

Improving Quality Of Life

By Ciaran O'Beirne

Research collaboration between University College Dublin (UCD) and Bio-Medical Research (BMR) led to the patenting of an innovative solution to an unmet clinical need and created real impact on the quality of people's lives. Following licensing of the technology by UCD, BMR validated it in clinical trials, secured regulatory approval and launched the product in Europe. Due to the attractiveness of the U.S. market, the strategic decision was taken to create Atlantic Therapeutics, a spin-out company of BMR, to raise investment to finance market expansion based on a strong patent portfolio.



INNOVO shorts, electrodes integrated into the shorts deploy pulses to strengthen the pelvic floor muscles.

Industry-Academy Collaboration



"IP management processes can benefit the smooth passage of a research project."

Brian Caulfield
Inventor and Professor
of Physiotherapy

BMR, based in Galway, Ireland, is a privately owned company with over 50 years' experience in the design, manufacturing, and marketing of medical-grade products based on electrical muscle stimulation (EMS).

In the early 2000s, BMR decided to explore the commercial potential of Multipath technology, an innovative approach to electrical stimulation. It engaged Brian Caulfield, a UCD physiotherapist with EMS expertise, as a consultant. The two parties submitted a grant application to Enterprise Ireland, the Irish state organisation responsible for the development and growth of Irish enterprises. With Enterprise Ireland funding, UCD and BMR undertook two collaborative research projects to investigate Multipath applications. An initial project in 2006, with a budget of around EUR 200,000, focused on obesity and stress-induced urinary incontinence (SUI). A 2008 project, with a total budget of EUR 1.15 million, had a broader focus, including lower back pain, SUI, spinal cord injury, and chronic obstructive pulmonary disease (COPD).

Collaboration Agreement

Enterprise Ireland's funding conditions required the parties to enter into a collaborative research agreement. UCD's Knowledge Transfer Office (KTO) negotiated the terms, including key IP terms on ownership and access rights, before then drafting the binding contract.¹

Contract Negotiation

Takeaway: The IP terms should fairly reflect both parties' collaboration input.

Complexities can arise when two or more parties jointly own IP. For example, who should lead the patent filing strategy? Who should pay for the patenting costs? And who is entitled to compensation from the revenues received?²

These complexities become even more pronounced in joint ownership arrangements between an academ-

1. The binding contract is the full research collaboration agreement between an academic party and a company. It includes IP terms, financial terms, liabilities, warranties, publication rights, termination, dispute resolution, etc.

2. There is no professor's privilege in Irish universities. The university owns the IP under its contracts of employment and in accordance with its policies, unless an agreement with a third party precludes this. Academic researchers benefit from licence income under the university's IP-revenue share policy.

ic institution and a company, which is able to directly exploit the joint IP. In contrast, the academic party can potentially only license or sell to a third party with the industry joint owner's permission unless there are specific terms in the collaboration agreement that grant the academic party the necessary rights.

Joint Ownership Agreement

Takeaway: A joint ownership management agreement is necessary to facilitate later commercialisation if joint foreground IP is anticipated.

Due to the above issues, the UCD KTO typically seeks to avoid joint ownership situations in collaboration with industry parties. However, given that BMR's contributions were not limited to the project costs since a BMR employee was a member of the research project team, the parties agreed that jointly created IP would be jointly owned, too.

Treating SUI With Multipath Technology

A wide spectrum of treatment options is available for patients with SUI. These include absorbent pads, surgery (*e.g.*, bladder outlet reconstruction), and electrical stimulation. However, treatments that are reversible, simple, non-invasive, and cost-effective are optimal for most patients. EMS meets these criteria. It has proven to be effective in a variety of areas ranging from muscle strengthening to spasticity management and the prevention of disuse atrophy.

EMS activates muscles, causing them to contract, similar to a voluntary muscle contraction. The technology was previously limited due to high skin resistance and difficulties targeting muscles in deeper tissues. These difficulties have been overcome thanks to an innovative approach to electrical stimulation, using novel pulse generation and a switching mechanism, known as Multipath technology. Multipath efficiently targets deeper tissues to achieve stronger muscle contractions, thus re-educating the pelvic floor muscles that control bladder function in a completely non-invasive and pain-free way. See Figure 1.

