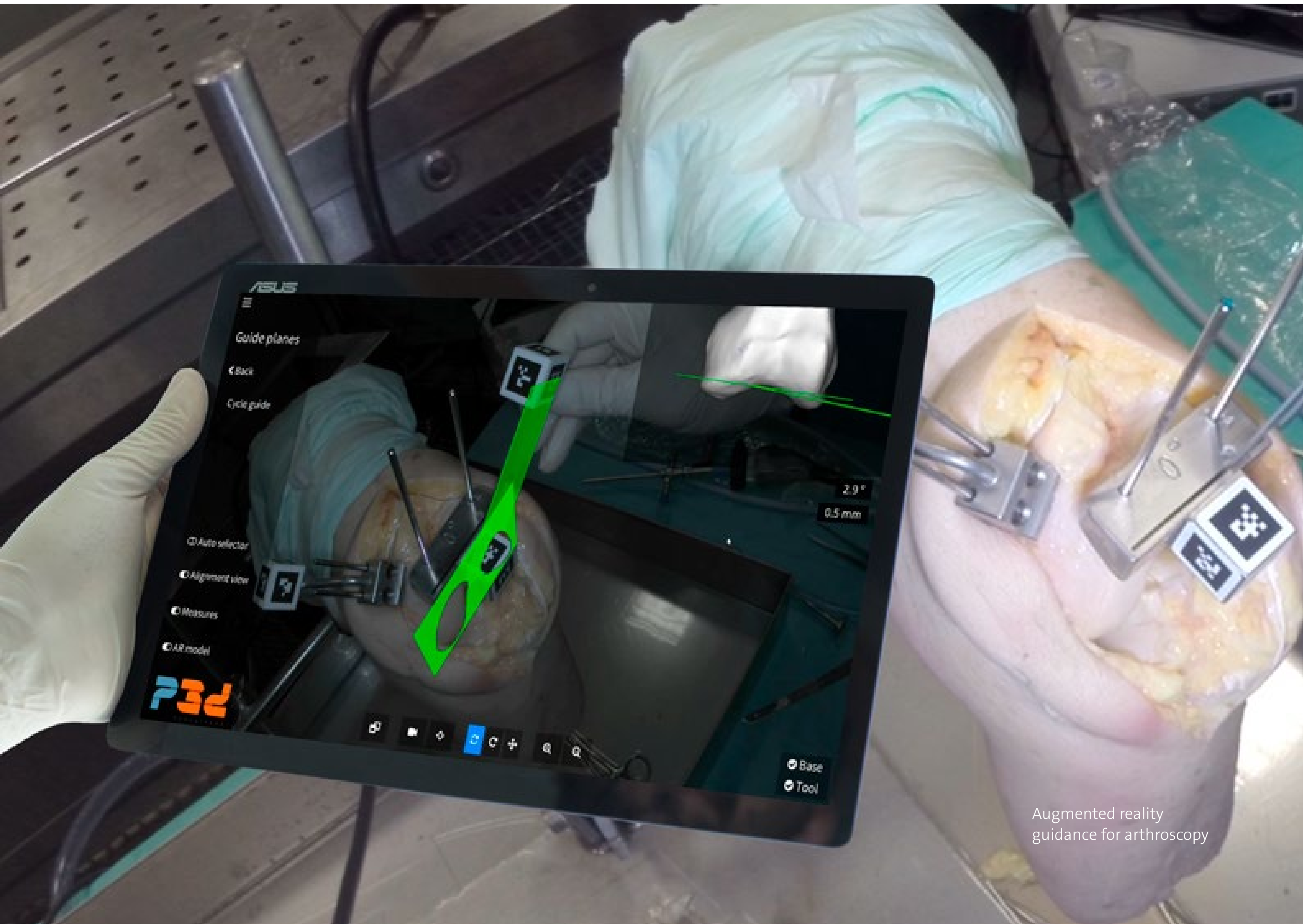
EPO TECHNOLOGY TRANSFER CASE STUDIES | **PERCEIVE3D**

Disrupting surgical navigation

Spinning out from the Portuguese University of Coimbra proved to be the best way forward for Perceive3D to commercialise a promising technology in the medical imaging area. Due to the small size of the local market, broad patent protection proved crucial to both targeting international markets and securing continuous investment during the long development and approval phases leading up to commercialisation of the technology.



