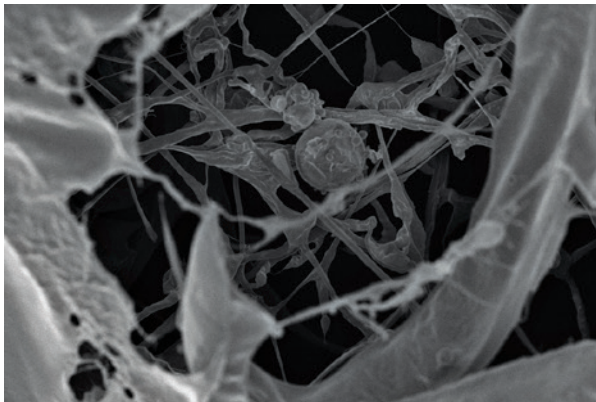


Healing Wounds

By Dr. Fazilet Vardar Sukan and Mustafa Çakir

R&D led by four female inventors from a Turkish university laboratory resulted in a product that can treat open wounds, such as diabetic ulcers. Although IP protection was secured early on with the help of the local technology transfer office, initial commercialisation attempts through licensing failed. Encouraged by their participation in a start-up acceleration programme, the female inventor team created the start-up Dermis Pharma. With the help of strong IP, the young company was able to secure the necessary venture capital funding for cost-intensive clinical trials and product development. A corporate partnership became possible through an IP-assignment deal with a big Turkish pharma company and accelerated the commercialisation process.



Once applied to scarred tissue, Dermalix wound dressing generates a web-like structure containing microparticles which form a new, skin-compatible layer over time.

Developing a Disruptive Technology

In 2012, a research team comprising Professor Özgen Özer, Professor Evren Homan Gökçe, Assoc. Professor Sakine Tuncay Tanrıverdi and Professor İpek Eroğlu from Ege University Pharmaceutical Technology Lab grew interested in substances that could be incorporated into microparticles for treating wounds.

The team decided to focus their research on the development of biocompatible and biodegradable matrices for wound-healing applications. Through market research they became aware that chronic wounds were a huge and growing challenge worldwide. There are approximately 400 million diabetic patients around the world and 10 percent of them suffer from diabetic foot ulcers, which can lead to a complete loss of mobility. The researchers quickly recognised the technology's

potential to speed up the healing process while reducing patients' pain and thereby improving their overall quality of life.

They came up with the innovative idea of using the technology to develop a skin patch that would help the skin to heal and then disappear when the body's own cells formed new tissue. In this way, Dermalix wound dressing was developed: a novel patch made from natural skin components for treatment of chronic and open wounds. Animal experiments showed that the patch provided a fast, effective, and convenient pharmacological treatment: a single dosage led to a wound's full recovery within two weeks. Its multiple-layer structure strengthened the skin's tissue-repair mechanism thanks to microparticles loaded with the antioxidant resveratrol. Since the dermal matrix was prepared with natural skin components, there were no adverse effects.

Figure 1: Dermalix Wound Dressing



Dermalix wound dressing is a skin patch used to accelerate wound healing, especially for foot wounds caused by diabetes.

Strong IP Protection for Market Success

In 2015, the four researchers decided to turn their invention into a marketable product. They knew that commercialisation in the healthcare sector was impossible without patent protection.

“A patent is like a birth certificate in the health-care industry. If the product does not have patent protection, you may lose most of your competitive advantage in the market. If there were no patents, we would not even have a chance to get in contact or co-operate with companies.”



Evren Homan Gökçe, Sakine Tuncay Tanrıverdi, Özgen Özer, İpek Eroğlu

Team of inventors and founders of Dermis Pharma

At the time, Turkey was still practising what is called the professor's privilege, meaning that the academics were expected to file their own patent applications.¹ However, not many patents were being filed at the time due to a lack of knowledge, time, and funding. The team consulted Ege University's EBİLTEM technology transfer office (TTO), which provided guidance and encouraged the R&D team to file and submit an invention disclosure.

The TTO's preliminary assessment showed that the invention was patentable. However, the researchers were not sure if they could spare the necessary time and secure financing to follow up on the patenting process.