Focus on SUI and Patent Capturing

The initial idea was for EMS to treat lower-back pain before the focus switched to its use in the treatment of SUI. This is a major medical problem, affecting up to one third of middle-aged women, as well as men, particularly after prostate surgery or a pelvic fracture. It has a significant impact on quality of life.

Firstly, Ruth Maher, who trained as a physical therapist in the U.S., joined Brian Caulfield's project team, adding her knowledge of incontinence to the 2008

project. In addition, positive results were achieved in a small controlled study on 13 volunteers, which focused on the use of EMS as a therapeutic modality for SUI. Further research proved that the novel device was significantly better than conventional EMS devices in reducing the symptoms associated with SUI.

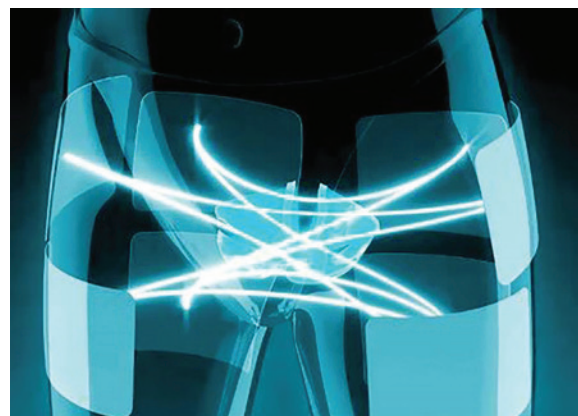
Based on this data and following internal due diligence led by the KTO, the parties agreed to file an Irish patent application to protect the technology and to establish a priority date. Based on this application, an international application under the Patent Cooperation Treaty (PCT) was filed in January 2010, which entered into the national/regional phase in the U.S. and in Europe in June/July 2011. The patents are now granted in both Europe (EP2389222B1) and the U.S. (US8494658B2) and in several other countries.

■ Dr. Ciaran O'Beirne,
Head Knowledge Transfer,
NovaUCD,
University College Dublin,
Dublin, Ireland
E-mail: ciaran.obeirne@ucd.ie

Protecting University Inventions

Currently, UCD's KTO files priority applications with the European Patent Office (EPO) in order to secure a search report within the priority year and then file under the PCT after 12 months. The EPO typically provides search reports within four months, meaning a request for search filed with the EPO guarantees an applicant answers in good time within the priority year.

Figure 1: Illustration Of Working Principle



Multipath technology embedded in shorts. It sends gentle muscle stimulations from the electrodes on the buttocks to the electrodes at the front. This criss-cross pattern stimulates the pelvic floor muscle at the centre.

Typically, the technology is licensed by universities to companies when the patent application is still pending, either during the priority year or during the international phase of the PCT application. It is then up to the company to pursue the patent applications and decide in which countries protection needs to be sought, depending on its key markets. Besides a sound IP strategy, this requires market research and foresight so that a cost-benefit analysis can be completed. But even then, it is sometimes difficult to anticipate the initial success of a patented product or business opportunities in various EU Member States.

Also, the current fragmentation of the European patent system and the costs of maintaining patent protection in several states can be a barrier. As a result, many companies often end up with protection only in a small number of countries. With the Unitary Patent, UCD would obtain protection in up to 25 participating EU Member States, thereby creating enhanced flexibility to enter the various national markets whenever opportune.

“The benefits of transferring the research, it’s not just getting a licence agreement over the line, it is the outcome, it’s the impact when new products or services are launched at the back of that.”



Ciaran O’Beirne
Head of Knowledge Transfer

The claims in the patent detail a method and apparatus for stimulating pelvic floor muscles through the use of externally applied electrodes to all related muscles of patients with SUI. Importantly, the claims anticipated integrating the electrodes into a piece of clothing. In this way, the device evolved from Vital Compact into the INNOVO shorts (see Figure 2).