Augmented reality
guidance for arthroscopy

How the journey began

It all started when Professor João Pedro Barreto and his PhD student Rui Melo embarked on a research project on camera calibration and real-time image processing for endoscopy systems which quickly led to the development of early-stage prototype software. João Barreto became aware of the importance of intellectual property (IP) in R&D projects after attending a training session addressing IP protection at the University of Coimbra (UC). The session was delivered by the Instituto Pedro Nunes (IPN), a private non-profit association which runs a business incubator. Immediately after the training, Professor Barreto contacted UC's technology transfer office (TTO) to disclose an invention that described a new way of solving radial distortions in images, a problem inherent in existing surgical navigation systems.

> TAKEAWAY
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> **IP AWARENESS**
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> IP awareness among researchers is key to ensuring that research results are properly assessed and protected prior to otherwise novelty-destroying publication.

As part of the disclosure, Professor Barreto had to complete an invention disclosure form, including information about the development path of the technology, the potential applications and what companies might be interested in licensing the IP, together with an outline of the potential early disclosures of the intellectual assets involved. With this information, in 2011, the UC TTO began the process of evaluating the patentability and technology transfer potential of the invention. Through the screening process it was determined that the invention met the criteria for patentability, and UC filed a first patent application (EP12772538) in July 2011.

Creating a spin-off

The next step in the process was to get a better understanding of market needs. Potential commercialisation partners were contacted with a view to out-licensing the technology right away, or cultivating relationships that could advance the research to the extent where it could be out-licensed. During this period, João Barreto was very involved in the initial attempts to find a partner and became interested in launching a spin-off company himself. According to the UC TTO's evaluation, this was an appropriate route to commercialisation, since a dominant IP position had already been established. Finding a licensing partner in Portugal on the other hand proved to be difficult for an early-stage, high-risk technology in a small local market. Larger multinational companies are usually not very keen to invest in technology directly emerging from universities, at least not until the technology reaches a certain market readiness level. At the same time, public funds to upgrade the prototype to a level which would be attractive to industry partners were scarce. So the decision was taken to launch a spin-off company that would advance the technology to more sustainable and market-ready solutions. The resulting company, Perceive3D (P3D), was incorporated in 2013, with João Barreto and Rui Melo as founders and first investors. An exclusive licence agreement was signed between UC and P3D in the same year.

Securing access to technology on preferential terms

Special conditions were defined by UC to facilitate the incorporation. It did not claim any upfront payment, and royalties were only due once P3D started to make its first sales. In exchange, P3D agreed to take over part of the patent administration and maintenance costs, not only for the initial patent application, but also for future patent applications arising from R&D co-operation with UC in the same technical field. This represented a considerable outlay for P3D, but it was able to apply for co-funding from structural European funds which allowed it to reduce its financial obligation by 80%. By way of a further advantage, such costs are tax-deductible under Portuguese law.

According to the terms of the licence agreement, P3D had to pay royalties to UC on gross sales arising from patents exploited by P3D. The agreement is constructed to ensure that the university can claim royalties not only from products but also from services arising from any of the licensed patents. The agreement further defines a ceiling value – the maximum accumulated royalty to be paid, after which the university would cease its claims – together with the obligation of the company to cover all legal and patent maintenance costs, with the possibility to deduct those costs later from the ceiling value. 2020 marked the first year in which royalties were paid by P3D under this licensing agreement. The agreement includes a future option for P3D to buy all these intangible assets from the university for a predefined lump sum.

