

V. Conclusion

The pharmaceutical industry is completely unique compared with other industries in terms of huge market, high R&D investment, high failure rates, and significance of patent as safeguard of innovator profits. First of all, in this pharmaceutical industry, the way to perform proper FTO (freedom-to-operate) was examined, taking into account the specific features in this industry.

One of the common strategies to achieve FTO is licensing-in the technology of the adverse patent. But it was found that licensing-in activity is not so easy in the pharmaceutical industry because the patent holder tends to monopolize the market to recoup its investment rather than making profit by licensing-out it to a competitor. Monopoly of the market is the best way to maximize the profit.

However, the IP strategy to prepare “aggressive patents” prior to license negotiation would greatly help to conclude a license-in agreement, in most cases, a cross licensing agreement. Therefore, it is significant for a pharmaceutical company to take this IP strategy long before it starts negotiating for a patent license. A pharmaceutical company should file patent applications not only for “defensive patents” to protect its core technology but also for “aggressive patents” to facilitate the licensing negotiation in the future.

Then, two issues of the FTO-licensing market in the pharmaceutical industry were examined. One issue is the FTO-licensing and EU competition law. In general, royalties on products produced without using licensed technology is considered to be anticompetitive under TTBER and the current Guidelines. However, in the pharmaceutical industry where the drug price would be determined by very complicated and unique factors, these general guidelines were found to be not appropriate anymore.

The other issue is the FTO-licensing between a pharmaceutical company and a bio-venture company. Despite the fact that both of them are willing to license-in/out, in reality, the number of licensing-in/out does not seem to be as large as it is expected. There are several reasons, but the inappropriate FTO that is conducted by a bio-venture company was deeply examined here and was found to be one of most decisive reasons. The concrete proposal to this issue was described. Normally, a bio-venture

company does not perform thorough FTO nor have careful IP strategy for future licensing negotiation. However, it is really important for a bio-venture company to grasp the whole map and prepare for “aggressive patents” on behalf of a pharmaceutical company, the future licensee or buyer.