How Knowledge Transfer Offices Can Successfully Operate as Facilitators

- Skilled and experienced staff
- Continuity in management of IP
- Good working relationship with researchers and company
- Mutual recognition of each party’s strengths

Figure 2: INNOVO Wearable Shorts



- Use of external patent attorney with domain expertise
- Pragmatic approach to legal agreements
- Deal structure benchmarked to be fair and reasonable, and reflect industry norms

Licence Agreement

UCD considered BMR as the commercial partner in the project and, under the terms of the collaboration agreement, granted BMR an option to negotiate an exclusive licence to UCD’s rights in the foreground IP. The KTO led the negotiation of key licensing terms, and then drafted the licence agreement, which was executed by the parties in 2011.

Industry Collaboration

Takeaway: In academy-industry collaborations, recognise all partners’ needs and define incentives and criteria so that the company can act as the commercial partner.

The company was granted a global, exclusive, but field-restricted licence to UCD’s rights in the patented technology and a non-exclusive licence to other non-patented IP in the treatment of stress incontinence. The agreed royalty rates were benchmarked against industry norms and on comparative deals in the medical technology sector. Based on this information, the parties agreed on fair and reasonable royalty rates that reflected the technology’s stage of development, the company’s contributions to the project and

the further development and validation efforts that would be undertaken by the company. The licence deal also included other financial considerations, such as an upfront fee and milestone payments.

Consistent with the KTO's practice, UCD assumed no liability and sought an indemnity from BMR through its use of the licensed technology. The company was also responsible for ongoing patent prosecution and maintenance, including full payment for the costs for obtaining and maintaining the patent given the licence's exclusive nature. Finally, through a grant-back clause the UCD secured a non-exclusive, royalty-free licence to use the technology for academic research and teaching purposes.

Benchmarking

Takeaway: The deal structure should always be benchmarked so that it is fair and reasonable and reflects industry norms.

The licence agreement included a commercialisation plan with mutually agreed milestones. Under these, the company committed to undertake trials to clinically validate the technology, secure relevant regulatory approval, and launch the product within an agreed time. BMR further developed and validated the product (approximately 500,000 treatment cycles were completed with zero adverse incidents) and successfully launched it under the brand name Vital Compact in 2014, following certification under the European Medical Devices Directive 93/42/EEC. It took three years from the execution of the licence agreement to the launch of product—a relatively short time based on comparable licence deals executed by the KTO.

Creating a “Win-Win-Win” Situation

The company secured exclusive rights that enabled it to invest further in validating the technology, launch the product, and develop new markets with associated revenue generation. UCD in turn has received royalties from sales of Vital Compact since its launch in 2014. BMR was also granted option rights to expand the field of use for the treatment of other medical conditions. Under the terms of a second licence, BMR was granted exclusive rights to the use of the patented technology for the treatment of lower-back pain. This area remains the subject of ongoing clinical studies.

Managing Collaborations

Takeaway: Agree on key development and commercial milestones early, to guide and facilitate market success, but be willing to amend as necessary.

This licensing case supports UCD's strategic objective of translating its research outputs for wider societal and economic good. In addition, it provided

a constant stream of royalty revenues for the university, a portion of which is distributed to the academic inventors in accordance with UCD's IP policy. The successful transfer of technology developed within the university exemplifies real impact through patient satisfaction and job creation.

UCD's IP Policy

UCD supports excellence in innovation and encourages UCD researchers to create IP. Its policy ensures that the creators of the IP receive recognition and a share of revenues from licensing, which are split between the creators, the academic centre (school) in which they are based, and the central university (UCD) in accordance with the sliding scale shown in Table 1.