> TAKEAWAY
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> **CONTINUOUS AND FLEXIBLE SUPPORT**
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> Universities should continue supporting their spin-offs once the licence agreement is signed and the spin-off has been created. In most cases, licence agreements should include the option to be adjusted to react quickly to rapidly changing economic environments.

Financing the journey

The first venture capital (VC) fund to invest in P3D was Portugal Ventures, a Portugal-based public VC fund. This investment, in 2013, followed the "classic" seed round approach of securing a minority share in the company, leaving the majority of the shareholding in the hands of the founders. This approach facilitated P3D's future development and any forthcoming rounds of investment. Part of the money collected in this first investment round was used to cover the patenting costs. Despite support from European Structural Funds, and as P3D needed patent protection in many markets, IP expenses consumed a substantial share of the amount received from the VC fund in P3D's first few years of operation. However, without this strong IP protection effort, it would have been more difficult to obtain funding for such an early-stage and R&D-intensive project. In fact, prior to the decision to invest in P3D, Portugal Ventures carried out a thorough due diligence to assess the company's IP strategy and ongoing patent application filings.

In 2017, P3D received a grant from the SME Instrument from EASME, the EU's Executive Agency for SMEs, now known as EISMEA. Currently, substantial additional funding from VC funds is on the agenda to boost P3D's operations, proving the effectiveness of the company's IP strategy and its effort to ensure broad and international IP protection of its key technologies.

The technology

P3D is built on a set of continuous developments in the medical imaging area. Beginning with image enhancing improvements, developments expanded into navigation and guidance technologies for arthroscopic and open orthopaedic surgery. The company offers simplified and cost-effective solutions, reducing the amount of sterilised materials needed for each surgery significantly, enabling faster and cheaper proceedings. All P3D's software solutions run on universal handheld smartphones/tablets, surgical cameras and even mixed reality headsets, thereby avoiding the need for more capital-intensive equipment that would not be portable and would occupy valuable operating theatre space.

At the first stage of development, P3D focused on new camera calibration methods applying pixel value and pixel position techniques to improve visualisation and correct the surgical camera lens distortion, or fish-eye effect.

An image-based surgical navigation, combining a pre-operative 3D surgical planning tool with real-time intra-operative guidance, based on augmented reality (AR) technology, was the next stage of development. This included the development of the first navigation system for computer-assisted orthopaedic surgery (CAOS) in arthroscopy. It overlays the existing video from an arthroscopy tower with clinical information displayed in AR,

