

File patents, expand your business in Japan

Successful cases by obtaining patents in Japan

March 2024

INVEST JAPAN WG



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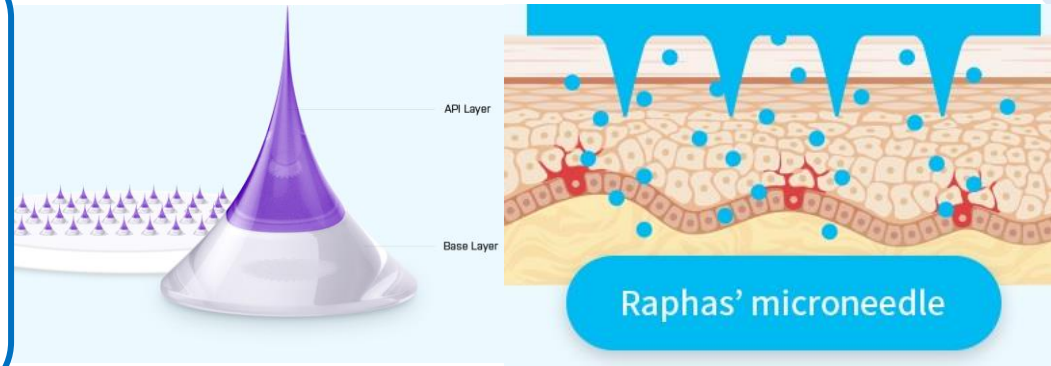
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RAPHAS JAPAN

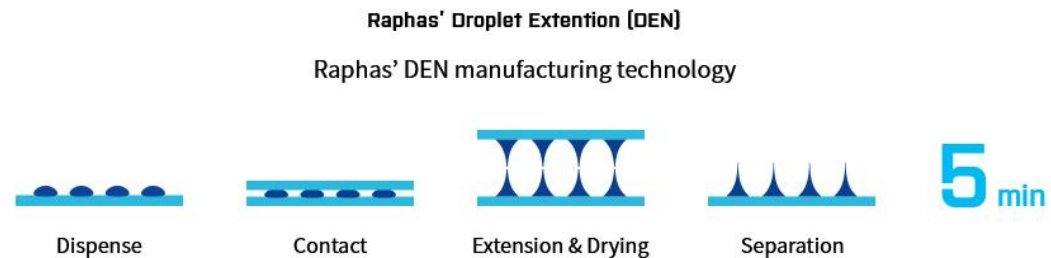
History

- March 2006: Founded in Korea
- Nov. 2012: Started export to Japan
- Oct. 2013: US Patent registered
- April 2014: Subsidiary founded in Japan
- Aug. 2015: Subsidiaries founded in China and US
- 2019: Factory founded in Shizuoka, Japan
- 2022: Research site founded in Shizuoka



Summary of Business

- RAPHAS produces and sells microneedle patch cosmetic products. Using “**soluble microneedle**”, a type of drug delivery systems (DDS), its products provide good permeability and stability of active ingredients.
- Conventional “molding” method, in which active ingredients are poured into a mold and dried to form solid, had problems in stability of ingredients, permeability of needles and mass productivity.
- Its “**DEN (Droplet Extension)**” **process** enables **short process time**.
- It conducts **joint research on drugs** with companies and universities using soluble microneedles, aiming to market pharmaceutical products in Japan.



Four Japanese patents including JP5863824B granted.

RAPHAS JAPAN

Expansion of Business to Japan

- Paphas aims for manufacturing and sales of **pharmaceutical products**, for which it needed **mass production system for safe and high-quality soluble microneedle**. It decided to establish the system for cosmetic products at first, and **Japan with stable cosmetic market** was selected as a sales area.
- Expansion to Japan is also good **chance to make partnership with Japanese pharmaceutical companies**, who own candidates of active ingredients for soluble microneedle.

