



EPO SME CASE STUDIES | MARINOMED

Using red algae to fight the flu

Founded in 2006, Marinomed is an Austrian biopharmaceutical spin-off from the Veterinary University of Vienna. The company's main technology platform is based on the natural polymer Carragelose, which is isolated from red algae and is active against respiratory viruses. As a drug discovery company, Marinomed is heavily dependent on patent protection. It has three main patents, which have been validated in almost 100 countries, and a trade mark registered in around 50 countries. The company actively manages its patent portfolio and grants licences for its technology. Marinomed has experienced infringement of its patents, but was able to resolve the cases without going to court.



Marinomed develops therapies against respiratory diseases based on an anti-viral respiratory technology platform.

Marinomed was founded in 2006 by four scientists, three of whom still work for the company. It was spun off from the Veterinary University of Vienna, where it is located to this day. With a staff of 25, the company develops biopharmaceutical products based on natural marine compounds.

Focusing on the therapy of respiratory disease, Marinomed markets anti-viral and immunological treatments. To do this it uses its innovative MAVIREX technology platform, which is based on the special antiviral properties of a natural polymer called Carragelose, derived from red algae. Despite being a rather young company, Marinomed has already been able to establish worldwide use of Carragelose in a variety of over-the-counter (OTC) medicines against respiratory illnesses such as colds and flu. Typical products include nasal sprays and lozenges.

The OTC market for such remedies is worth about 30 billion US dollars globally and two billion US dollars in Germany alone, with significant growth in emerging markets. The industry is highly fragmented, with intense competition between large multinational companies and a number of smaller players, some of whom have high market shares in certain limited geographical areas.

A promising technology pipeline

Marinomed applies its MAVIREX technology to the development of additional influenza treatments and combination therapies for asthmatics and other high-risk patients.

Marinomed also develops novel treatments against type I allergies and eye diseases based on the MARINOSOLV technology platform. MARINOSOLV, which enables stable aqueous solutions of substances that are normally hardly soluble, is intended for use against diseases affecting mucosal tissues such as those found in the nose, throat, eyes and lungs. One of the products is already scheduled for Phase III clinical trials. The company offers licences for the technology to interested companies working in other fields.

Patents in pharmaceutical research

The biopharmaceuticals area is subject to the same business rules as the general drug development business. This entails a major R&D investment to find new active compounds, and subsequently a long and expensive approval phase.

Current products and product pipeline using the MAVIREX and MARINOSOLV compound platforms

Compound platform	Products	Indication	Discovery	Development (MD*)			Commercial	Regulatory status
MAVIREX Carragelose®	Three nasal sprays, lozenges, throat spray	Common cold & influenza-like illness	■		■		■	OTC, MD*
Compound platform	Products	Indication	Discovery & Lead optimisation	Preclinical & Phase I	Phase II	Phase III	Commercial	Regulatory status
MAVIREX Carragelose®	Decongestant antiviral nasal spray	Common cold & influenza-like illness	■	■	■	■		OTC, MD*
	Antiviral NA inhibitor combination	Seasonal influenza	■	■				Prescription
	Steroid/ Carragelose® combination	Allergic rhinitis – cold prophylaxis	■	■				OTC
MARINOSOLV	Dissolved Budesonide nasal spray	Allergic rhinitis	■	■				OTC
	Dissolved Fluticasone nasal spray	Allergic rhinitis	■	■				OTC
	Dissolved Fluticasone eye drops	Conjunctivitis, blepharitis	■	■				OTC/ Prescription
	Dissolved acrolimus/ FK506 eye drops	Inflammatory eye diseases	■	■				Prescription

* Medical device (different development route)



Nasal spray containing Carrageose, a natural polymer.

