



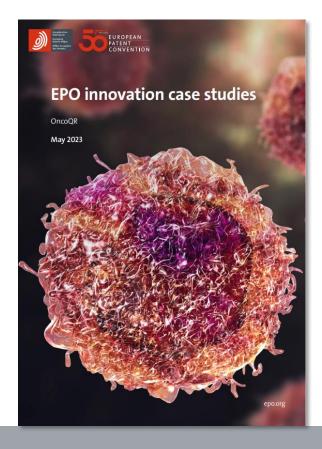
From Lab to Market: Successful Tech Transfer Journeys Driving Innovation Against Cancer

OncoMark: Smarter Prognostic Tests for Early-Stage Breast Cancer *Ciaran O'Beirne, Head of Knowledge Transfer – University College Dublin*



Agenda

- Setting the Scene: EPO Innovation Case Studies
- OncoMark: Smarter Prognostic Tests for Early-Stage Breast Cancer
- Outlook: Upcoming Training Sessions & Joint Activities

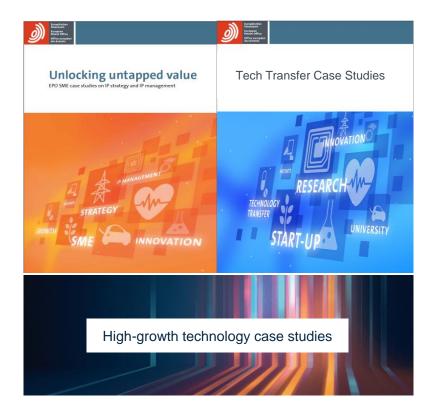


Setting the Scene: EPO Innovation Case Studies

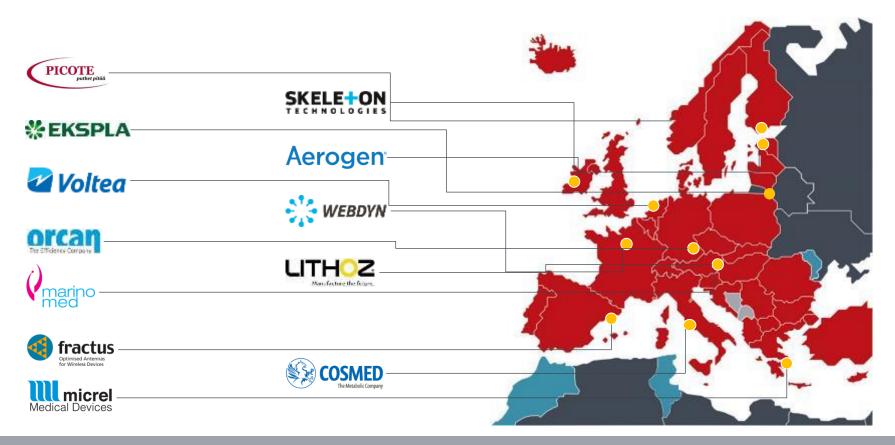
EPO innovation case studies

- Over 30 case studies on how
 European SMEs can create strategic
 value from patents
- How patents facilitate tech transfer from European research institutions
- Diverse tech transfer and business model scenarios
- Good practices in IP strategy and IP management

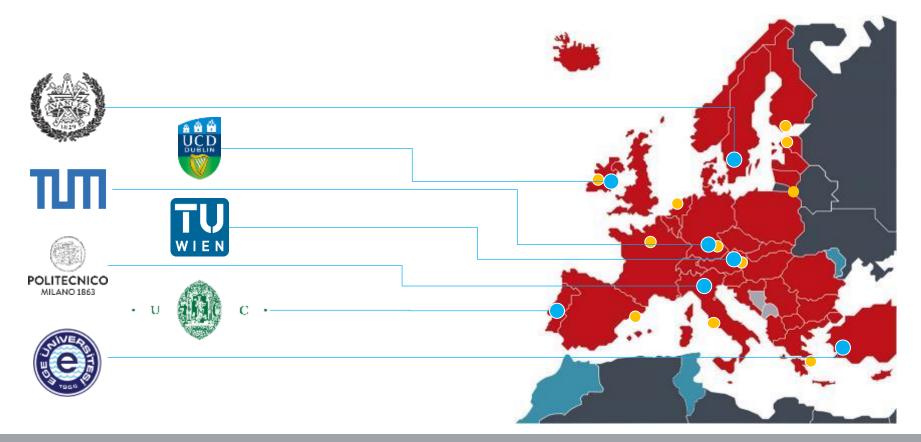
www.epo.org/case-studies



EPO SME case studies



EPO technology transfer case studies



EPO High-growth technology case studies





Build-to-sell

Kindred Bravely (fashion, e-commerce - USA)	+
Dr Paul Atherton (fibre optics, energy storage, biotechnology - UK)	+
APS Technology Group (electrical machinery, software - USA)	+
Bender MedSystems (biotechnology - Austria)	+