R&D and Manufacturing Site in Japan

- Raphas established manufacturing site in **Shizuoka** in 2019, and **started R&D** in 2022, where it succeeded in **automated manufacturing** of soluble microneedle patch.
- Most important reason to select Shizuoka was **generous support**. City of Shizuoka conducted careful interviews and introduced a facility matched with Raphas' needs.
- Raphas conducts joint research with **local universities and pharmaceutical companies in Japan**, aiming to market pharmaceutical products of soluble microneedle, such as vaccine. The results of these joint research will be **applied for patents in Japan**.

IP Strategy

- Although Raphas has received warnings of patent infringement, it has objected based on **the originality of its technology**. **There has been no problem to continue its business**.
- Patents in Japan are very helpful because it can demonstrate to its Japanese partner companies that its technology cannot be copied by other companies.
- Korean stock market has "**technology special listing**" system where a company is listed as having excellent technology. Obtaining patents in foreign countries including Japan **worked as an advantage in listing examination for the stock market**.

History

- 1951 Founded in Castres, Southern France by pharmacist Pierre Fabre
- 1961 Established Pierre Fabre SA
- 1985 Established Pierre Fabre Japon Co., Ltd. as a joint venture with Shiseido Company, Limited
- 2014 Opened "Asia Innovation Center PFDC" in Japan

Summary of Business

- Pierre Fabre is a leading French manufacturer of **pharmaceutical products and dermatological cosmetics**.

Activity in Japanese Market

- In 1985, Pierre Fabre and the Japanese group Shiseido funded a joint venture. Thanks to this joint venture, "Eau Thermale Avène", a brand of Pierre Fabre, has become rapidly one of the first dermo cosmetic brand in the Japanese market. Since that time, **the Japanese market for Pierre Fabre Group has been a market of prime interest for more than about 40 years**.
- "Asian Innovation Center", which is a research and development center dedicated to Dermo Cosmetic, was opened in Tokyo, Japan in 2014. The consumer expectation and the trends in beauty and cosmetics product are very different from Europe and Asia, in particular Japan. Also, the regulation is very different between Europe and Japan, so some ingredients are authorized in Europe and not in Japan, and vice versa. Therefore, **it was necessary to have innovation, research and development tailored to the need of the Japanese or Asian market**.

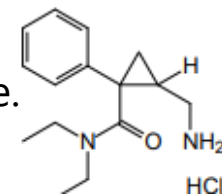


IP Strategy

- **Japan is the one of the key markets for pharmaceutical products and cosmetic products. Also, Japan is a high tech and innovation-oriented country.** Therefore, it's more than necessary to get patent protection in Japan. With respect to the Cosmetic business, which is usually a kind of turnover innovation markets lasting for few years, it is needed to innovate quite rapidly and to make or keep a competitive advantage so the patent in Japan play an important role. With respect to pharmaceutical business, it cannot be considered to market a new drug without patent protection in Japan.
- Japan is always in the filing list whatever it is for medical/pharmaceutical or for cosmetics, and **Pierre Fabre almost systematically files patent application in Japan.**
- It is recognized worldwide that the quality of the prosecution and the patent granted by the Japan Patent Office is undisputed so it's clear that **obtaining patent granted in Japan is a good strength and a good sign of solidity of the inventiveness, the validity of the patent and the possibility to go with PPH (Patent Prosecution Highway) in other jurisdictions.** Pierre Fabre sometime uses Japanese granted patent to support the PPH elsewhere and sometime uses the granted European patent in the PPH at the Japanese Patent Office, and it usually works well.

Success Stories

- A successful case having patent in Japan is **"Milnacipran", anti-depressive drug.** It's a molecule patented in the 90s and has been very quickly marketed in Japan and Europe. **This is definitely thanks to the patent protection of the molecule and it would have never been such a success without patent.**
- Pierre Fabre **never had any infringement issue in Japan.**



History

- 1927: Pharmacy founded by Caspar Friedrich Hausmann in St. Gallen, Switzerland pioneering iron products
- 1944: Vifor Ltd. founded by pharmacist René Grosclaude, marketing hospital supply products.
- 1952: Ferrum intravenous iron product developed by Laboratorien Hausmann AG is introduced in Switzerland for hospital use
- 1983: Acquisition by Vifor/Galenica of Laboratorien Hausmann AG hospital supply
- 2022: CSL Vifor was founded through the acquisition by CSL

Summary of Business

- CSL Vifor is **a pharmaceutical company based on Switzerland**. It develops, produces and sells pharmaceutical products for **iron deficiency, kidney disease and cardiorenal disease**. In 2022, it was acquired by CSL, an Australian biotech company, and became CSL Vifor.

