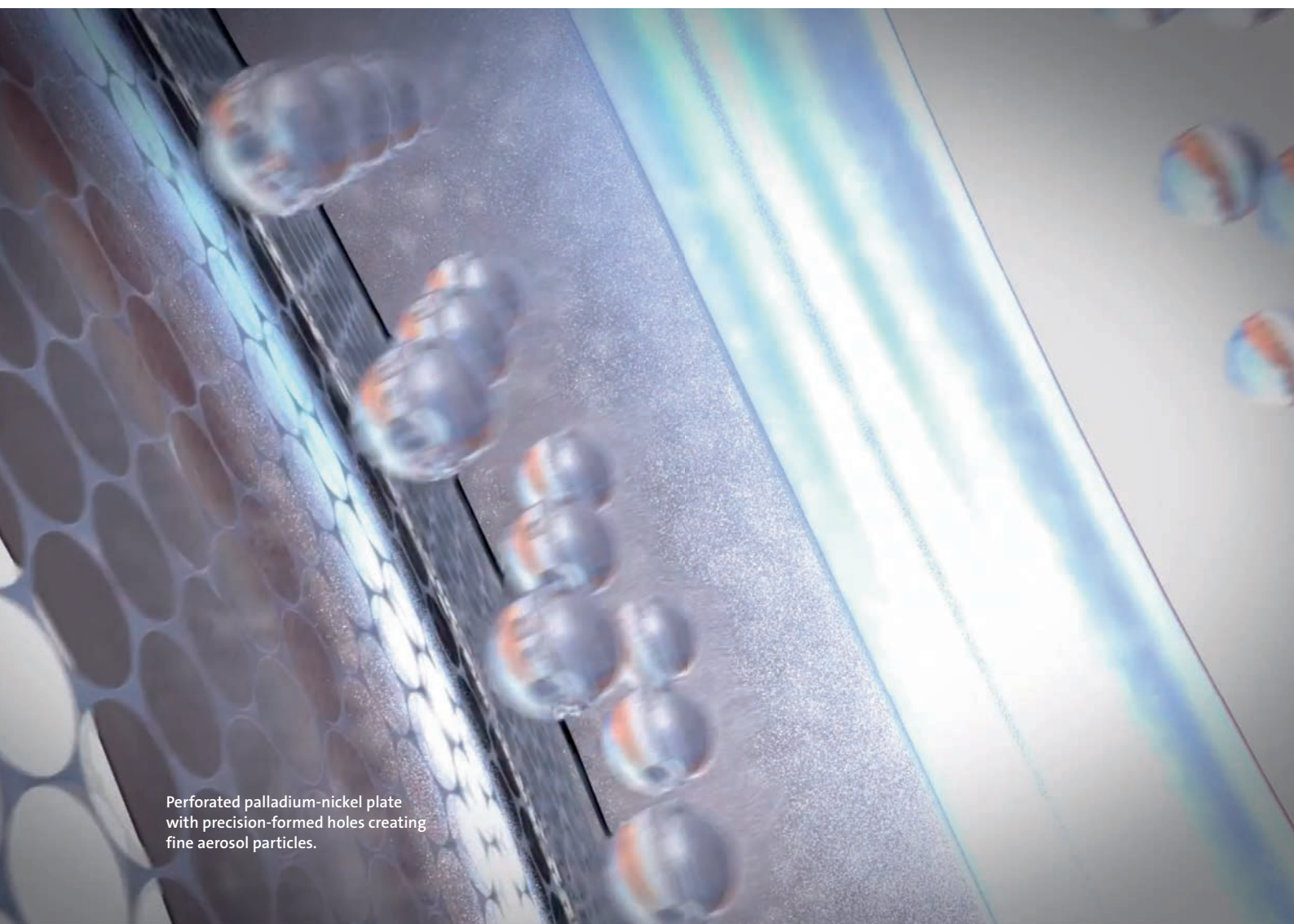




EPO SME CASE STUDIES | AEROGEN

# Breathing new life into aerosol drug delivery

Aerogen began as a small start-up in Ireland based on an aerosol technology and has established itself as a global leader in the hospital sector for high-performance aerosol drug delivery for ventilated patients. At the heart of the aerosol technology is a nebuliser that differentiates Aerogen's products from competitors and is central to an extensive patent portfolio, which has proved to be a valuable asset in creating strategic partnerships with global leaders in the critical care respiratory sector and accelerating the acceptance of Aerogen's technology in the market. The company has found it beneficial to conduct an annual meeting with its IP management team to review and refine its IP strategy. Collaborations with outside research groups also support Aerogen's R&D and IP activities.