Open innovation



Licensing

IonQ (IT Services - USA)	+
Unilab (pharmaceuticals - Philippines)	+
Dispelix (waveguide displays - Finland)	+

Growth financing

Roboze (additive manufacturing - Italy)	+
Plasmapp (medical electronics - South Korea)	+
DyeMansion (additive manufacturing - Germany)	+

3 new case studies on IP to fight cancer

Damae Medical (FR)



Main product	Business model
Advanced	Product sales
medical imaging	and related
system	services

OncoMark (IE)



Main product Technology transfer model Diagnostic University spinoff Company acquisition

OncoQR (AT)



Main product

Technology transfer model

Immunology vaccines Technology licensing

OncoMark:

Smarter Prognostic Tests for Early-Stage Breast Cancer



EPO TECHNOLOGY TRANSFER CASE STUDIES OncoMark

Smarter prognostic tests for early-stage breast cancer

Abstract

OncoMaSIR is a multi-parameter prognostic test for early-stage breast cancer that can rapidly, accurately and reliably stratify patients into low or high risk of cancer recurrence. This aids clinicians confidentially determine the best treatment options, thus avaiding overfreatment with unnecessary and aggressive chemotherapies. The test is based on patented technology that arose from a collaboration between Prof. Adrian Bracken at Trinity College Dublin (TCD) and Prof. William Callagher at Univensity College Dublin (TCD) in 2012 and was then exclusively icensed to OncoMark, a UCD spin-out, in 2014. OncoMark subsequently developed and validated the test which led to an acquisition of the company by a large US frim and the creation of a new start-up company.



Cepheid's GeneXpert platform, which will be used to deliver the OncoMasTR technology to the clinic

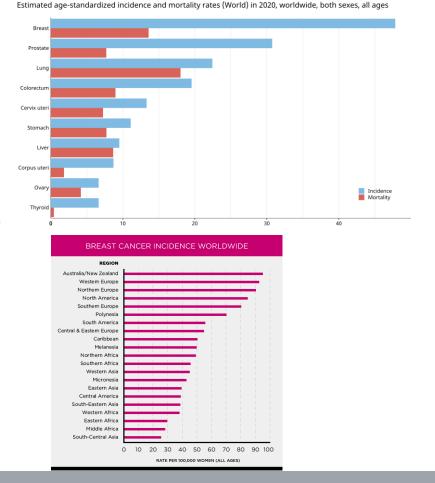
Background

Breast cancer is the most common cancer among

adults, and it is the first or second leading cause of

female cancer deaths in 95% of countries:

- 2.3 M women diagnosed with breast cancer in 2020
- 685,000 deaths globally



Source: World Health Organisation (WHO)

BREAST CANCER DIAGNOSTICS MARKET SIZE, 2020 TO 2030 (USD BILLION)

PRECEDENCE RESEARCH

Background – market trends

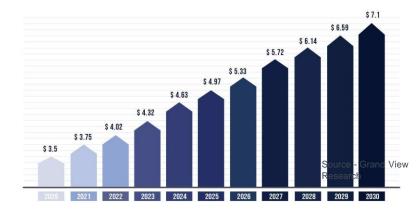
Global breast cancer diagnostics market

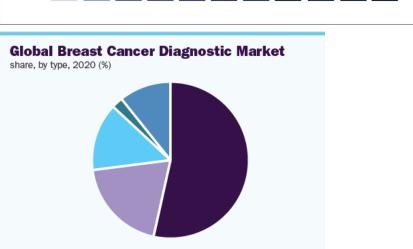
size valued at ~USD 4.0 billion in 2022

and is expected to expand at a compound

annual growth rate (CAGR) of 7.0% to the

end of the decade





Background

- Patient outcomes are consistently improving
- However, the heterogeneous nature of breast cancer presents significant clinical challenges in determining disease progression, particularly when the disease is detected at an early stage
- By default, the majority of patients are prescribed endocrine therapy in combination with chemotherapy yet chemotherapy may only benefit around 30% of women with early-stage breast cancer
- Despite this, many women are still prescribed chemotherapy even though it can have significant physical, emotional and psychological side-effects.