Activity in Japanese Market

- For a relatively small company like Vifor has been in the past, it may economically not make sense or be too complex to found a local affiliate in Japan.
- **It is critical to find a reliable Japanese partner** with ability of local development and with an experienced medical and commercial organization. CSL Vifor has licensed out its products to **Zeria Pharmaceutical** (Ferinject®) and **Kissei Pharmaceutical** (P-TOL® and Tavneos®).

IP Strategy

- It has obtained Japanese patents; JP7065115B, JP6710754B, JP6431540, JP6172691B et cetra
- In the field of pharmaceutical, **Japan is one of the important TOP3 markets** as well as Europe and US because it has **matured market and well-established healthcare system**. CSL Vifor always selects to file patent applications in Europe, US and Japan for future investment. The Tier 2 list of countries includes Australia, Brazil, Canada, China and Korea.
- When CSL Vifor enters Japanese market, it often needs to change formulation and dosage for Japanese population and needs further investments. In view of the diverse investments (clinical, formulations, medical awareness (for health care professionals or patients), **it is necessary to have exclusivity for certain amount of time to have a return on the investment**. This exclusivity period is also **important to convince local partners to in-license** CSL Vifor's pipeline candidates to initiate local development.
- So far, CSL Vifor protected its products with patents but has had no litigation. While at the same time, in case of patent invalidation action by generic companies, it reviews its Japanese patent portfolio to check if it has potential weakness.
- According to CSL Vifor, Japan has matured patent system. Because **the rules of inventive step and patent term extension are clear**, it is easy to understand the pathway to obtain patents. **The result of patent examination is predictable because variation between examiners' decisions is small, and quality of the examination is high.**

History

- 1988 : Sabinsa Corporation, New Jersey USA was founded
- 1991 : Sami Chemicals and Extracts Pvt Ltd was founded in India
- 1996 : First US patent was granted for the product BioPerine®
- 2000 : Sabinsa Japan Corporation was started
- 2001 : Name of the company Sami Chemicals and Extracts Pvt Ltd was changed to Sami Labs Limited
- 2006 : Sabinsa Europe GmbH was set up in Germany
- 2020 : Name of the company Sami Labs Limited changed to Sami-Sabinsa Group Limited



Fruits of amla :
One of the 3 subject
fruits of Ayurveda

Summary of Business

- Sabinsa Corporation is a multinational health science company and a leading producer of nutraceuticals, cosmeceuticals, **standardized herbal extracts from Indian traditional herbal plants.**
- Most of their products are **based on Ayurveda, traditional medicine originated in India more than 3000 years ago.** There is little concern about allergies or other side effects due to its long history of use.
- Sabinsa Corporation differentiates itself by **using raw material plants from its own plantation in India or closely monitoring the cultivation of medicinal herbs** so that the production history can be traced.

Expansion of Business to Japan

- **Japan** is well placed as **the top three economies in the world**.
- Japanese people have less prejudice against traditional medicine because Chinese herbal medicine has already been popular in Japan .
- Nearly 30% of the population in Japan is over 60 years old. So, there is potential demand for Sabinsa's core area of nutritional and cosmetic ingredients isolated from herbs and plants.
- **Sabinsa supplies its products to DHC, Fancl, Kagome and other Japanese companies.**

IP Strategy

- Sabinsa Corporation **decides their IP jurisdictions based on product fit to the current market demands and future potential.**
- For Sabinsa Corporation, **Japan is a promising market, second only to the U.S.,** and along with Europe.
- Sabinsa Corporation has about **400 patents worldwide** and **10%** of them are **Japanese patents.**
- **By obtaining a patent in Japan, Sabinsa can protect its business as well as the interests of its customers boosting their confidence.**