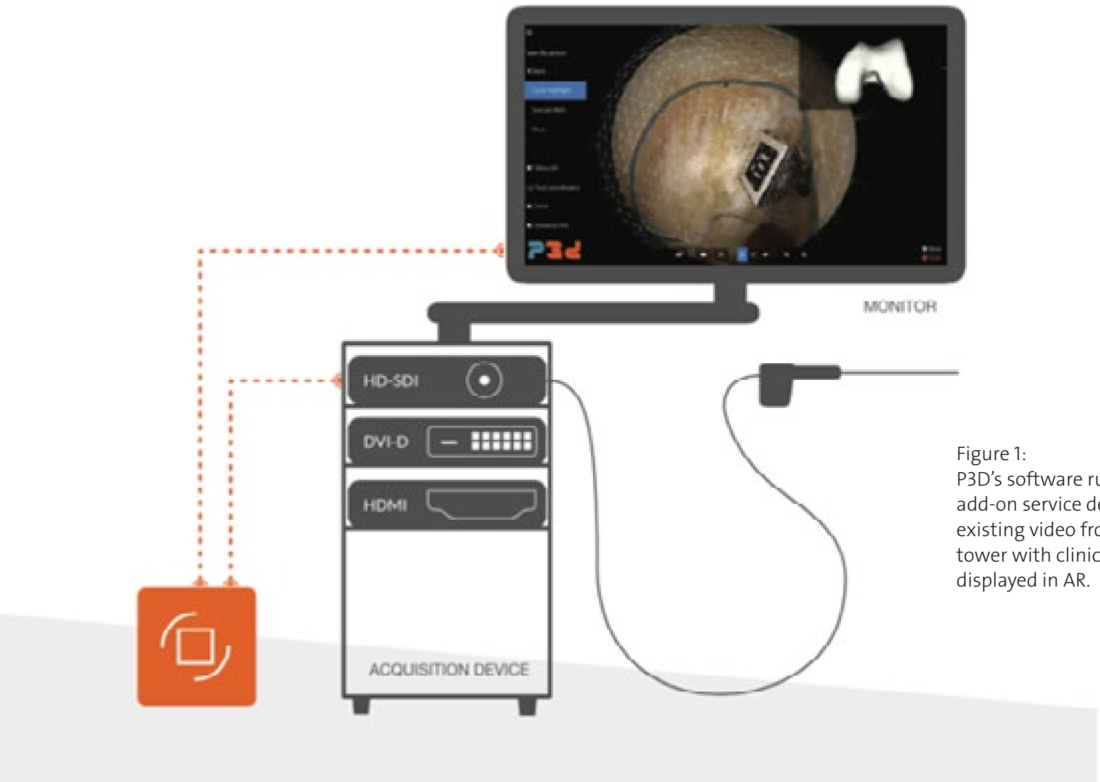


Figure 1:
P3D's software runs in a universal add-on service device, overlaying the existing video from the arthroscopy tower with clinical information displayed in AR.