As a result, they transferred the IP rights to the university. This gave them full access to TTO support to manage the patent application process, as well as access to university funds to cover the costs.

1. The professor's privilege was abolished in Turkey in 2017. All inventions made by employed scientific staff are deemed to belong to the university.

2. Clarification of legal aspects such as ownership of the inventions was a prerequisite for bringing a proposal to the IP Commercialisation Committee.

Funding Protection

Takeaway: Patent cost funding can be an important factor for technology transfer in the pharmaceutical industry. It regularly takes more than 30 months until a sustainable commercialisation deal is closed.

Assessing the Technology

The university required the approval of its IP Commercialisation Committee to process the patent application. The committee aims to make the best possible use of the university's funds to promote promising inventions, achieve revenue payback, and ultimately bring recognition to the university.

In preparation, the Ege University EBİLTEM TTO conducted a comprehensive technology assessment in three major dimensions:²

- **Technical:** technology-readiness level, feasibility, novelty, development needs, possible claim coverage;
- **Market:** market size, market predictions, value propositions, status of freedom to operate, competitors; and
- **Strategy and Finance:** compatibility with university innovation strategy, portfolio position, project sustainability, inventor support, financial support from stakeholders.

Technology Assessment With IPscore

Takeaway: The TTO team used the EPO's free IPscore tool as a basis for the technology assessment. IPscore makes it possible to qualitatively analyse, graphically visualise, and document the pros and cons of technologies and research projects identified during the assessment.

The committee was won over by the invention's technical novelty, commercial opportunities, and a target market of over 50 million patients worldwide.³ As a result, the IP rights were transferred to the university

3. IDF Diabetes Atlas, International Diabetes Federation, Sixth Edition, 2013.

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“Technology evaluation or assessment are key elements in the technology transfer process in order to select the most valuable technologies to focus the efforts put into commercialisation.”



Mustafa Çakır
Patent attorney and
commercialisation manager at
the time at EBİLTEM TTO

in return for institutional technology transfer services to bring the invention to the market.

The positive decision of the IP Commercialisation Committee marked the starting point in the team’s entrepreneurial journey. Based only on a Turkish priority patent application, the TTO team developed an IP protection strategy, with a strong claim set and broad patent protection around the core invention. In addition, to keep all commercialisation options open, it agreed to seek broad geographical protection to cover all the main markets.

Challenging the Options

Regulations categorised Dermalix wound dressing as a medical product (medical device, class 3), not a drug. This helped to speed up the certification process as the market entry requirements for medical products were not as strict. However, the categorisation required further tests for approval that needed to be funded.

The TTO team considered two options: to license the patented technology at this early stage, or to find a partner who would provide funds and know-how to develop the technology by increasing its readiness level so that it could meet market requirements.

Before reaching out to international companies for licensing or collaboration, the TTO and the research team unanimously agreed to implement the IP protection strategy developed and to extend the patent protection by using the Turkish priority application to file an international application under the Patent Cooperation Treaty (PCT). This secured the option to obtain patent protection in a large number of countries while also providing an important advantage: more time to decide in which countries protection of the invention should eventually be sought.⁴

Initially, the inventor team and the TTO were inclined to license the technology to either a Turkish or a global pharmaceutical company, since establishing a spin-off was considered riskier and more time-consuming. The TTO team used different channels, such as medical clusters, industry associations, and direct personal contacts to identify potentially interested

companies. However, this approach did not lead to any concrete results because the technology was still not considered to be mature enough and success was too uncertain.

The second option to engage either Turkish or global pharmaceutical companies in a research co-operation failed as well. After analysing feedback from various established contacts, as well as conducting several interviews with Turkish and global executives of pharmaceutical companies and carrying out an additional market assessment, the team realised that the “not-invented-here” syndrome of many large pharmaceutical companies was too large an obstacle to overcome. Although the technology had some initial favourable in vitro results from cell-line and animal tests, global pharma companies still considered it too much effort to make it market-ready.

The Turning Point

Accessible local grants were quickly being exhausted. New applications to local and European Union Horizon 2020 grants required substantial time and effort, with an uncertain outcome. Nevertheless, the TTO team and the inventors still believed that Dermalix wound dressing could change the wound care solutions market and deserved to be tested in the market.