History

- 1660-1850 : The Heraeus family, a pharmacy in Hanau, Germany, worked on the precious metals
- 1851-1888 : The first German platinum smelter was founded
- 1889-1927 : Expanded into the American market
- 1927-1945 : Metal alloys production began / Developed into a multi-product group
- 1946-1969 : Expanded into international markets
- 1970- : Entered a wide range of businesses including electronics, environmental, health and Industrial applications sectors

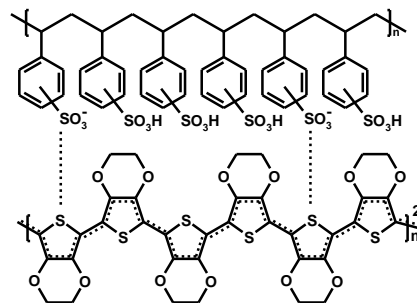
Summary of Business

- Heraeus is one of the largest family-owned technology company in Germany. The headquarter of Heraeus is located in Hanau. **It regards Asia as a key market for its business.**
- It consists of **12 global business units**, and each unit operates independently.
- It is focusing the business on four different areas.
 - Electronics: joining and coating products, producing and processing high purity quartz glass for the semiconductor business
 - Environmental: the production of power by a solar cells, precious metals recycling, purification of air and water etc.
 - Health: biomaterials for orthopedic, medical components for cardiology and surgery
 - Industrial: the production of measurement technology, sensor technology and electronic chemicals

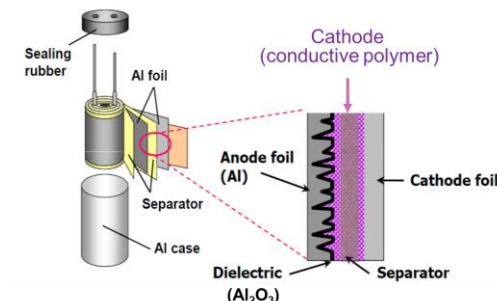
Activity in Japanese Market

- For 30 years, Heraeus has been **continuing the business of conductive polymers for the market of electrolyte capacitor in Japan, having partnerships with several Japanese companies.**
- It has a subsidiary company in Tokyo which have sales teams and technical support teams.

Conductive Polymer dispersion based on PEDOT:PSS



Application: : Electrolyte Capacitor



IP Strategy

- Regarding selection of file and/or obtain patents, Heraeus makes much account of production sites of customers and competitors: Europe, China, Japan, Korea, Taiwan and US.
- Japan is the primary country of patent applications for inventions related to conductive polymers.** Heraeus is improving continuously and applying for patents in order to stabilize its business in the future. It has about 60 active patent families related to conductive polymers, all of which have been filed in Japan. It recognizes that **a strong patent portfolio in Japan is important to successfully entering the Japanese market.**
- Heraeus feels that Japanese companies respect third party's IP, and they take the issue of IP infringements very seriously. Therefore, **its patent portfolio in Japan supports its business and the business of its customers.**
- Heraeus has the impression that Japan has a well-established legal system and patent examination is very clear.

FREE Bionics Japan

History

- 2012: The predecessor R&D project at ITRI of the Taiwan Ministry of Economic Affairs started.
- 2015: Business tie-up with Saga University Hospital in Japan started.
- 2016: FREE Bionics Inc. founded in Taiwan.
- 2017: FREE Bionics Japan founded in Japan.
- 2018: Invited as a speaker to the Japanese Association of Rehabilitation Medicine.



Summary of Business

- Based on the concept of "wanting people with lower body disabilities to stand up again", FREE Bionics conducts research and development, sales, and rental of **the walking support robot "FREE Walk"**.
- FREE Bionics has high technical capabilities in terms of hardware, software, and services for its "FREE Walk".
- Since "FREE Walk" is equipped **with the center-of-gravity movement sensor**, it is possible to support walking even for patients with complete paralysis in the lower half of the body.