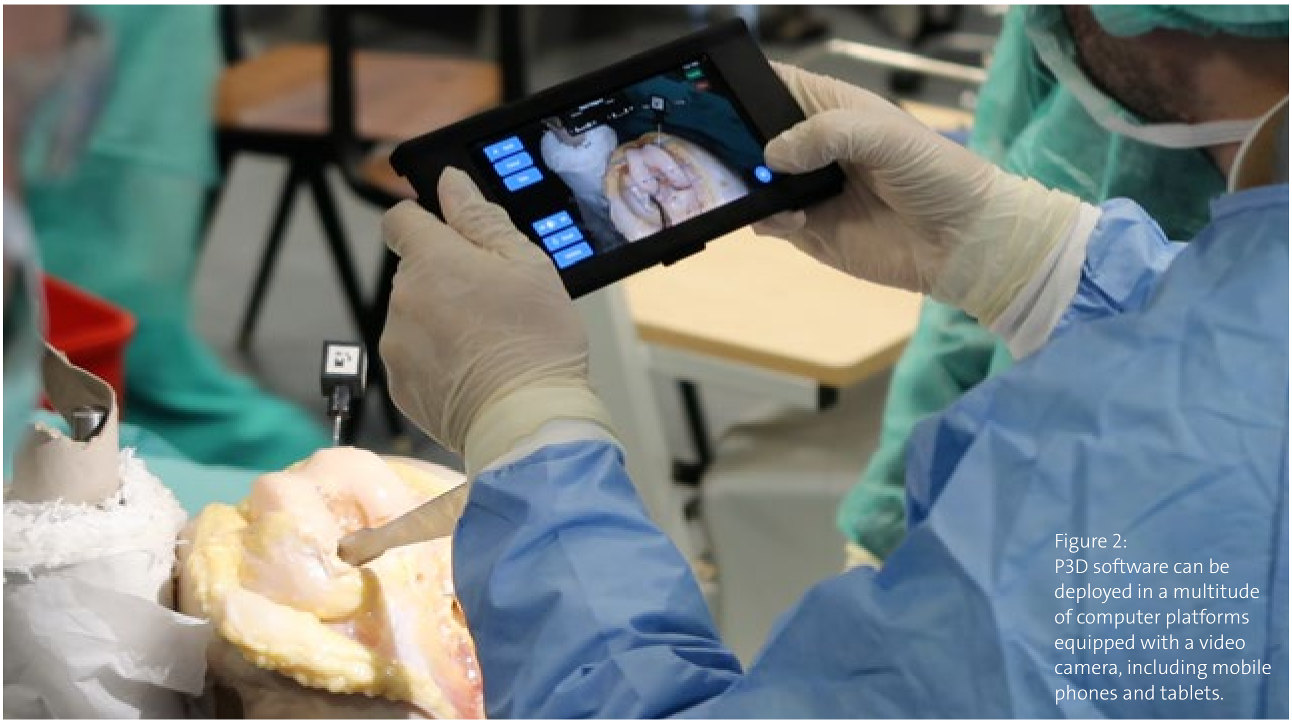


Figure 2:
P3D software can be deployed in a multitude of computer platforms equipped with a video camera, including mobile phones and tablets.

which means that the tunnels can be placed depending on patient-specific anatomy with unprecedented accuracy and control.

The latest and current phase of improvements is centred around the idea of "open surgery". P3D's proprietary software runs in commercial off-the-shelf devices (mobile phones or tablets), overlaying AR guidance information to the device's video feed. This brings together a guidance system based on video that unites real-time image processing with AR for cutting, drilling, rimming or aligning parts with confidence and accuracy. Further developments in open surgery include an image-free navigation system for total knee arthroplasty that does not require pre-operative information. Since surgical planning is performed intra-operatively, this reduces medical costs and eliminates the need for pre-operative planning.

The market

P3D's technology is adjustable to many procedures and anatomies in orthopaedics (hip, spine, shoulder) and, taking into account both open and minimal invasive surgeries, has an estimated total potential market of EUR 4.2bn. Thanks to its superior navigation technology, it also has the potential to reduce surgical revisions by 20%, with estimated direct savings of EUR 2bn. This estimate comes from a recent study that shows that the percentage of revision procedures after 12 years is 12%, from which at least one fifth, corresponding to more than 312 000 surgeries per year, could be avoided by ensuring accurate implant placement.[1, 2]

P3D acts in a very competitive technical field, populated by big multinational companies. On top of that, healthcare-related markets have typically a considerably longer time to market compared with other technological areas, due to the extensive regulatory and approval processes that exist in many countries. This results in a long and challenging process that needs to be overcome before any product can be offered for sale, and requires significant initial capital investment as well as patience on the part of all stakeholders involved.

The business strategy

In the healthcare industry, it is vital to convert the ideas and prototypes covered by patent applications into actual products that can be used by healthcare professionals. In the early days, P3D showcased its technical achievements to practitioners at trade fairs and other events, looking for

1 C. W. Jones and S. A. Jerabek. "Current Role of Computer Navigation in Total Knee Arthroplasty," The Journal of Arthroplasty 33 7 (2018) 1989-93.

2 K. Thiele et al. "Current failure mechanisms after knee arthroplasty have changed: polyethylene wear is less common in revision surgery" The Journal of Bone and Joint Surgery, American Volume 97 9 (2015) 715-20.

direct sales. These patent applications were filed prior to any relevant technical disclosure, to keep the inventions' novelty secured. P3D finally managed to find a "shortcut", launching its navigation system for hip surgery by licensing its technology to a global implant manufacturer. The development phase for the product has been successfully concluded and the system is expected to enter the market in early 2022.

In parallel, P3D is also working on launching its own branded product, a navigation system for total knee arthroplasty that runs on a small device like a smartphone or tablet. The regulatory phase is expected to kick off by the end of 2021 and launch on the market in 2022. This will enable the company to prove market readiness through initial direct sales, and increase its potential value in the event of an exit strategy.

IP at the centre of the core value

This dual business strategy is only possible due to the broad patent coverage that was taken care of early on by UC and P3D. Originating in a relatively small country, while targeting competitive international markets and working with a long time-to-market period, it was important for P3D to continue to invest in R&D, in order to improve and offer new solutions. At the same time, it had to make sure that its technology was properly protected by patents and other IP rights in its main markets, Europe and the US.