Table 1: UCD's IP Policy

Net Revenues	Creators of IP	School	UCD
Up to €100,000	75%	15%	10%
Portion of Net Revenues From €100,000 to €200,000	50%	30%	20%
Portion of Net Revenues From €200,000 to €1,000,000	40%	30%	30%
Portion of Net Revenues Over €1,000,000	30%	30%	40%

Targeting the U.S. Market

Vital Compact was initially sold via referrals from urologists and gynaecologists. Later, the company adopted different distribution channels, including internet sales, primarily in Germany, Ireland, the UK, and the Middle East. Following encouraging sales, the U.S. was viewed as the next major target market due to its size and its overall share of the global incontinence market, which is expected to reach USD 13 billion³ by 2022.

Investment was needed to gain market traction in the U.S. and drive product innovation. This led to a strategic decision to spin out Atlantic Therapeutics (AT) from BMR to attract investment and maximise the product potential, first in the U.S., and then worldwide. UCD supported the company's decision and the licence was transferred from BMR to AT in 2017, after its incorporation in Ireland. The Vital Compact product was rebranded as INNOVO.

3. Source: Global Market Insights.

Financing Expansion

Key players in the global market for SUI include major international companies such as Johnson & Johnson; Boston Scientific Corporation; and Becton, Dickinson and Company. It is not easy for a small company to gain market share from incumbents with well-established branded product lines and extensive distribution channels. By 2021, AT has raised nearly EUR 50 million in investment to overcome that challenge.

In 2017, two European venture capital firms Seroba Life Sciences (Ireland) and Earlybird (Germany) supported the spin-out of AT from BMR and invested EUR 15 million in funds for the company. The investment was preceded by comprehensive due diligence, including a competitor analysis and a review of market trends, the licensing agreement with UCD, and the IP rights (two freedom-to-operate reports were commissioned). This due diligence and a technology that has proven itself in Europe persuaded investors that INNOVO afforded first-mover advantage as a non-invasive therapy in the treatment of SUI. See Figure 3.

As part of this initial investment, a key early milestone was to secure clearance from the U.S. Food and Drug Administration (FDA). In November 2018, the INNOVO therapy device became the first-ever transcutaneous electrical stimulator to be cleared as a safe, clinically effective, and non-invasive product to treat

Figure 3: INNOVO Therapy Device In Practical Use



“For an investor, the key attraction of INNOVO is a large, unmet medical need. Plus, it is non-invasive and easy to use. The



strong IP allows us to develop the technology for many other indications.”

Daniel O'Mahony
Partner in Seroba Life Sciences

SUI. FDA approval triggered a further EUR 28 million investment in 2019, led by LSP, one of Europe's largest healthcare investment firms along with Andera Partners (France) and Atlantic Bridge Ventures (Ireland). A further EUR 12 million was raised in 2020 and 2021 with two new investors, Borski Fund (Holland) and WDC (Ireland). The company is aiming for Series C financing to further accelerate growth.

Scaling Up

Takeaway: Follow the markets and seek growth financing.

The investment has also been used to drive product development. The external electrodes were incorporated into wearable shorts that were the subject of priority UK patent applications in 2017 and 2018 that led to another international patent application (under the PCT; WO2019110595A1). This innovation also reflected increasing consumer demand for wearable therapies. Further innovations, including a smartphone app to control the device, are in progress.

In 2020 the company opened an office in Boston and has recently featured on a number of major U.S. TV media outlets. These PR activities feature Dr. Ruth Maher, whose knowledge of SUI and involvement in the development of INNOVO reinforces brand credibility and trust. In parallel to ramping up and scaling of its U.S. activities, AT is continuing to develop existing sales channels in Europe. It is also exploring opportunities in Asia, which, with an annual growth rate of 5 percent is forecast to be the fastest-growing market for SUI. See Figure 4. ■

Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=4099730>

Further technology transfer case studies can be found at epo.org/case-studies.