Four Japanese patents including JP6729869B2 granted.

| FREE Bionics Japan

Expansion of Business to Japan

- FREE Bionics has chosen Japan as its first overseas destination. This is because **Japan is advanced in the field of rehabilitation robots**, and Japan is highly attractive as a business market.
- FREE Bionics has **won the Global Innovation Challenge 2021** (in Japan) life support robot contest, which is aimed at organizations developing robots that support the "independent walking" of people with paralysis in the lower body.
- FREE Walk is registered with NASVA (National Agency for Automotive Safety and Victims' Aid) so that victims of traffic accidents can use FREE Walk as an aid in hospitals.

Acquisition of Business Partners in Japan

- FREE Bionics has a business alliance with USCI Japan Ltd. and has successfully raised funds from the company, and is receiving support for business development.
- In addition to Saga University Hospital, FREE Bionics has formed business alliances with multiple hospitals and are continuing to expand its business.

IP Strategy

- Obtaining patents in Japan not only protects company's rights, but is also very useful for business success (For example, **the existence of patents reassured partners** when introducing FREE Walk to hospitals and having a business alliance with USCI Japan.).
- Acquiring patent rights while expanding business in Japan is extremely important in its business strategy.
- Acquisition of patents in Japan enhanced **the persuasiveness of the high level of technology**.

History

- 2013: Founded in Korea
- March 2019: Japanese Patent granted
- Aug. 2019: Japanese subsidiary founded
- 2021: Started 3D interior simulation service, floorplan 3D conversion service, and Urbanbase AR app.

Summary of Business

- Urbanbase owns its original technology **to automatically convert 2D floorplan images to 3D models in real time basis**. It owns **patents in Korea, Japan, US, Europe and China**.
- Basis on the technology, it provides **interior simulation service using the 3D conversion technology, AR and VR** in Japan.
- It has business connections with Japanese companies such as Softbank, Dentsu, Toppan Cosmo, Nitori and Mitsubishi Estate.



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A.I. Architect

Just 2 sec



Indoor VR

Expansion of Business to Japan

- When Urbanbase visited Japan for market research, it learned that Japanese real estate industry had **a culture to provide customized room layouts** by placing stickers. It proposed **to apply its simulation technology** and started business in Japan.
- Japan is advanced in some points such as a culture to provide customized room layouts. It aims **to learn from Japan and provide its excellent technology**.

Business Activities in Japan

- Urbanbase founded a subsidiary in Japan in Aug. 2019. Since then, it has extended its business, including sales of 3D interior simulation service “Urbanbase Studio” in 2021.

IP Strategy

- It has registered Japanese patent No. 6490220. In addition, it has filed about 10 international patent (PCT) applications. Because it owned a patent in Japan, it could do business with Japanese big companies.
- **As a technology-based startup company**, Urbanbase feels **it is important that intellectual property should be respected and protected**. It is currently conducting patent litigation in Korea because its core technology has been imitated.
- **Japan has the strongest culture to respect intellectual property rights in East Asia**. It is taken for granted that they should pay for valuable rights.
- **Obtaining patent in Japan worked as an advantage when it received investment** because investors viewed Japanese patents as important. It will be the same when it is listed on the Korean stock market.
- Because **Japanese patent examiner understood technology and explained thoroughly**, it was easy to respond when it obtained a patent in Japan.

Micron Technology

History

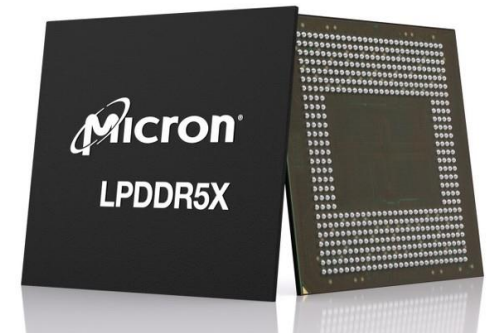
- 1978: Micron Technology is founded in Boise, Idaho, USA
- 1981: Entering the DRAM business
- 2013: Micron Memory Japan is founded in Hiroshima, Japan (Micron Technology acquired Elpida Memory in Japan)
- 2023: Announcing up to 500 billion yen to introduce EUV technology to its Hiroshima site which enables the production of 1-gamma process node.