Main players involved in the technology transfer and their roles

- University College Dublin and Trinity College Dublin leading research institutions
- Technology Transfer Offices (TTOs) experienced staff in both institutions
- OncoMark a UCD spin out company focused on developing cancer diagnostics
- Cepheid a leading American molecular diagnostics company
- OncoAssure a spin off company developing new panels of cancer biomarkers for applications in prostate cancer, melanoma and other cancers

Overview - 10+ year journey starting from research to product

Research collaboration between University College Dublin (UCD) and Trinity

College Dublin (TCD) led to the development of a patented **prognostic test for** early-stage breast cancer called **OncoMasTR**

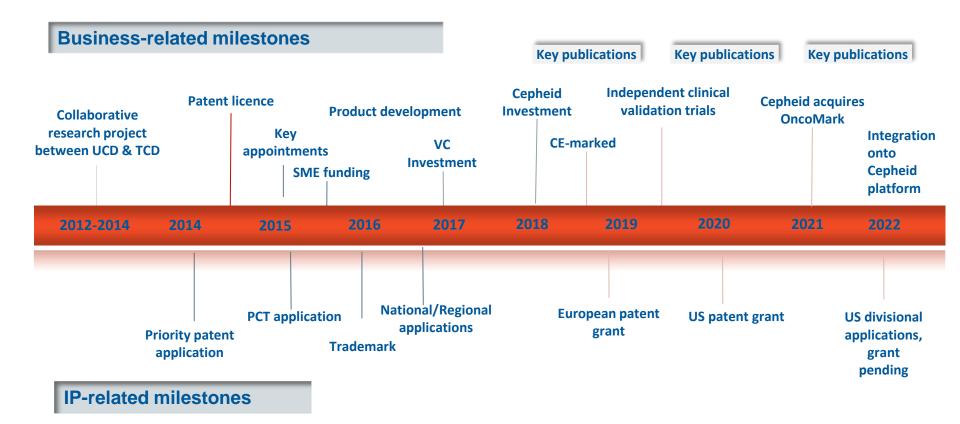
 Technology licensed to OncoMark who developed the OncoMasTR product to rapidly and accurately stratify patients into low or high risk of cancer recurrence

OncoMark acquired by Cepheid

Product due to be launched as Xpert® Breast Cancer Insight by Cepheid



OncoMasTR technology - timeline



Analysis of IP issues

IP Management - How and by whom?

- Creation jointly developed by UCD and TCD
- Selection
 Ied by TTOs in UCD and TCD
- Protection led by TTOs in consultation with OncoMark
- Value creation led by OncoMark and Cepheid

IP management before, during and after the technology transfer

- Background IP
 - UCD and TCD research expertise in oncology and experienced TTOs
 - OncoMark expertise and know how in diagnostics and prognostics
- Foreground IP
 - Pre-licence –protection strategy led by UCD and TCD
 - Post licence initially led by OncoMark in consultation with UCD and TCD. Now led by Cepheid..

Analysis of strategic issues

- Leveraging research funding
- Experienced management
- Clinical validation
- Partnering with a larger company



Prof William Gallagher Co-founder of OncoMark



Des O'Leary CEO, OncoMark



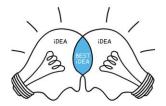


Scott Campbell Senior VP and General Manager, Oncology, Cepheid

Key Lessons

Collaborate to innovate

 A research collaboration that brings together the diverse expertise and interests of partners can lead to groundbreaking inventions with commercial potential.



Research funding

 Research grants can give time and flexibility to develop technologies and leverage collaborations while at the same time prevent early dilution of equity in the spin-out company.



Key Lessons

Spin-outtoincreaseTechnologyReadiness Level (TRL)

 For university inventions, licensing the technology to a spin-out company can help increase the TRL and the probability of a successful commercial outcome.

Patented IP is a key asset

 Strong patent protection is an essential asset for a life science spin-out company in helping to secure initial investment.

