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Japan: Sawai's Generic Drug is approved by the MHLW amid patent litigation with Bristol-Myers Squibb, but the Court orders preliminary injunction against Sawai soon after

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On November 28, 2023, the Tokyo District Court issued a preliminary injunction order against Sawai Pharmaceutical Co., Ltd. ("Sawai") to suspend the manufacture and sale of Sawai's pharmaceutical product ("Sawai's Product") developed and sold as a generic drug of Bristol-Myers Squibb ("BMS")'s cancer drug "Sprycel®" (Case No. 2023 (Yo) 30214; *AIK represented BMS in this case*). The active ingredient of the generic drug is dasatinib anhydrate although Sprycel®'s active ingredient is dasatinib hydrate.

BMS owns Japanese Patent No. 3989175 claiming the compound of dasatinib, which patent has an extended patent term until January 27, 2024 based on a marketing approval of Sprycel® for the indication "chronic myelogenous leukemia (except for those resistant to imatinib)." Based on this patent, BMS filed the preliminary injunction suit against Sawai on July 18, 2023 in concern of the rising risk that Sawai's Product would obtain marketing approval from the Ministry of Health, Labour and Welfare ("MHLW") for the indication "chronic myelogenous leukemia"[1] and be sold in the market soon. To BMS's surprise, amidst the litigation, the MHLW granted marketing approval to the indication "chronic myelogenous leukemia" for Sawai's Product on October 4, 2023. However, the Court was quick with its proceedings and issued the aforementioned preliminary injunction order against Sawai in less than 2 months from the MHLW's approval.

This case is important for the pharmaceutical industry in two aspects:

1. Whether "hydrates" and "anhydrates" are substantially the same in relation to BMS's extended compound patent

The issue in the preliminary injunction that attracted great attention throughout the industry was whether the scope of BMS's extended compound patent would cover Sawai's Product, particularly because the active ingredient of BMS's product Sprycel® was "dasatinib hydrate" while the active ingredient of Sawai's Product was "dasatinib anhydrate." Under Japanese patent law (Patent Act Article 68-2), the effect of an extended patent shall extend only to the same product (with the same specific use, if specified) as the originator's approved product which was the basis for the patent term extension. There is also an IP High Court Grand Panel decision (Case No. 2016 (Ne) 10046; Decision rendered January 20, 2017) which rules that in case of an extended patent directed to an ingredient of a pharmaceutical product, even if the accused product has partial differences from the approved originator's product as identified by "ingredients, quantity, dose and administration,

indication" in the marketing approval which was the basis for the patent term extension, if those differences are slight or formal when seen overall, and the accused product is substantially the same as the approved originator's product, the effect of the extended patent would extend to the accused product.

In the preliminary injunction case, although the preliminary injunction order does not state any specific reasons for the decision, the Tokyo District Court seemed to find dasatinib "hydrate" and dasatinib "anhydrate" as substantially the same in relation to the compound patent and found that the scope of BMS's extended patent would extend to Sawai's Product.

2. The MHLW's patent linkage practice

Japan has not statutorily adopted the patent linkage system, but the system is said to have been adopted in the governmental notification level, under which marketing approval shall not be granted for a generic drug while the originator's patent (covering the active ingredient or indication or dose and administration of the originator's product) is validly existing. The determination of whether or not a generic drug is covered by the originator's patent is made by the MHLW themselves without any court involvement in Japan.

The approval of Sawai's Product as a "generic" drug of Sprycel® means that the MHLW acknowledges that Sawai's Product has the same active ingredient as Sprycel® (as that is the requirement for being approved as a "generic" drug). Thus, the normal expectancy in this case would have been that the MHLW would reject Sawai's marketing approval request, but surprisingly the MHLW made the approval in the middle of the preliminary injunction suit. Whether this was a mistake at the MHLW or was based on a change in the MHLW's practice is unknown. As mentioned above, Japan's patent linkage system is only based on governmental notifications and theoretically can easily be changed, so it is important to keep a close watch on the MHLW's approval practice for generic drugs.

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[1] Sawai had already obtained marketing approval for this generic drug in February 2022 for the indication "acute lymphatic leukemia," but had not obtained marketing approval for the indication "chronic myelogenous leukemia".

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