estimated 716 billion Euro at ex-factory prices in 2015 in the

1 "Freedom to Operate (FTO) is the ability to proceed with the research, development and/or commercial production of a new product or process with a minimal risk of a new infringing the unlicensed intellectual property (IP) rights or tangible property (TP) of third parties" (Stanley P. Kowalski, *Freedom to Operate: The Preparations,* ipHandbook of Best Practices (last visited September 5, 2016), http://www.iphandbook.org/handbook/ch14/p02/).

world.[2] This market is still growing rapidly in some highly populated countries. Second, the cost of a research and development (hereinafter referred as "R&D") for a new drug is very expensive. One of the reasons for the high cost is clinical trials, which would cost approximately 2 billion Euro according to the recent survey.[3] Third, in spite of such an expensive R&D cost, success rates are extremely low. It is reported that the total success rate is calculated to be 0.01%.[4] For this characteristic, R&D for a new drug is a highly risky business. Fourth, a duplication of the drug made by another company is quite easy compared to conducting R&D for a new drug on its own. Accordingly, patent protection in the pharmaceutical industry is much more essential to recoup R&D investment than that in other industries. In order to recoup the investment, pharmaceutical companies in general wish to monopolize the marked and sell the drugs rather than to conduct licensing-out because selling the drugs in the monopolized market is the most profitable way. Taking into account this low probability of obtaining a license from another company, a pharmaceutical company must conduct a thorough FTO search at the beginning.

Because of the above-mentioned obligation, the part III of this paper focuses on how to achieve the FTO in the pharmaceutical industry. I would like to describe not only the characteristic points regarding the FTO in the pharmaceutical industry but also an FTO in general. It should be noted that even if 99% of an FTO is conducted properly, the other uncompleted 1% could ruin the whole FTO search because that 1% might contain the relevant third parties' patent which covers the technology that the pharmaceutical company intends to include in its product/service. To perform a thorough FTO, it is important to first describe how to build an FTO team, how to search relevant patents, how to interpret potentially adverse patents and how to deal with adverse patents, especially pointing out the characteristic features about the FTO in the pharmaceutical industry.

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2 European Federation of Pharmaceutical Industries and Associations (hereinafter referred as "EFPIA"), *The Pharmaceutical Industry in Figures, 2016 Edition* 14 (last visited September 5, 2016), http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf.

3 *Id.* at 6.

4 M. Dickson, J.P. Gagnon, *The Cost of New Drug Discovery and Development* (June 20, 2009), http://www.discoverymedicine.com/Michael-Dickson/2009/06/20/the-cost-of-new-drug-discovery-and-development/.

In part IV of this paper, I would like to describe two issues with regard to FTO-licensing, and analyze them. The first one is the issue on FTO-licensing and EU competition law. When a pharmaceutical company wishes to license-in, it concludes a license agreement which includes the obligation on royalty payment. Basically, the parties of a technology license are free to determine the amount and nature of royalty payments. But in some cases, the license will have the risk of being interpreted to be anticompetitive. Royalties on products produced without using licensed technology is one of these cases. I analyzed the TTBER and the Guidelines, taking into account the characteristic features in the pharmaceutical industry, then I pointed out the possibility that the Guidelines should not be applied to the royalty on drugs. The second one is the issue on FTO-licensing between a bio-venture company and a pharmaceutical company. Recently, an increasing number of pharmaceutical companies have mapped out the strategy to license-in the technology of a bio-venture company mainly because they want to diminish the risk of R&D failure. These companies tend to license-in or buy a promising candidate for a new drug regarding certain type of disease. And nowadays there are many bio-venture companies that are willing to license-out their technologies to pharmaceutical companies. However, the reality of licensing-in/out is contradictory to their high expectations. After analyzing the situation, I proposed some solutions.