Figure 4: Technology Transfer Timeline

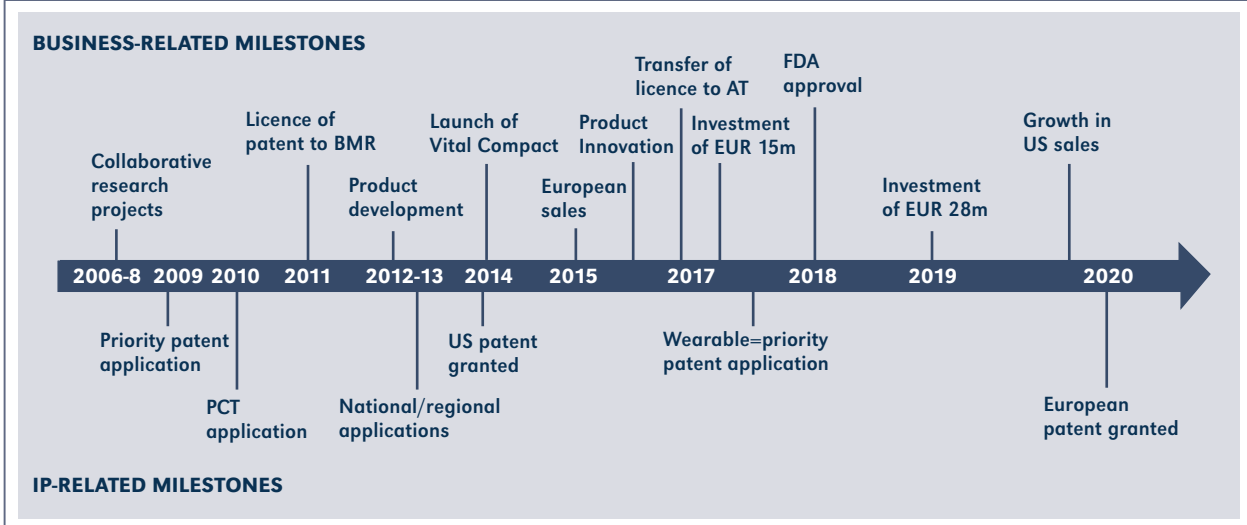


Table 1: Patent Portfolio

Patent number	Title	Priority Date
EP2451525B1	Apparatus for stimulating the lower back and abdominal muscles	10.07.2009
EP2389222B1	Apparatus for stimulating pelvic floor muscles	26.01.2009

Source of IP

Brian Caulfield

- Main inventor and physiotherapist
- His UCD IP portfolio includes eight invention disclosures, four priority patent applications, six licenses and two spin-outs

Ruth Maher

- Main inventor
- Clinical Advisory Board member for Atlantic Therapeutics

Univeristy College Dublin (UCD)

- Founded in 1854, Ireland’s largest university with over 30,000 students from 136 countries

Tech Transfer Catalysts

Knowledge Transfer Office

- Facilitated the collaboration between UCD and BMR
- Led the negotiation of key licensing terms and drafted the licence agreement
- Facilitated the commercialisation plan and licence agreements between UCD, BMR and Atlantic Therapeutics

Enterprise Ireland

- Provided funding for collaboration projects between UCD and BMR

Andera Partners, Atlantic Bridge Ventures, Borski Fund, Earlybird, Life Science Partners, Seroba Life Sciences, WDC

- Provided investment for U.S. and global expansion to Atlantic Therapeutics

IP Commercialisation

Atlantic Therapeutics

- Company created in 2017 as a spin-out from BMR
- Winner of 2019 Innovation of the Year Award–Irish Times and the London LSX Medtech Company of the Year 2019
- 29 employees
- Licence transferred from BMR
- Products sold under the registered trade mark INNOVO (registration number 1311618: Priority date 31 August 2015)

BIO-MEDICAL RESEARCH (BMR)

- Privately owned company with over 50 years experience
- Industrial partner of UCD
- Turnover of EUR 29.5m with a profit of EUR 1.5m and 73 employees (2018)

Editors: Thomas Bereuter, Yann Ménière, Ilja Rudyk
 Collaborators: Jörg Scherer, Stephanie Weber (European IP Helpdesk), Anna Malec (EPO)

Photos: Atlantic Therapeutics Group Ltd.
 Disclaimer: Any opinions expressed in this case study are those of the author or the company and not necessarily those of the European Patent Office.