Perforated palladium-nickel plate  
with precision-formed holes creating  
fine aerosol particles.

“Aerogen is the first company in the world to develop technologies for high-performance aerosol drug delivery in acute care,” says founder and CEO John Power. The company has established itself as the global market leader in acute care drug delivery for ventilated patients. Strategic partnerships with leading companies in the sector played an important role in the acceptance of Aerogen’s innovative nebuliser technology for application in aerosol drug delivery.

Aerogen established its credentials in the sector by integrating its technology into the global leaders’ products and demonstrating that it brought superior performance. This acknowledgement and acceptance of the technology gave rise to strategic licensing and distribution partnerships that brought Aerogen’s technology into hospitals.

The company was originally created in 1997 by John Power as a small start-up in Galway, Ireland. It grew steadily through a US merger, followed by an initial public offering on the NASDAQ, a subsequent acquisition by a leading biopharmaceutical drug discovery company and, finally, by a management buyout in 2007, which Power saw as “an opportunity to grow our business and expand our product offerings.” Today, the company employs 160 people specialising in the development, design, manufacture and commercialisation of aerosol drug delivery systems, with headquarters in Galway and offices in the US, UK and China. The products are sold both directly by Aerogen and also under licence by its partnered companies.



The Aerogen Solo Nebulizer is suitable for solutions, suspensions, proteins and peptides.

A vibrating mesh technology lies at the heart of Aerogen’s nebuliser products. From its early inception, the company’s goal has been to apply its patented technology to the development of nebulisers for application in the field of medical care. The nebuliser technology enables liquid medication to be transformed into a fine particle mist, gently and effectively delivering a broad range of drugs deep into the lungs of critically ill patients, which results in drug deposition rates far greater than can be achieved by conventional aerosol technologies.

“Undoubtedly, our greatest success as a company has been that, to date, over five million patients throughout the world have benefited from our aerosol technology and products and we are extremely proud of being the first people in the world to introduce aerosol delivery to premature babies.”



**John Power**  
Founder and CEO, Aerogen

In recognition of these achievements, Power was named RSM European Entrepreneur of the Year 2016.

## A portfolio with substance

Aerogen is an innovation-driven company earning its success from a suit of patents that enables it to stand apart from other technologies and products. The patent portfolio currently consists of 14 patent families, which bring clear benefits to the company from both a tangible (monetary) and intangible (business support) perspective. At a fundamental level, these patents are important, because they enable Aerogen to defend its technology in a competitive environment. They also support the customer’s perception that they are investing in a unique and technically superior product. In discussions with clients and investors, Aerogen emphasises the formidable presence of patent protection for its products. Its patent portfolio has been a valuable marketing tool for promoting integrity, confidence and the uniqueness of its technology and products.

## TAKEAWAY

## PORTFOLIO AND GROWTH

Customers and investors consider it very important for a young company to have strong IP. Company scale-up must then focus on building the IP portfolio. The larger the company, the greater the customers' expectations for strong IP that will be properly defended.

## Establishing a presence

"Aerogen, as a small company, had to find a way to address the large global international markets," says Power. As a newly-formed SME with a technology that is suitable for delivering better patient care throughout hospital units, the initial strategy was to approach leading companies in the acute care respiratory sector and to convince them that Aerogen's drug delivery technology would add value to their own life support ventilator products. Key to overcoming this challenge and gaining recognition from global leaders was a patent portfolio with broad geographical coverage and a wide scope of patent claims protecting the core technology and a diverse range of product applications. Partnered companies could gain access to the technology under licence and integrate it into their own products. Aerogen has thus established partnerships with some of the world's leading mechanical ventilation companies, such as Philips Healthcare, GE Healthcare, Maquet, Hamilton Medical, Medtronic, Covidien and Dräger.