Summary of Business

- Micron delivers a rich portfolio of high-performance DRAM, NAND and NOR memory and storage products through Micron® and Crucial® brands.

Expansion of Business to Japan①

- Micron has made significant, enduring investments in Japan to facilitate semiconductor development for the last decade **following the merger of Elpida Memory, Inc.**, accelerating industry-leading technology advancements particularly in the domain of DRAM production.
- Micron has placed emphasis on enhancing its technology development and smart manufacturing capabilities in Japan and forging **strategic partnerships with local suppliers to establish a robust and streamlined supply chain** to meet the specific needs of its customers.



In 2022, Micron obtained 82 patents in Japan.

| Micron Technology

Expansion of Business to Japan②

- Micron is actively partnering with academic institutions at all levels to fund research and advance STEM education to develop next-generation talent. In Hiroshima specifically, **Micron has various programs collaborating with Hiroshima University in fostering semiconductor talent.**
- In expanding its business in Japan, Micron is able to obtain the **Japanese government's support** to enable the leading-edge DRAM technology R&D and manufacturing in Japan, from 1z, 1β to 1γ and also R&D in HBM, which is critical to sustaining its our global DRAM leadership and strengthening Japan's semiconductor ecosystem at the same time.

Merits of acquiring patents in Japan

- Having a lot of patents in Japan supports our business including mass production of DRAM in Japan.
- **A big patent portfolio including Japanese patents can advertise that Micron is focusing on R&D for cutting edge technologies.**

IP strategy

- As to joint R&D projects with other company(s), ex-Elpida had jointly owned some patents with the company(s). On the other hand, **Micron typically pursues solely-owned patents to make a process to exercise patents easier.** In that case, which patents (patent applications) are solely owned by which company(s) is determined based on a contract.

History

- 2015: EXOTEC was founded in Lille, France.
- 2017: The first Skypod® system was operational.
- 2019: The first APAC office was opened in Tokyo, Japan.
- 2020: Expanded into North America and Central Europe.
- **2022**: Became **the first industrial unicorn in France**.
- 2023: Expanded into Korea, second APAC country.

Summary of Business

- EXOTEC supplies **Robotics Warehouse Automation "Skypod"** and relating thereof to **more than 100 customer sites in Europe, Asia and North America**.

Expansion of Business to Japan①

- EXOTEC met **FAST RETAILING (UNIQLO®)** at a trade show in Europe and then started business with them in Japan.
- The first Asian office was opened in Tokyo, Japan in 2019.
- EXOTEC cooperates with **IHI** and **OKURA YUSOKI** as **integrator partners** and provides a holistic warehouse automation from consultation, installation to full maintenance service of Skypod system

EXOTEC



Expansion of Business to Japan②

- Tokyo Demo Center was opened in Shin-Kiba, Tokyo in 2023.
- Skypod® systems have been **installed in warehouses of various companies** such as **FAST RETAILING, YODOBASHI CAMERA, ACCA INTERNATIONAL, ALPS LOGISTICS and MITSUI-FUDOSAN.**

Merits of acquiring patents in Japan

Japan is one of the countries having a huge market of robotics warehouse automation, where EXOTEC holds **several patents* relating for Skypod® systems**, directed to robots, picking stations and also rack installations. Filing patent applications in this technology-advanced country demonstrates Exotec's commitment to protect its solutions and to reward its R&D efforts: this provides ultimately its customers with **confidence and reliability.**

(*Oct. 2023)

IP strategy

Japan has a well-established legal framework for intellectual property protection. Patent protection in Japan can be leveraged as a **powerful marketing tool**. This is a super differentiating tool, signaling to customers that our **offerings are unique, innovative, and legally protected**. In a market where customers value innovation and quality, this advantage can lead to **increased sales and brand recognition.**