The commitment of its founder João Barreto and his team to identifying opportunities to protect the company's technical improvements and his and the team's direct involvement in the patent drafting process was a key factor in the success of their strategy to build up a strong and geographically broad patent portfolio. This allows the company to be competitive in the MedTech sector and improves its chances of attracting more investment from VC funds in the pursuit of a successful exit.

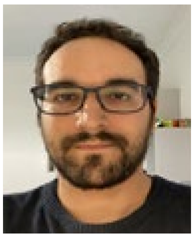
The protection of the key enabling technologies early on was a crucial factor in P3D's success, especially in the initial phase of its development. It allowed the company to block competitors' movements in the same fields, providing it with more time to reach the market and simultaneously giving it freedom to operate while reducing the chances of third-party infringement.

TAKEAWAY

KEY ENABLING TECHNOLOGIES

Protecting the IP of the core technologies is a critical success factor in the initial phase of technology and business development.

"Once in place, the unitary patent will open new perspectives for the future of patents in Europe, in particular because of the wider protection available in up to 26 participating member states, not to mention the reduction in complexity and administrative burden."



Rui Melo
Co-inventor, co-founder and CTO

Managing IP

From the outset, the P3D team had a clear strategy when it came to patents: "patent the roots, not the branches". Protecting only enabling and multi-purpose computer-implemented inventions rather than those with specific and more focused inventive steps was the key to covering a broader scope of technical applications of the technology with fewer patents. This allowed the company to maintain a sensible trade-off between costs and protection, which is a crucial issue for any early-stage start-up.

It is worth mentioning that protection was obtained for the first patent application in Europe, the US, Japan and China, whereas the following applications were restricted to Europe (Germany, France and the United Kingdom) and the US, as these two economic areas account for roughly 70% of the potential market for the company's products. In Europe, the first patent is still maintained in Germany, France, United Kingdom, Switzerland, Portugal and the Netherlands. This invention would clearly have benefited from a unitary patent, as this would have reduced the overall costs of protection.

Choosing a skilled patent law firm with a good reputation (especially in the US) is vital to ensuring the technical and legal correctness of the patent documents, while the credibility and reputation of the patent attorneys concerned sends a signal to the market, competitors and future investors alike.

"As a researcher you might feel tempted to stick to science and stay away from the business side of the venture. However, if your venture does not have a business person as an early founder, then staying away from business is not an option."

João Barreto
Professor, co-inventor, co-founder and CEO

This "teacher-entrepreneur" approach is epitomised by João Pedro Barreto, P3D's CEO and founder, who keeps up his teaching and research at the university alongside his duties as company CEO.

The role of the TTO

With the aim of promoting knowledge transfer from academia to the market by liaising between researchers, public authorities and private companies, the UC TTO supported P3D's creation and development from the moment João Pedro Barreto first contacted it to disclose his invention. The UC TTO helped draft and manage the first IP applications and registrations and promoted the licensing of the IP from UC to P3D. P3D has benefited from this innovation ecosystem from the start, combining a vibrant and open-minded approach with the direct support of UC's business incubator IPN.

P3D is currently working on filing new international patent applications as the sole applicant,[3] demonstrating its strength and solid growth, as well as keeping IP as a central priority in its business strategy.

The teacher-entrepreneur approach

The involvement of the research team in the commercialisation process was fundamental, not only because of their scientific and technical background, which made it easier to assess market opportunities, but also to ensure that the negotiated agreements met the expectations of all stakeholders, including the university, the inventors/ entrepreneurs and any future investors. However, to achieve that, the entrepreneurial skills of the researchers, whose efforts are traditionally focused on the academic side (teaching, publishing and performing fundamental research) had to be improved. They therefore attended business courses and workshops provided by IPN and UC, developed the initial value proposition for the company, participated in the negotiation of contacts with potential investors and validated the opportunity with potential clients worldwide.

"Although not without risks in the long term, helping to create local spin-off companies such as P3D greatly contributes to the regional and national economy by creating highly skilled jobs, retaining qualified staff in the region and increasing the competitiveness and robustness of the national industrial sector."