"Our partners expect strong IP and that the company is prepared to defend it. They performed a thorough due diligence investigation of our IP during negotiations."



**Brendan Hogan**  
Senior VP Engineering, Aerogen

The vibrating mesh technology was placed inside the ventilators of some partner companies and also distributed by others, which accelerated the acceptance of Aerogen's technology as the most advanced aerosol drug delivery technology available in the critical care market. The patent portfolio proved to be a valuable asset at each phase of the company's growth and today it underpins company valuation. It also attracts investment capital for its speciality pharmaceutical division Aerogen Pharma, which is engaged in product development and clinical trials for new drug-device combinations.

## IP and R&D that draw profits

There are also clear monetary benefits that Aerogen can point to in assessing the value of its patent portfolio. "We work from a 60% gross margin platform and our strong IP position affords us this, which is at a considerable premium to our competitors," says Hogan. "The cheaper products on offer are quite different to ours and generally not patent-protected. Compared with the basic jet nebuliser products on the market, our products are priced forty- to fiftyfold, or tenfold compared with the more sophisticated forms." From its partnership agreements, Aerogen receives a one-off licence fee for customisation of its nebuliser products, e.g. the Aerogen Solo®, or a royalty on sales for the more sophisticated products that combine a drug and nebuliser in one device.

## TECHNOLOGY PROFILE



The technology that differentiates Aerogen's products from other nebulisers lies in the aerosol generator Aerogen Vibronic®, which is a vibrating mesh constructed from a palladium-nickel plate (5 mm diameter) perforated with 1000 precision-formed holes, which pulses at 128 000 times per second, drawing the liquid through the mesh and creating a fine aerosol containing particles less than 5 µm in diameter. This is the optimal size to achieve lung penetration of a drug and is particularly important in acute care intervention.

Since 2008 the company has achieved an annual growth rate of 30% through product sales in over 75 countries worldwide, and recorded revenues of EUR 40 million for 2015. Aerogen owes this impressive growth rate to its investment in R&D: “We see innovation and IP as the very core of our business,” says John Power. This has allowed the company to exploit market opportunities as they have arisen, and it continues to reinvest a large portion of its turnover back into research, which for 2016 amounted to EUR 5.2 million.

## Defending intellectual property

A core objective of the company’s IP strategy is to constantly build on the patent portfolio with a wide scope of patent claims, which can be called on to challenge reverse-engineered products entering the market and to set down a marker that the company is prepared to defend its market position. Aerogen has already drawn on this “defensive role” of its patents by initiating an infringement action, which is currently ongoing. New patent filings focus on strengthening protection for current products and identifying strategies for new products, such as those based on drug-device combinations, for the future direction of the business. Technologies and product applications that are not specifically in the company’s current plans for commercialisation are also closely considered, with the aim of widening the scope of protection for potential future technology applications.

The Unified Patent Court (UPC) could influence Aerogen’s strategy with respect to “opting in” to the Unitary Patent, as the company is currently defending a European patent validated in an EU country and has issued infringement proceedings against a competitor. This is a lengthy and unpredictable process. In future it might be beneficial to obtain a Unitary Patent instead of a classical European patent, as a decision in infringement proceedings will be issued much more quickly by the UPC than by a national court and be based on harmonised laws. Moreover, the court decision will be binding in up to 26 countries at once.

