Generic Cialis drug makers absolved from liability for patent infringement after Patent Court finds Cialis dosage patent based on common clinical tests does not satisfy inventiveness

On February 3, 2017, the Patent Court of Korea invalidated Korean registered patent no. 0577057, a dosage patent that limits the dosage of Tadalafil, a substance for treating erectile dysfunction contained in Cialis, to 20mg per day and unit dosages to 1mg to 20mg (the "Dosage Patent").

After the expiration of the Cialis substance patent on September 4, 2015, about 60 domestic pharmaceutical companies have been making and selling generic versions of Cialis in Korea. If the Dosage Patent were found to be valid, these companies would have been subject to considerable liability for patent infringement. Accordingly, the entire pharmaceutical industry in Korea has been closely following this case.

This case is all the more significant because it is the first case where the element of inventiveness for dosage patents is considered after the Supreme Court acknowledged in an en banc judgment that dosage regimens for medicines are patentable (2014Hu768 Judgment on the case of confirmation of the scope of a patent right). Representing Chong Kun Dang Pharmaceutical Corp., the leading generic Cialis drug maker in Korea, we researched relevant precedents of the Supreme Court and the courts of the U.K. and Japan and argued that dosages that can be deduced based on prior art through common clinical tests should not be acknowledged as non-obvious, and the significance of such effects should not be acknowledged unless the effects of the proposed dosage can only be achieved by adhering to such dosage regimen.

ICOS Corporation, the owner of the Cialis patent, argued on the basis of statements of the inventor who conducted the clinical tests and expert witnesses, including a pharmacology professor, that the claimed dosage cannot be deduced by common clinical tests because such low dosages cannot be easily expected from prior arts, as well as asserting that the effects of the Dosage Patent are significant because lower dosages resulted in unexpected pharmacological effects while reducing side effects. However, we presented evidence to the contrary, using documentation made available through the

US FDA's approval process for Cialis and the testimony of expert witnesses. We were able to show that ordinary skilled persons could deduce dosages similar to that of the Dosage Patent by applying their general skills, and the effects of such dosages were not significant when compared with prior art, in terms of treatment or reduction of side effects. Consequently, we argued that the Dosage Patent should be invalidated because it lacked inventiveness.

The Patent Court accepted our argument and ruled "it is within the scope of ordinary creativity of ordinary skilled persons to optimize dosage conditions, including the amount/cycle of dosage, for enhancing the effects, and reducing side effects, of the disclosed medicine to the extent such optimization does not cause any toxicity or side effect, etc.; provided, however, in extraordinary circumstances, where favorable effects caused by a certain dosage or regimen are significant beyond the scope predicted by ordinary skilled persons, or if ordinary skilled persons cannot predict a certain dosage or regimen that maintains the pharmacological effects of the relevant pharmaceutical invention at the same level, minimizing any toxicity or side effect from the prior art, the inventiveness of such dosage or regimen should not be denied," presenting clear standards for determining the inventiveness of new dosage patents. Based on these standards, the Patent Court invalidated the Dosage Patent ruling that the Dosage Patent lacked inventiveness given there was no significant difficulty in deducing the claimed dosage through common clinical tests, and that the effects generated within the scope of the dosage claimed by the Dosage Patent were not significant or unique enough to warrant acknowledgement of inventiveness.

This judgment is meaningful because not only does it absolve domestic pharmaceutical companies manufacturing generic versions of Cialis from liability for patent infringement but it also establishes clear standards of judgment for determining the inventiveness of new dosage patents. Original pharmaceutical companies holding a substance patent will now need more than common clinical tests on different dosages to satisfy the necessary element of inventiveness for a dosage patent in Korea.

If you have any questions or need assistance in relation to the subject of this newsletter, please contact:

Shin & Kim's IP Team

- Ghyo-Sun Park, Partner TEL : +82 2 316 4233 E-Mail: gspark@shinkim.com
- Bo Kyung Lim, Partner TEL : +82 2 316 4041 E-Mail: bklim@shinkim.com
- Hyo Jin Cha, Associate TEL : +82 2 316 1698 E-Mail: hjcha@shinkim.com
- Tae Young Lee, Patent Attorney TEL : +82 2 316 4079 E-Mail: tylee@shinkim.com