José Ricardo Aguilar
Head of Legal/IP, IPN

3 In accordance with the agreement between UC and P3D, all patent applications were filed with UC as applicant. An exclusive licence was granted automatically to P3D.

UC IP POLICY

Under UC's IP policy, the university owns intellectual property that is developed through research conducted using its facilities and resources. If the IP commercialised by UC generates income, the "net revenues" (after deduction of UC's out-of-pocket expenses for protection and licensing) is shared with the people who created the IP, with 55% going to the inventors and 45% to the university.

Although UC has a strong portfolio with a huge market potential, its TTO soon discovered the difficulties involved in commercialising such assets, whether through licensing or by selling direct to big players.

It therefore came up with a specific strategy to boost healthcare-related technologies into the market by enriching UC`s innovation ecosystem through partnerships, with the goal of:

– increasing synergies and collaboration with local infrastructures (e.g. the IPN business incubator) to promote the launch of university IP-based spin-off companies
– enabling researchers with an entrepreneurial profile and skills and competencies to create the conditions to explore their entrepreneurial paths
– involving local and national private investors to leverage the early investment needed to bring the technology to a more mature stage, where it can become attractive to bigger, global investors

Whenever the UC TTO was called on to assess a possible patent submission from a research team, it started also to identify possible entrepreneurial profiles amongst the group, sharing with them the creation of a spin-off as an alternative path to the classic out-licence of IP to third party companies and supporting them to acquire new skills/competencies needed to move forward. As a result, researchers in a number of R&D units and departments started to talk around coffee tables about colleagues that decided to start-up companies and their achievements.

UC has a strong technology cluster on healthcare-medical devices and biotech, with over 300 active patents in 2020. Its portfolio is mostly composed of patents relating to healthcare, from a mix of very different scientific backgrounds such as ICT, mechanical, electrical and chemical engineering, pharmacy, biotechnology, neuroscience and, of course, medicine.

IPN BUSINESS INCUBATOR

Instituto Pedro Nunes, the private non-profit association founded in 1991 by UC, is today the most successful business incubator in Portugal, responsible for multiple success stories in the field of tech-based entrepreneurship. It has become a powerful and diverse hub of support and networking to more than 300 companies, accounting for a combined turnover of around EUR 190m, mostly from exports. These companies currently employ a total of more than 2 500 highly qualified staff and have a survival rate (number of companies still in operation five years after incorporation) of more than 70%.

IPN included P3D from its incorporation in its incubation programme, providing direct support to the founders in the early-stage phase of the company. Recently, IPN has expanded P3D's follow-up under its acceleration programme as a result of the proven success of the company.

UNITARY PATENT

The unitary patent will help UC address the challenge of patenting new inventions that are still at an early stage of research and development. Under the current system, the initial decision to validate a patent in specific EPO member states means that the university has to decide early as to which national markets it might want to enter at a later stage. As a result, it may decide not to enter certain new markets due to the lack of patent protection, or to operate in them without it. The introduction of the unitary patent will benefit UC, since the university can then decide whether to enter new markets at any time, depending on the success of the technology or on new business opportunities in other EU markets, and not on where the patent has been previously validated.