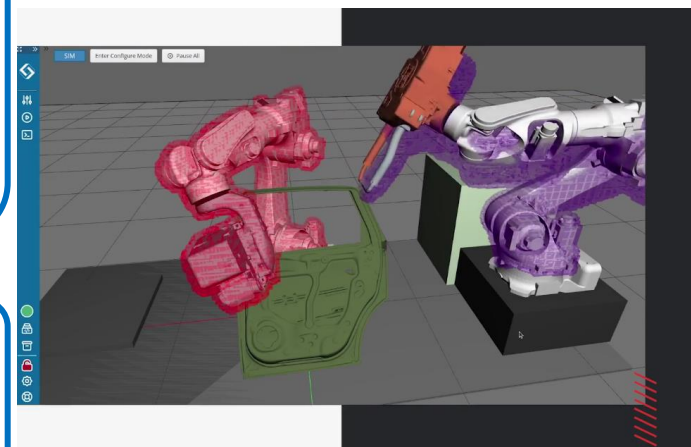
Realtime Robotics

History

- 2016: Realtime Robotics (**RTR**), university-launched, was founded and presented at RSS conference which put technologies on the map with robotic technologists.
- 2019: **RTR** began selling the first commercial **RapidPlan**.
- 2019-2022: **RTR** expanded into Europe, Japan and China.



realtime
ROBOTICS



Summary of Business

- **RTR** supplies software and systems of robot motion planning, such as **RapidPlan**, especially for automated collision-free navigation for multiple industrial robots.

Expansion of Business to Japan①

- Even from the beginning, FANUC and some Japanese companies took interest in **RTR**.
- 2018-2019: Mitsubishi Electric, Toyota AI Ventures and OMRON VENTURES invested in **RTR**.
- 2021: **RTR** founded a Japanese subsidiary and opened Tokyo office.
- 2023: **RTR** was selected for the JETRO Investment Program.

Realtime Robotics

Expansion of Business to Japan②

- **RTR's** products have been provided to varietal companies, **(1) robot makers** such as FANUC, Mitsubishi Electric and YASKAWA ELECTRIC, **(2) end users of robots** such as Honda, Toyota and DENSO, and **(3) robot Sler** such as YUTAKA ELECTRONICS INDUSTRY.

Merits of acquiring patents in Japan

It is important to obtain patents in countries **where robotic technologies are highly developed and competitive. Japan is one of such countries.** At the moment*, **RTR** holds several patents in Japan. It proves **the technological superiority** of **RTR** and provides **customers with reliability.**

(*January, 2024)

IP strategy

Technological development works are mainly done in Boston, USA and Berlin, Germany while more than 40 members are also committed to the works in Japan, all over USA, and Brazil. At the moment*, most of patent applications filed in US, EU, JP and CN, some also in TW, considering the cost/benefit trade-off since JP, US, CN and EU are the main markets for robotics, as well as where most robot technology is being developed.

History

- 2006 : Ciel et Terre was founded in France.
- 2011 : "Hydrelia®" to make floating solar island was launched and later patented.
- 2013 : Started export business.
Ciel et Terre International and Ciel Terre Japan was started.
The world's first floating solar power plant of over 1 MWp was developed in Saitama, Japan.
- 2016-2024 : Expanded into US, Taiwan, India, Thailand, Korea, Brazil etc.



Summary of Business

- Ciel et Terre is a company that develops, sells, plans and manages floating solar power generation installations.
- In particular, they are **specialized in floating solar power plant development** by providing their own patented floating system called "Hydrelia®" which allow the creation of floating solar islands
- They **meet the global need to produce clean energy in a more efficient and land-saving way.**



Expansion of Business to Japan

- When Ciel et Terre launched their first product "Hydrelia®" on the market in 2011, they received many inquiries from many companies in the world. Also, they managed some prototypes and pilot tests to provide insights and return on experience regarding floating solar reliability and benefits. **Japan was identified as a promising market considering Japanese geography** with 70% of mountains and so, little few space available on lands, but a lot of irrigation reservoirs to install floating solar plants.
- They **collaborated with local governments** that manage ponds and rivers that are candidate sites for floating power generation, and **with companies such as ITOCHU, Tokyo Century and Kyocera that were interested in their technology.**
- Currently, there are many 2MW projects in the Japanese market, but they are planning to expand the scale and expand nearshore in the future.

