Intellectual property

Creating new value through advanced intellectual property strategies and proprietary technology brands

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Overview of intellectual property related to generic drugs

The development, manufacture, and marketing of generic drugs depends on the proper management and utilization of intellectual property, especially patent rights, which greatly affects their competitiveness and sustainable growth.

In the early stages of development, it is essential to research and analyze the patent status of the original drug in question. Generic drugs cannot be put on the market if the substance patent for the active ingredient is still in force. However, even if the substance patent has expired, peripheral patents for efficacy, manufacturing methods, etc., may act as barriers, restricting manufacturing and marketing.

Therefore, any IP strategy for a generic drug should consider measures to circumvent the network of patents built by the original drug manufacturer. In addition, not only substance patents, but also use patents, manufacturing method patents, and formulation patents must be scrutinized from various perspectives to accurately identify risks.

As a result, the development, manufacture, and marketing of generic drugs are closely related to intellectual property. A multifaceted approach is essential, including thorough patent research and analysis, and setting up patent circumvention and invalidation strategies. These efforts minimize development risks, ensure efficient development planning and optimal allocation of management resources, and increase the probability of successful market entry.

Types of patent rights

Patent right	Summary
Substance patents	Patents on new active ingredient substances
Use patents	Patents on drug indication/efficacy
Process patents	Patents on methods of manufacturing active ingredients
Formulation patents	Patents on new innovations in formulation design (e.g., improved stability and absorption)
Crystalline form patent	Patents on the crystalline form of active ingredients

Strengths of our intellectual property strategy

The Sawai Group's highly advanced intellectual property strategy leads the industry, along with its extensive experience in the generic drug field. In the selection of items for development, we precisely ascertain the timing of substance patent expiration, enabling prompt market entry immediately after patent expiration. We also thoroughly investigate and analyze peripheral patents such as use patents, process patents, formulation patents, and crystalline form patents to optimize the timing of approval applications, thereby ensuring our competitive advantage.

To prevent the risk of patent infringement, we conduct thorough patent research from early development stages to avoid unnecessary investments and losses in later stages. We also identify the potential for patent circumvention or invalidation, and skillfully circumvent the patent networks of original drug manufacturers through a variety of approaches. These include devising new crystalline forms and formulation technologies, and employing different manufacturing methods. We have extensive experience and expertise in patent circumvention and filing for patent invalidation, and select the best strategy for the situation, taking into account the risk of other companies following suit.

Furthermore, we are mindful of the risk of litigation from patent holders, and practice adaptive and strategic IP management that balances the first mover advantage by launching first with the benefits of stable business growth.

Our IP management system rigorously ensures continuous monitoring and updating of information. We regularly check pending patents and competitors' application trends to keep our patent information database up-to-date, enabling us to respond swiftly and with precision. In addition, we solicit legal advice and conduct risk assessments in collaboration with IP-specialized attorneys, and decision-making processes are standardized and paperless to ensure consistent research, evaluation, and knowledge accumulation.

The Group's proprietary formulation and development technologies are also actively protected and branded through patents, designs, and trademarks. Proprietary technologies such as SAWAI HARMOTECH® and QualityHug® are not only protected as intellectual property, but are also used as brand strategies to differentiate products and attract excellent human resources.

Proprietary technology branding: QualityHug®

The QualityHug® brand of technologies by Sawai Pharmaceutical is based on the philosophy of being close to the safety and security of patients, and aims to bring greater peace of mind to their lives by using science and technology to address their concerns and anxieties when taking medication. QualityHug® is not just a collection of formulation technologies, but a proprietary technology brand where we sincerely listen to feedback from patients and medical practitioners, meeting society's needs for safety, security, and trust.

Of our many technologies, we carefully selected a group of highly novel technologies included in this brand that would create an awareness of safety and reassure patients; as a result, QualityHug® is a brand that helps provide great peace of mind with respect to patients' own medications and lifestyles. For example, the distribution of counterfeit pharmaceuticals has become a worldwide concern. To address this, our Kazaria® technology improves both anti-counterfeiting and identification by transferring a unique pattern onto drug tablet surfaces, and in this specific case offers a new identification method different from conventional printing or marking. This is making a significant contribution to creating an environment where patients can take their medication with confidence. Our contributions are expected to help prevent errors in handling and taking medicine both for medical practitioners and during medication administration.

In addition, as social demands for pharmaceutical quality and safety increase, addressing the risk of contamination with nitrosamines (carcinogens), is another important pillar of QualityHug®. Sawai Pharmaceutical is pioneering the industry in this area, including cultivating technology to predict the risk of nitrosamine impurities and developing additives that inhibit their formation. These technological developments contribute to the development and stable supply of safe and reliable generic drugs.

QualityHug® is a design project that not only solves technological issues in the pharmaceutical industry, but also actively addresses social issues between healthcare and patients. Another key feature is that we continue to contribute to the improvement of quality in the industry as a whole, with a view to sharing our technology with other companies as well. In recognition of these efforts, QualityHug® received the Good Design Award in 2024. The project received high praise from judges as an initiative to generalize pharmaceutical technology and deliver peace of mind to patients, a technological innovation in the pharmaceutical manufacturing process, and a forward-looking design project to solve social issues.

Sawai Pharmaceutical will continue to innovate in formulation design and manufacturing technologies, and develop new evaluation and analysis methods to ensure a stable supply of high-quality generic drugs, together with its proprietary technology brands such as QualityHug® and SAWAI HARMOTECH®.

Our mission is to continue to improve our technology and quality in order to earn the trust of patients, the medical community, and society as a whole.

Number of products launched in the past three years and number of sole market or strongly competitive launches

FY	Numbers of items launched	Of which, sole market or strongly competitive launches		Sawai Pharmaceutical's advantages		
		Items	Main items	Patent strategy	Formulation design strategy*1	Quality assessment strategy*2
2022	23	4	IGURATIMOD Tablets [SAWAI]		○	
			ARIPIPRAZOLE Tablets [SAWAI]	○	○	
			ARIPIPRAZOLE Oral Solution Packet [SAWAI]	○	○	
			DAPTOMYCIN for Intravenous Injection [SAWAI]		○	
2023	10	2	ZINC ACETATE Tablets [SAWAI]	○	○	
2024	13	5	ZINC ACETATE Granules [SAWAI]	○	○	
			RIVAROXABAN Tablets [SAWAI]		○	
			SAXAGLIPTIN Tablets [SAWAI]		○	○
			HYDROXYCHLOROQUINE SULFATE Tablets [SAWAI]		○	○

*1 Including circumvention of formulation patents or creation of inventive/novel formulation technologies
*2 Establishment of quality standards based on ICH criteria and scientific evidence