Thankfully, an award from a start-up acceleration programme opened up a new avenue and directed the commercialisation strategy towards a university spin-out. The special programme provided hands-on training to the inventor team on how to assess the product-market fit of a technology and how to evaluate a product’s market potential. It provided the opportunity to conduct many expert interviews, as well as further market studies, and to visit new and established wound care providers and pharmacies in Istanbul to learn about the critical dynamics of the market.

Start-Up Creation

Takeaway: Having a strong business orientation is a great benefit for academic spin-out formation.

4. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries through the filing of a single, “international” patent application instead of several separate national or regional ones. Applications under the PCT can be filed directly or within the 12-month period provided for by the Paris Convention for the Protection of Industrial Property from the filing date of a first application, which has legal effect in all of the over 150 contracting states to the PCT. When an applicant files a PCT application, in most cases they have up to an additional 18-19 months from filing (or usually 30-31 months from the filing date of the initial patent application from which priority is claimed) before they have to begin the national phases with individual patent offices and to fulfil the national requirements.

The Dermalix wound dressing team was selected as the most successful team and, due to its favourable product-market fit characteristics, the technology was ranked first in the start-up acceleration programme. This gave the research team national visibility and encouraged it to invest yet more time and effort in its entrepreneurial activities.

Both the TTO and the researchers realised, however, that field-specific support was necessary for this specialised application area. The technology promised market value, but needed the expertise and mentorship of medical and commercial experts. An improved and well-defined start-up commercialisation plan had to be defined to attract funding, investors, and big-pharma companies as partners or customers.

University Spin-Off Interaction

Around that time, EBİLTEM TTO was selected as an official partner of the TÜBİTAK entrepreneurship initiative and entrusted to implement a start-up funding and acceleration programme. With a revised business concept targeting spin-off creation, the Dermalix wound dressing team was successfully selected as one of the most feasible technology-based submissions. Their business concept was awarded TRY 150,000 (EUR 50,000 in 2015) in government funding for the creation of a start-up called Dermis Pharma with the aim of increasing the technology's readiness from technology-readiness level (TRL) 4 to 6.⁵

In accordance with its IP policy, Ege University expressed an interest in becoming a shareholder of the spin-off company in return for financial and in-kind contributions. The technology patented by the university was transferred to the spin-off company in return for an equity deal through a dedicated agreement signed between the parties. This was the first example of its kind, since the tech-transfer ecosystem was in its infancy in Turkish universities. The partnership agreement between the university and Dermis Pharma allowed the TTO to continue supporting the inventor team on its entrepreneurship journey.

University Innovation Ecosystem

Takeaway: A well-defined IP policy, qualified commercialisation experts, the support of university administration, and a widespread network are critical success factors for IP-based spin-off companies.

IP Strategy and Market Segmentation

As the PCT patent application was approaching the

5. There are nine TRLs. TRL 6 is defined as technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).

end of the 30/31-month period, the team had to decide where to obtain patent protection.

The TTO team further developed the initial market analysis with the goal of identifying the most promising countries and regions in which Dermis Pharma could commercialise the invention. In addition, the TTO team used its personal networks at organisations such as the Licensing Executives Society International, the Enterprise Europe Network and the European IP Helpdesk, as well as contacts in big pharma companies, to inquire about their patent strategies for wound care technologies.

IP Expertise

Takeaway: Involving a global IP and licensing network can provide deeper insights and novel pathways for better IP strategy and IP management facilitating commercialisation.

This led to the selection of a wide set of patent jurisdictions, ensuring the best chances for subsequent commercialisation: the U.S., Canada, Russia, China, Japan, South Africa, Brazil, Australia, and Europe (validated in 36 countries through the European patent system under the European Patent Convention).

Approaching Venture Capital Companies

As well as the initial start-up financing, the young company still needed additional funds to further develop the technology, complete clinical tests, and progress with the patenting process. Through its national network, the TTO arranged pitching sessions with several venture capital (VC) companies in Turkey, two of which selected Dermis Pharma for more in-depth assessments.