IP Strategy & Merits of acquiring patents in Japan

- Ciel et Terre has applied for patents in Japan, Europe, US, South Korea, China, and other countries, mainly in the countries where it actually does business.
- **Obtaining patents in Japan were certainly a strong advantage to convince investors, developers and EPCs* to work alongside Ciel & Terre for floating solar projects and also, Kyocera to co-develop the floating solar market.** *EPC is an abbreviation of E=Engineering, P=Procurement, and C=Construction., and EPC companies do all three at once.
- Japanese customers are focused on getting the best products with high quality. Although poor quality and defective copies are proposed in the market by competitors. **But at Ciel & Terre, their team is focused on providing high quality products and services and suggesting the best to our customers. Patents are one of the proofs of high quality and product reliability.**

Ultragenyx Pharmaceutical Inc.

History

- 2010: Ultragenyx Pharmaceutical Inc. is founded in Novato, Calif., USA
- 2010: In-licensed therapeutic program for a rare genetic disease (mucopolysaccharidosis type VII) from St. Louis University
- 2013: Entered into **Collaboration and License Agreement with Kyowa Hakko Kirin** to develop and commercialize anti-FGF23 antibody for treatment of rare bone disorders
- 2020: Entered into **License and Technology Access Agreement with Daiichi Sankyo** for gene therapy manufacturing technology
- 2022: Japanese corporation **Ultragenyx Japan was established** and started selling Mepsevii®, an enzyme replacement treatment for mucopolysaccharidosis type VII



Summary of Business

- Ultragenyx is a research-based biopharmaceutical company (Product Category: Traditional biologics, Small Molecules, Gene therapy, Nucleic acid therapies) **focused on the area of rare diseases** and also has **strength in the manufacture of gene therapies**.

Expansion of Business to Japan①

- Ultragenyx worked with Kyowa Hakko Kirin to develop successful clinical trials of burosumab (Crysvita®), an anti-FGF23 antibody drug created by Kyowa Hakko Kirin to treat various rare bone disorders. The agreement was structured to give Kyowa Hakko Kirin commercialization rights in Europe and Asia, and Ultragenyx commercialization rights in the United States and Latin America. **This partnership has greatly benefitted both companies and rare disease patients.**

Ultragenyx Pharmaceutical Inc.

Expansion of Business to Japan②

- In 2020, Daiichi Sankyo entered into a License and Technology Access Agreement to obtain non-exclusive rights to Ultragenyx's gene therapy manufacturing technology for the production of AAV gene therapy vectors. Daiichi Sankyo paid US \$150 million to Ultragenyx and invested an additional US \$75 million for access to the gene therapy manufacturing technology.
- Ultragenyx is currently consulting with PMDA regarding several clinical stage product candidates, including gene therapies, antibodies, and nucleic acid therapeutics.

Merits of acquiring patents in Japan

- JPO's examinations are timely and provide patent applicants with a consistent and predictable process. The examiners have strong technical knowledge, the reasons for refusal are reasonable and easy to understand. Japan's court system is very well-developed and allows companies to enforce and defend their intellectual property.
- Japan has an environment where intellectual property is respected, allowing companies to protect their innovations and technologies in the Japanese market and conduct appropriate business activities.

IP strategy

- Ultragenyx has filed multiple patent applications in Japan to protect its platform manufacturing technology. This gives partners the confidence to make prudent investments and obtain not only the technology, but also access to the patents that protect it.
- In Japan, Ultragenyx will regularly file patent applications to protect its therapeutic products and key platform advancements. Meanwhile, for incremental improvements in its manufacturing and purification methods, and for those technologies that are easy to design around and/or difficult to enforce, Ultragenyx may keep these improvements as trade secrets.