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# Recent changes in antitrust laws with respect to pharmaceutical companies


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Over the past decade, the number of companies involved in patent related lawsuits has increased significantly. In a recent development, certain pharmaceutical companies have found innovative ways to leverage their patent portfolios as a means of deterring business competition in industries that are heavily reliant on research and technology. The Korea Fair Trade Commission (KFTC) recently issued amendments to the Guidelines for Examination of Improper Enforcement of Intellectual Property (the Guidelines) that affect the enforceability of intellectual property by pharmaceutical companies. In particular, the amendments will have a significant effect on the pharmaceutical market where patent-related lawsuits have long been used to create unfair business advantages for those filing lawsuits whilst knowing that there is no actual infringement. Any company found to be in violation of the Guidelines may be subject to fines and penalties.

Earlier this year, the KFTC surveyed almost 50 domestic and multinational pharmaceutical companies with respect to their patent applications, licensing arrangements, and intellectual property disputes involving key prescription drugs that were distributed, or for which marketing approval was requested or granted in Korea from 2000 to 2009. An official at the KFTC said that the survey aimed to "promote correction and competition by causing pharmaceutical companies to voluntarily address unfair acts." Although the results of the surveys were not publicised, one may infer from the subsequent actions of the KFTC that the results identified an immediate need to amend the Guidelines.

Since the surveys were conducted, the KFTC has begun taking measures to deter pharmaceutical companies from abusing their patent rights related to brand name drugs by interrupting or delaying the entry of generic drugs into the market. Under both the previous and amended Guidelines, the abuse of intellectual property rights can be classified into two groups. The first group involves an "agreement with respect to a patent dispute," where a party may attempt to maintain the validity of an invalid patent for a brand name drug to delay the entry of generic drugs into the market. Often in such cases, a brand name drug manufacturer is able to persuade generic drug makers into an unfair agreement known as a Reverse Payment Settlement, wherein the brand name drug manufacturer will make a payment to the generic manufacturer in exchange for the generic manufacturer agreeing to delay production or marketing of the generic product.

The second group of intellectual property disputes involves an "abuse of patent lawsuit" where a party "unfairly" files a patent invalidation or infringement lawsuit in order to interfere with its competitors' business activities through legal or administrative procedures. Under the previous Guidelines, "a business operator filing a patent infringement lawsuit to impair or restrict the ability of other business operators to conduct business, while being aware that the other business operators do not infringe on its own patent rights" is considered an act of impeding or obstructing the business activities of other business operators.

The newly revised Guidelines identify antitrust violators as "a business operator impeding or obstructing the business activities of other business operators by unfair use of patent infringement lawsuits, patent invalidation trials, or other legal or administrative procedures relating to intellectual property rights." This revision broadens the definition of the abuse of intellectual property rights in that the act of the patent owner no longer needs to be intentional, but only unfair. Given the broader scope of application, brand name pharmaceutical companies may be placed under stronger scrutiny if they enter into Reverse Payment Settlements or engage in abusive patent lawsuits.

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