Marinomed incurred heavy costs in the identification of Carrageose, and this was followed by a long and equally expensive phase to obtain the necessary regulatory approvals for the new product. A typical example, Marinomed's nasal spray, has been approved in almost 50 countries so far. Although the approval process for over-the-counter products is usually shorter and cheaper than for prescription drugs, it still takes around three to five years and costs several million euros. The time taken for a new medicine to come to market is therefore relatively long. Solid financing is essential to bridge the gap between the research and the revenues generated after market entry. Finally, most medical compounds can easily be copied once they are available, so strong IP protection is an absolute prerequisite for any business activity in this field, in order to recover the associated investment and approval costs. Patents help to effectively fend off possible copycats or generic producers during the patent lifetime. This is why Marinomed has patented its main inventions in just under 100 countries.

For a drug discovery company like Marinomed, patents are a prerequisite for attracting investors and getting funding agencies on board. Without solid IP there would not be any funding. The company recently received financial backing from public funding institutions, venture capitalists and bond investors to cover the global roll-out of its products, as well as the costs of R&D and patenting.

“Marinomed is an IP-driven company. It is vital that we own and manage the IP associated with our products.”



Andreas Grassauer
CEO, Marinomed

Dual IP exploitation approach

Based on its patent portfolio, Marinomed has developed two distinct business models, both of which focus on the creation and exploitation of IP. The first is a classical licence agreement, according to which the licensee receives the rights to produce, market and distribute the product in certain countries, resulting in upfront payments, milestones and running royalties for Marinomed.

The second is a distribution partnership, according to which the partner purchases the products from Marinomed for distribution in a defined geographical territory. The products are fully customised according to the needs of the partner, and include the partner's name and logo only. Marinomed does not manufacture the product itself, but outsources and supervises its production.

The choice of model depends on the business partner, the product licensed, the technology and the commercial environment. For Marinomed's partners, it is essential to have patent protection in each of their main markets. That is why Marinomed validates its core patents in an exceptionally high number of countries. Currently, the second licensing model is more successful, not only in terms of sales. Under the second model, Marinomed is closer to the individual local market and can provide its partners with various forms of support.

TAKEAWAY

LICENSING

Flexibility in licensing models increases the chances of creating win-win situations for all parties.

TECHNOLOGY PROFILE

Activity of polymers against HRV types 2 and 14

Polymer	HRV-2	HRV-14
Iota-carrageenan	+	+
Kappa-carrageenan	+	-
Lambda-carrageenan	+	-
Chitosan	-	-

Carragelose (iota-carrageenan) is a sulphated galactose polymer derived from red seaweed which has unique anti-viral properties. It works by coating viruses, preventing them from binding to and entering mucous membrane cells. Viral replication and associated symptoms are reduced, and the polymer forms a soothing and protective film of moisture on the mucous membranes.

Managing IP

Marinomed's CEO, Andreas Grassauer, knows a lot about IP. He is the (co-)inventor of numerous patents and has founded several companies, all of them based on IP. All Marinomed employees are expected to have a basic understanding of patents. In other words, they need to know what IP means and be able to read and understand patent specifications. To this end, all staff, including lab researchers, receive dedicated in-house training.

“It is very important for all our staff to have a basic understanding of IP. You cannot delegate this understanding to one single expert.”

Andreas Grassauer
CEO, Marinomed

Marinomed also involves an external IP specialist at a very early stage in its R&D. It knows it would be too late to wait until after an invention has been created. The goal of the company is not only to identify a new drug, but also to bring it successfully to market, which means it must be ring-fenced for specific market applications in the specific territories that are commercially relevant for the company. It seeks the IP expert's advice on how to design the first experiments so as to show not only the activity of a new compound, but also to obtain research data for equivalent compounds in order to anticipate work-arounds by competitors. This kind of data can support a strong and broad patent application, something that really pays off in the mid-term.

TAKEAWAY

EXTERNAL EXPERTISE

IP specialists can make a valuable contribution at the R&D planning stage. Their early involvement can help create the data required for strong patent protection for commercial applications later in the process.

Protecting IP

So far, Marinomed has never been accused of infringing third-party patents: before starting any new project, it makes sure to commission an FTO analysis from external specialists. On the other hand, it has been the victim of a number of infringements of its own IP. That's why the company and its licensing and distribution partners work together to implement an active monitoring process for detecting infringers. This is usually not too difficult, since medical products need regulatory approval before they can be sold.