Following an extensive due diligence analysis, the TTO selected one of the companies. Despite the company's difficult terms and conditions, the parties managed to reach a consensus and sign an investment agreement.

Criteria to be Considered When Assessing Venture Capital:

- Business networks
- Prior knowledge about technology and targeted markets
- Past experience in life-science technologies
- Flexibility
- Equity sharing strategy
- Capacity for business growth
- Personal attitudes
- Business philosophy
- Company development perspective
- Relations with former co-investors

The Real Power of Patents

The funds provided by the VC company were used to finance clinical trials, technology development needs, and patent protection in ten countries. However, establishing production and sales pipelines and obtaining regulatory approval from different countries still required significant additional funding.

Dermis Pharma did not want to sacrifice too much of its autonomy in return for further investment. The researchers and the TTO therefore decided to pursue an alternative path and collaborate with an established pharma company.

Technology Transfer Models

Takeaway: Spin-off and corporate partnership models are attractive approaches that can be widely implemented by technology transfer offices.

The Turkish pharmaceutical company Abdi İbrahim was soon identified as a strong potential partner. In line with its strategic vision for 2025, Abdi İbrahim was aiming to identify new products for international markets and assessing acquisition and partnership opportunities. Last but not least, it had gathered prior collaborative research experience with Ege University's research teams.

Abdi İbrahim's Open Innovation Strategy:

- Expand and improve the product portfolio by relying on local scientists and universities
- Develop new R&D projects with universities in order to enhance innovation capacity and stay close to the latest developments
- Develop a vision to establish a well-structured IP portfolio to become one of the leading companies in the respective sector
- Be open to adding new over-the-counter (OTC) products to the portfolio in growing treatment areas such as oncology, metabolism (osteoporosis, diabetes, obesity), the immune system, ophthalmology, the cardiovascular system, and the respiratory system
- Be able to quickly and successfully add original and generic biotech products in international markets to the portfolio through start-up investments and academic partnerships
- Be open to opportunities to mutually develop products to improve patients' lives

The key to convincing Abdi İbrahim proved to be the product's well-established patent protection with its broad geographical coverage, as well as it being a perfect match for patients' needs in terms of price-benefit ratio.

"We always think that it is all about the development of new technologies. No, it is all about converting these new technologies into solutions touching people's lives. And technology transfer is one of the best ways for early-stage university technology to do so."



Professor Fazilet Vardar Sukan

TTO director at the time and Professor at Ege University at the time at EBİLTEM TTO

The TTO team helped the spin-off company to negotiate with Abdi İbrahim. It was important to carefully define how much of Dermis Pharma's rights and autonomy could be given up in the course of the negotiation.

Preparing for Negotiations

Takeaway: It is important to hold training sessions with academic inventors to inform them about the terms of the possible deal and provide negotiation tips before any meeting with venture capital companies.

The main issues concentrated on developing strategies for better commercialisation outputs:

- Customer segments
- Marketing channel
- Cost and pricing management
- Sustainable know-how management and transfer from researchers to the company
- Developing the best patent protection strategy in different countries
- Possible exit strategies for the research team members

After two years of negotiations, the two signed a deal, assigning all patent rights from Dermis Pharma to Abdi İbrahim. Dermis Pharma remained responsible for R&D activities, and the inventors were able to stay on as researchers at the university. Abdi İbrahim, strong at logistics and in bringing a product to market, took over responsibility for production and marketing. This clear-cut definition of roles helped to eliminate potential conflicts.

The product Dermalix wound dressing received CE certification for meeting EU standards for health, safety and environmental protection. It has been on the shelves in Turkey since June 2021. Abdi İbrahim is also ready to sell Dermalix wound dressing in international

markets, after clarifying the marketing strategy.