Figure 3: Technology transfer timeline

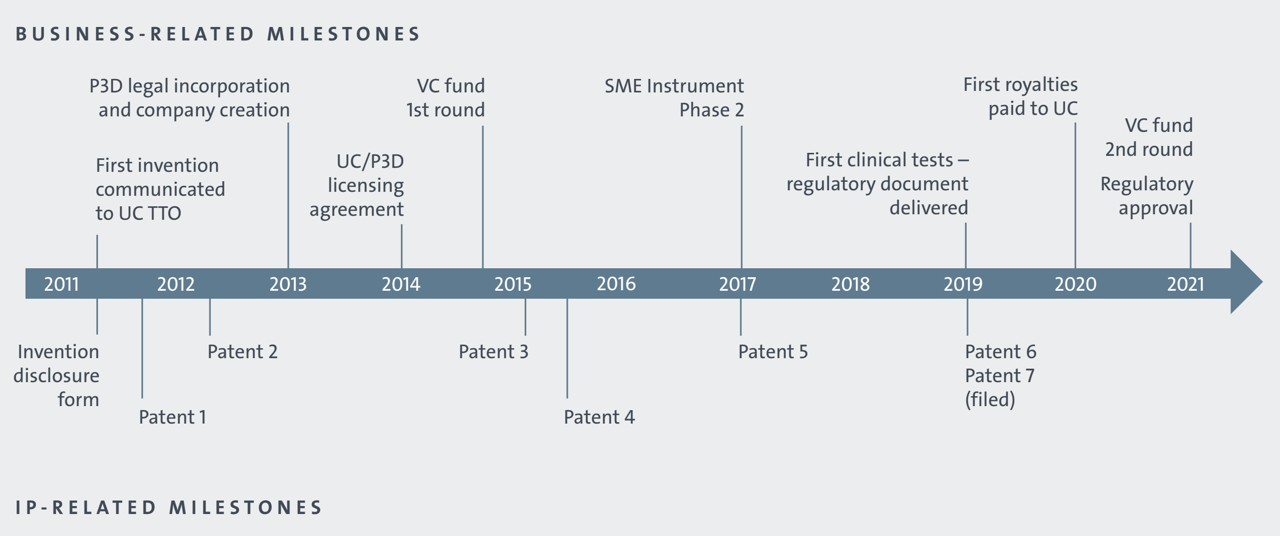


Table 1: P3D's patent portfolio

Patent number	Title	Priority date
EP2742484B1	Method and apparatus for automatic camera calibration using one or more images of a checkerboard pattern	25.7.2011
EP2904584B1	Method for aligning and tracking point regions in images with radial distortion that outputs motion model parameters, distortion calibration and variation in zoom	5.10.2012
EP3273854B1	Systems for computer-aided surgery using intra-operative video acquired by a free moving camera	26.3.2015
EP3284252B1	Methods and systems for camera characterisation in terms of response function, colour, and vignetting under non-uniform illumination	13.4.2015
EP3596657A4	Systems and methods for 3D registration of curves and surfaces using local differential information	14.3.2017

Some of the EP applications listed are still pending and no decision to grant has been taken. Granted patents may also undergo an opposition or appeal procedure, in accordance with the procedures laid down in the European Patent Convention, which could limit the scope of protection of the patent. All legal events are published in the European Patent Register and can be accessed via www.espacenet.com.

MAIN PLAYERS INVOLVED

SOURCE OF IP

João Pedro Barreto and Rui Melo

- inventors, founders and managers of Perceive3D

University of Coimbra (UC)

- founded in 1290
- owner of the initial IP

TECH TRANSFER CATALYSTS

Instituto Pedro Nunes business incubator

- private non-profit association founded in 1991 by UC
- supported more than 300 companies since 1995
- combined turnover approx. EUR 190 million
- over 2 500 highly qualified staff
- survival rate (companies still in operation five years after incorporation) of more than 70%
- supported P3D with its launch and in negotiations with VC funds

UC TTO

- created in 2003
- drafted and managed IP applications and enforcement (patents, trade marks)

IP COMMERCIALISATION

Perceive3D

- university spin-off established in 2013, headquartered in Portugal, specialising in surgical navigation systems for orthopaedics
- partnered with a global implant manufacturer
- turnover (2020) EUR 203 600 with 13 employees (5 PhDs plus 8 MsC)
- selected awards:
  - Building Global Innovators (MIT Portugal Program) 2013, award granted by ISCTE and MIT Portugal
  - Top 25 Portuguese StartUps (2017, 2018, 2019), award granted by ScaleUp Portugal
  - SME Instrument Phase II (2017), comprising a co-financed grant of EUR 1.3 million
  - “Bartolomeu de Gusmão” award (2018) from the Portuguese Patent and Trademark Office in the “Innovative Start-Ups” category

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