Up until now, the company has been able to resolve all these cases by contacting the infringers through a local patent attorney and reaching a settlement under which the infringers agreed to take their products off the market, although Marinomed would have been prepared to go to court if necessary.

TAKEAWAY

INFRINGEMENT

FTO and infringement analyses are crucial for any technology company. Negotiations can often solve potential infringement problems. Litigation is a means of last resort.



The Carragelose polymer is derived from marine red algae.

Developing sound patent protection

When Marinomed was spun off from the university, the two parties came to a special arrangement. Since the initial funding was public money, the university was awarded a share in Marinomed in return for giving access to its research facilities. Marinomed, however, owns all the IP.

Marinomed has three core inventions, which are protected in a number of jurisdictions, providing a very broad geographical coverage. The first and main patent family relates to the use of Carragelose against rhinoviruses, which cause the common cold. It has been validated in the 99 countries in which Marinomed's licensing and distribution partners are active. The second patent family protects the use of the compound against other respiratory viruses, and the third relates to a different polymer and its use in combating viruses.

This extensive coverage represents a huge investment, so the patent portfolio must be carefully managed. It may be necessary, for example, to consider abandoning patent protection in countries where it might be no longer needed or abandoning a patent altogether. Marinomed's management team reviews the portfolio at least once a year in close co-operation with the business development department and adjusts it where necessary.

Any strategic decisions it takes are based on business criteria such as costs versus benefits, and must be approved by Marinomed's board of directors. Licensing and distribution partners are included in the decision-making process, as they might disagree with Marinomed and be in favour of retaining protection in a specific country. If this happens, a solution might be for the business partner to bear the cost of maintaining protection.

TAKEAWAY

ACTIVE PORTFOLIO MANAGEMENT

It is important to invest time not only in filing patents but also in evaluating the follow-up payments, balancing costs against benefits.

Marinomed also owns a trade mark for Carragelose. Partners with a classical licensing agreement have their own trade marks and hence do not need the Carragelose mark. However, under the second business model or distribution partnership arrangement, the licences for the patents are usually, although not always, combined with a trade mark licence as well. As a result, the trade mark has been registered in 50 of the 99 countries where the patent is valid. The trade mark gives partners the opportunity to capitalise on the international use of the brand. The decision on whether to file for trade mark protection is again based on a cost/benefit analysis, taking into account the needs of the partners.

TAKEAWAY

COMBINING PATENTS WITH TRADE MARKS

A trade mark can add value to your patent and extend protection and licensing revenues beyond the patent's lifetime.

The new Unitary Patent system

Marinomed has closely followed discussions on the Unitary Patent over the last few years. The Unitary Patent will bring a substantial reduction in validation costs, both in terms of renewal fees as well as in terms of indirect costs arising from the validation and maintenance of a European patent, such as translation fees and publication fees as well as fees charged by local attorneys. This is a big advantage.

Another important aspect of the new system is the Unified Patent Court, which offers Europe-wide enforcement. This is a real benefit, since one action at the Unified Patent Court will result in a single judgment covering almost all EU countries and will mean that the owner will not have to start cost-intensive and complex parallel proceedings in different jurisdictions individually, with the risk of contradicting outcomes. Of course, it will also be possible to challenge the validity of a patent with one action at the UPC, which may be perceived as a risk. But in the end this will also lead to a harmonised assessment of granted patents, instead of diverging decisions on patent validity by national courts, and will result in a more predictable business environment.

COMPANY PROFILE

MARINOMED BIOTECH AG

- > Headquarters: Vienna, Austria
- > Year of establishment: 2006
- > Staff: 25
- > Turnover: > EUR 5 million
- > www.marinomed.com

PRODUCTS/SERVICES

Anti-viral and immunological treatments

MARKET AND TECHNICAL AREA

Biopharmaceuticals, biotechnology, medical devices

CUSTOMERS

Hospital intensive care, home care

SELECTED AWARDS

- 2010 Step Award
- 2016 Houskapreis

PATENT PORTFOLIO

12 patent families, including EP2178533, EP2101792 and EP2046345

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