Beyond the potential commercial success of Dermalex wound dressing, Dermis Pharma is growing steadily as a well-respected research and development company catering to pharmaceutical and cosmetic sectors. ■

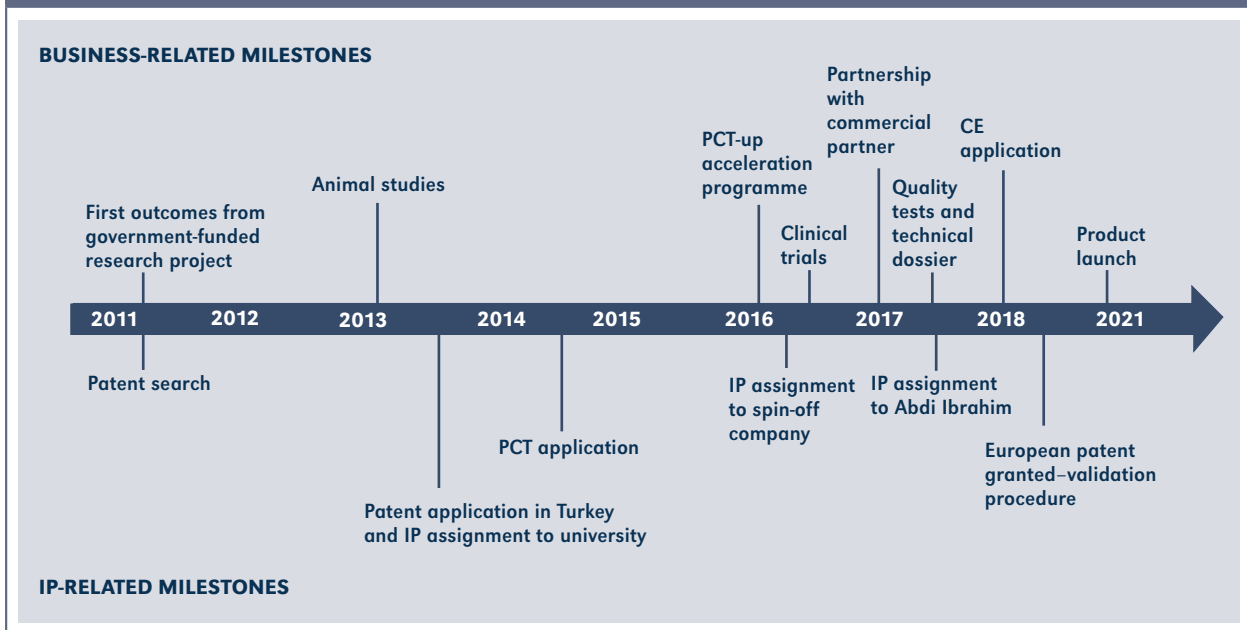
Available at Social Science Research Network (SSRN): <https://ssrn.com/abstract=4099733>

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

Table 1. Patent Information

| EPO Patent Number | Title | Priority Date |
|-------------------|---|---------------|
| EP3024505B1 | A dermal matrix and production method thereof having synergistic effects comprising microparticles, which provide tissue repair | 25.07.2013 |

Figure 2: Technology Transfer Timeline



Source of IP

Özgen Özer, Evren Homan Gökçe, Sakine Tuncay Tanrıverdi, İpek Eroğlu

- Four female inventors and founder fo Dermis Pharma
- Original owners of IP rights (due to professor's privilege)

Ege University

- Established in 1955, one of Turkey's leading scientific institutions with a strong research infrastructure and 3,150 academic staff
- Owner of IP rights during patent application: IP rights later transferred to Dermis Pharma

Tech Transfer Catalysts

EBİLTEM Technology Transfer Office

- Pioneered as the first university-industry co-operation interface institution in Turkey in 1994
- Established to strengthen university R&D through industry co-operation and technology commercialisation
- Provided guidance and encouragement to the R&D team to file an invention disclosure

- Conducted a comprehensive technology assessment covering technical, market, strategy, and finance aspects

- Developed an IP protection strategy

TÜBİTAK and venture capital company

- Provided funding for clinical trials and patent protection

IP Commercialisation

Dermis Pharma (dermispharma.com)

- IP-based university spin-off
- Founded in 2016 to commercialise the technology for chronic wound care
- remains responsible for R&D activities

Abdi İbrahim

- Commercialisation partner, responsible for production and marketing
- Final IP Assignee (from Dermis Pharma)
- A market leader in the pharmaceutical industry in Turkey for more than 15 years, with a history going back 109 years
- Prior experience in collaborative research with Ege University
- Products are sold under Turkish trademark Dermalix (201672034)

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Photos: Dermis Pharma

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