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TIPLO News

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This news mail distributed in Japanese and English from time to time provides updates on the development of law in Taiwan with focus on intellectual property rights law. For more information about the status of intellectual property right protection and practice in Taiwan, please visit our website www.tiplo.com.tw

Topics in this issue

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01 ITRI and Applied Materials Inc. ink MOU to establish open innovation platform

Taiwan-based Industrial Technology Research Institute (ITRI) and U.S. headquartered Applied Materials Inc. (Applied Materials) concluded a memorandum of understanding on open innovation platform on June 11, 2019. The two sides will join hands to establish an open innovation platform to share information and spur commercialization of innovative technologies. Also through this platform, ITRI and Applied Materials will forge new cooperative programs so as to upgrade Taiwan-based electronics industry's R&D performance with multinational enterprises and foster new commercial opportunities.

The MOU aims to mainly develop a "platform for open innovation and commercial cooperation" and deepen both sides' collaboration in the processes of displays, advanced packaging and new venture investment. Under this MOU, both sides will

organize annual summit conference on yearly basis to periodically review cooperative progress and examine new cooperative proposals. (June 2019)

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02 Taiwan FDA completes draft of Enforcement Rules for Western Pharmaceuticals Patent Linkage

Taiwan Food and Drug Administration under the Ministry of Health and Welfare issued a press release with respect to the Enforcement Rules for Western Pharmaceuticals Patent Linkage on July 1, 2019.

According to the press release, Taiwan Pharmaceutical Affairs Act has incorporated a new chapter of "Patent Linkage of Western Pharmaceuticals" since its amendment passed the third reading at the Legislative Yuan at the end of 2017 and the amendment was promulgated by presidential order on January 31, 2018. Under the patent linkage system, a new drug marketing approval holder may complete listing and reporting of the patent information with respect to his/her pharmaceutical patent(s). On the other hand, a generic drug approval applicant who seeks grant of drug approval for his/her generic drug shall make relevant certification or declaration in regard to the patent(s) listed by the new drug approval holder with the competent authority, and the competent authority will stay issuance of drug approval for a period of 12 months to clear relevant patent disputes. The first applicant of generic drug approval to successfully challenge patent validity or make non-infringement declaration against the new drug and to have produced complete in full the materials required of his/her application for approval of the generic drug will be granted an exclusive marketing term of 12 months. The introduction of this system will clear potential patent infringement dispute before the marketing of generic drugs, which will ultimately upgrade the research and development of Taiwan's pharmaceutical industry and expand international market.

Ministry of Health and Welfare has formulated and completed the draft of the "Enforcement Rules for Western Pharmaceuticals Patent Linkage" in accordance with Taiwan Pharmaceutical Affairs Act. The draft compiles and mainly sets forth the contents as summarized below, which are in connection with (1) method of filing patent information, content of patent information to be filed, amendment, deletion, publication and/or disclosure of the patent information filed and listed, (2) generic drug approval applicant's patent-related declaration or statement, required written notices, examination procedure for generic drug approval applications, and issuance of drug approval, (3) required notice to be issued by the new drug approval holder with respect to the patent infringement action initiated by the patentee or exclusive licensee or with respect to the final judgment that sustains occurrence of infringement, (4) grant and duration of exclusive marketing term, (5) the applicability of provisions, with appropriate and necessary alterations, to the drug approval applications for the new drugs and biosimilars other than those of new chemical entity, and (6) exclusion of indications, declaration and statement, and other compliance matters.

After announcement and compilation on September 11, 2018 and January 30, 2019, respectively, this draft promulgated on July 1, 2019 also incorporates and lays down the applicability of the provisions governing the drug approval application for generic drugs to biosimilar products for protecting the patents regarding biologics. Also based on the conclusions made in the public meeting held for the supporting measures of the inclusion of biosimilars into patent linkage system on May 15, 2019, the draft rules stipulate a transitional clause that the relevant provisions of the chapter of patent linkage system shall not apply to the biosimilars, for which official approval

for clinical trials has been issued by the central competent authority before the patent linkage is officially implemented.

In addition, in response to the launch of patent linkage system, the Ministry of Health and Welfare will work with relevant agencies and departments to formulate relevant supporting measures and policies for international market expansion. (July 2019)

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03 National Tsing Hua University goes ahead of the world to develop the first-ever spray synthesis process for preparing perfect multicolor PQDs

The team led by Dr. Hao-Wu Lin of Department of Materials, Science and Engineering of Taiwan National Tsing Hua University successfully developed an innovative technology titled “Spray synthesis technique to fabricate multi-color PQDs with excellent emission properties” by using simple and cost-effective spray synthesis technology to create perovskite quantum dots (PQDs) with near 100% quantum yield, high color purity, and good emission stability. Also, the emission wavelength and spectra of the PQDs created possess an ultra-broad color gamut to be applicable to various display technologies. Moreover, this innovative research result has been featured in the journal, *Advanced Materials*.

Dr. Lin’s team has not only successfully broken through the previously poor crystallization and instability of PQDs. The spray process also largely extends the feasibility of mass production in industry. This innovative technology has been successfully patented in Taiwan. Moreover, Seoul National University and University of Tennessee of the U.S. have also sought cooperation because of the new technology, which forges Taiwan’s position on the international market to outshine other countries based on the scientific performance. (June 2019)

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