## Trusted counsel

Aerogen has a long-established relationship with three patent attorneys – one in Ireland, one in the US and one in Germany – and relies on their counsel for IP strategy. They not only provide the routine services of filing and prosecuting patents, but also engage closely with the company to understand its business model and technology strategy, so that they can advise appropriately on how to achieve the company’s business goals. The Irish attorney’s firm has advised the company since its very first patent application

and has grown to know the business intimately. For this reason the firm remains a key adviser on IP strategy, patent portfolio building and competitor intelligence. The US is a major market for the business, and having a patent attorney present in the territory to advise on specific aspects of US patent practice and to contribute knowledge of competitor patents and businesses in the US adds considerable value to IP strategy discussions. Likewise, Germany is Aerogen’s largest market in Europe, and local knowledge, particularly in supporting its action to defend its patents, is essential.

### TAKEAWAY

#### EXTERNAL COUNSEL

For an SME, it is critical to build trusted relationships with dedicated patent attorneys who have the technology-relevant expertise required for claim drafting. Clear communication about the technology, product goals and business needs establishes expectations and sets the focus moving forward.

The IP team is managed by Brendan Hogan, Senior VP Engineering, with support from R&D manager Conor Duffy and a number of his staff. They have implemented management processes that support the creation and capture of IP and assist in developing the portfolio. Tools related to these processes include confidentiality agreements, laboratory notebooks, invention disclosure forms and an evaluation and selection process.

## Regular strategy meetings

Patents play a critical role in supporting Aerogen’s business objectives, so in addition to regular consultation, a one-day meeting with the patent attorneys is convened once a year. This annual meeting, which focuses on technology strategy, products and technical advancements, is instrumental in formulating the company’s IP strategy. Innovations in areas the company would like to exploit and intends to expand into are examined with the goal of identifying developments that could be included in new patent applications and patent claims. The IP management team is presented with a clear understanding of Aerogen’s intended direction and goals for creating value through IP.

The strategic objectives from the annual meeting translate into practical endeavours to achieve agreed IP objectives and provide advice on what to patent and what not to patent, where to patent, assessing potential infringers and monitoring the status of competitors’ patents and relevant third-party patents and their prosecution.





Aerogen's technology applied in patient care.

#### TAKEAWAY

##### IP STRATEGY

Successful commercialisation of an innovative technology must be guided by a clear IP strategy that is aligned with other key functions of the business.

## Tracking and managing competitors

Maintaining up-to-date patent database searches for new patent applications, freedom to operate (FTO) searches, competitor watches and patent trend analyses are primary aspects of IP management that influence the company's IP filing strategies. The team regularly creates and updates a list of company names on which it performs a competitor sweep every quarter using RSS feeds from the EPO search products and its patent lawyers. These searches track the prosecution of relevant patent applications to see what claims are being granted. Patent specifications are reviewed to obtain an FTO clearance and also to assess whether products derived from a competitor's patent might give rise to an infringement of Aerogen's patent claims. Aerogen relies on this intelligence to remain agile and responsive to market conditions, and fine-tunes its IP strategy and policies accordingly.

In addition to monitoring the list of patents and competitors, Aerogen's sales team and distributors constantly highlight anything in the market that might compromise the company's product sales. When Aerogen is alerted to such instances, it gathers product information for analysis, such as the "directory for use," photographs, samples where possible and any other relevant information. The samples are dissected and examined against the Aerogen patent claims. A consultation with the Irish patent attorney fol-

lows and the matter is subsequently referred to the patent attorney in the relevant region to advise on the most appropriate course of action.

#### TAKEAWAY

##### SEARCH MATTERS

Competitor watches and patent searches are essential components of IP management.

## Portfolio-building

Proposals for inventions are shared via the company's invention disclosure form. These are reviewed by the IP team and sent to the patent attorney for discussion. They also provide the essential information for drafting a patent application in the event a decision to file is agreed.

Aerogen organises in-house IP training twice a year, as an introduction for new employees and a refresher for existing staff. This pays dividends in the reporting and capture of new IP. Although there is no formal system for documenting specific methods, processes, formulations and other industry know-how, the relevant information is included in process designs and specifications, which are recorded electronically, as well as in the laboratory notebooks. Proposed inventions are analysed to see if the method for manufacture, the design or the function could be reverse-engineered from the final product. If not, then a decision to retain the information as a trade secret is often preferred to patenting.

Traditionally, Aerogen's core IP has been developed in-house, and although the company does not have a formal "open innovation" strategy, its IP portfolio is supplemented by outside collaborations with universities that perform explora-

tory work on the technology. “We go outside to access expertise that is not available internally and to determine if there is a particular skill-set we have a need for, or wish to bring in-house. It also allows us to do exploratory research work at a reasonable cost compared with doing it in-house, where the immediate demands of product delivery can delay these kinds of early-stage activities” says Conor Duffy, R&D manager. It is Aerogen’s policy to acquire the IP developed in these collaborative projects and negotiate a grant-back licence for applications outside its field of use.

## TAKEAWAY

**OPEN INNOVATION**

Collaborating with universities and research organisations provides an opportunity to perform early-stage research and acquire new skill-sets at a reasonable cost without having to compete for overstretched internal resources.

## Filing considerations

Aerogen’s patent filing strategy is only driven by the necessity to protect innovations central to the company’s technology and products as this is paramount for creating value through IP.” Priority patent applications are filed at the EPO, and thereafter, international applications cover territories worldwide on a case-by-case basis and reflecting market importance. The patent applications are evaluated and reconsidered at each important stage: priority filing, end of the priority year, publication, and national filing. Initially, the EPO filing is used to obtain a quick search report, which on review may cause the company to modify the patent claims or file divisional applications. If claims granted by the USPTO are considered too narrow, Aerogen will often file continuation applications prior to grant to try and protect other aspects of the invention separately.

When selecting countries for IP protection in Europe, Aerogen conducts a cost-benefit analysis to ensure its market choices are strategic and prudent. “We don’t see the current system as a problem, because we generally validate in Ireland, the UK, Germany, the Netherlands and France, and in some cases some of the Nordic countries, which are relatively cheap,” says Hogan. “This covers most of our major markets.” However, upon request by licensed partners who are active in countries outside this selection, a patent will be validated in additional territories as agreed and the corresponding patent costs covered by the licensee.

On the other hand, Hogan sees clear advantages to a Unitary Patent. It would be considered a very significant improvement for the business compared with the classical European patent, as it would lead to a higher value and lower cost outcome

by providing protection for up to 26 countries without fragmentation in the EU market. This in turn would give Aerogen enhanced flexibility to enter countries that are less important to the business currently, but which may become relevant in the future. “We are always exploring options to expand, either directly or through licensing, and the extended geographical coverage of the Unitary Patent may assist us in this regard, as countries not important to Aerogen for direct sales, but important for our licensees, would be covered by the wider scope of the Unitary Patent,” says Hogan. Patent filing decisions will still be subject to a strategic analysis, and many decisions will be made on a case-by-case basis.

“Initially, I would anticipate that for some inventions we may opt for the basket of countries provided by the Unitary Patent, but for others (possibly those which are the most important commercially) we will likely continue with the classical European patent and individual country selection. We are closely monitoring progress on the Unitary Patent and regularly discuss it with our patent attorney, who keeps us updated,” says Hogan.

## COMPANY PROFILE

**AEROGEN LTD**

- Headquarters: Galway, Ireland
- Year of establishment: 1997
- Staff: 160
- Turnover: EUR 40 million (2015)
- [www.aerogen.com](http://www.aerogen.com)

**PRODUCTS/SERVICES**

High-performance aerosol drug delivery technology. The aerosol generator Aerogen Vibronic® is a vibrating mesh creating a fine aerosol containing particles less than 5 µm in diameter. This is the optimal size to achieve lung penetration of a drug.

**MARKET AND TECHNICAL AREA**

Medical devices, hospital care health systems and health providers, ventilation in critical care, life-support ventilators

**CUSTOMERS**

Medical device and healthcare companies, hospitals, health systems and health providers, ventilation companies, including: Medtronic, Philips and GE

**SELECTED AWARDS**

- 2013 Medical Technology Company of the Year
- 2016 RSM European Entrepreneur of the Year

**PATENT PORTFOLIO**

14 patent families, including EP1278569, EP1896662

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