TRL 9	System proven in operational environment
TRL 8	System complete and qualified
TRL 7	Integrated pilot system demonstrated
TRL 6	Prototype system verified
TRL 5	Laboratory testing of integrated system
TRL 4	Laboratory testing of prototype component or process
TRL 3	Critical function, proof of concept established
TRL 2	Technology concept and/or application formulated
TRL 1	Basic principles are observed and reported



Key Lessons

Experienced management

• The appointment of a commercially experienced CEO can be key to the company's ability to raise investment and drive product development.

Networking

 Attendance at medical/industry conferences is essential to keep abreast of market trends and to network with key stakeholders. Having a network of collaborators can also greatly assist clinical validation.

Clinical validation

 Clinical validation is usually a prerequisite for partners to consider the business opportunity. Partnering can be instrumental to achieve that at reasonable costs.

Role of TTO

- Skilled and experienced staff
 - Quickly agreed a Joint Ownership Management Agreement (JOMA) when IP was created.
- Engage external patent attorney with domain expertise
- Good relationship with researchers and company
- Pragmatic approach to legal agreements
 - Benchmark financial terms against industry norms.
 - Recognise the tangible and intangible assets of the licensee company.
 - Agree key development and commercial milestones. Be willing to amend as necessary.

Let's talk!

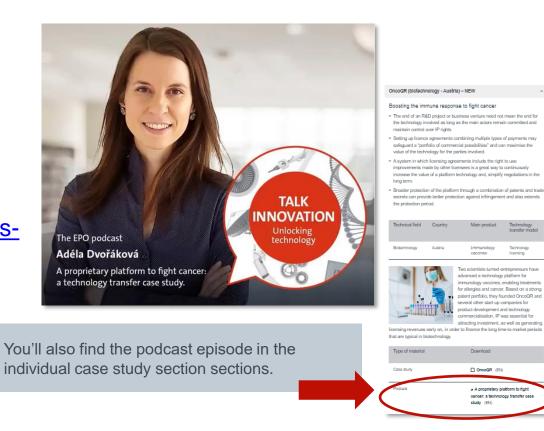


Outlook: Upcoming Training Sessions & Joint Activities

"Talk Innovation" podcast

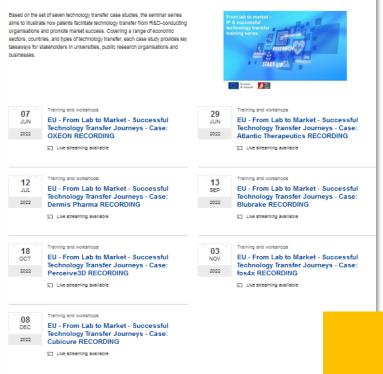
Listen in!

https://www.epo.org/newsevents/podcast.html



From Lab to Market: Recordings 2022

From Lab to Market - RECORDINGS 2022



Training Cooperation with EPO

Patent protection for EU funding beneficiaries

Training cooperation with the European Patent Academy of the EPO

Patent protection for EU funding beneficiaries

This lecture series, organised in co-operation with the European Patent Academy, addresses the IP-related aspects of EU-funded projects in five areas: medical technologies, artificial intelligence, green technologies, digital communication and biotechnology.

It introduces the main aspects of IP management: notably IP ownership, protection and exploitation. Each lecture explores the interface between patents and the respective technical field. The lectures may be of interest to a variety of audiences, from researchers to technology transfer officers. The online sessions include Q&A and are complemented with optional selfpaced courses.



Training and workshops

EU - Webinar EPO Coop: Patent protection for EU funding beneficiaries - Green Technologies

Live streaming available





Training and workshops

EU - Webinar EPO Coop: Patent protection for EU funding beneficiaries - Digital communication

Live streaming available

15 NOV 2023

Training and workshops EU - Webinar EPO Coop: Patent protection for EU funding beneficiaries - Biotechnology

Live streaming available

Registration: www.ec.europa.eu/ip-helpdesk

High-growth technology business (HTB) community

Goals

- Support for decision-makers & IP professionals in tech driven enterprises
- Sharing how intellectual property can support their business
- Training in IP strategy, operational excellence, financing and strategic transactions

linkedin.com/company/htbcommunity epo.org/sme

Join the community

- Stay updated on best practices
- Get access to training material
- Learn about upcoming offers







European Patent Academy

Upcoming HTB events

HTB forum: Build-to-sell

29 June 2023, 17:00-19:00 (CEST)

✓ Case study presenter: Ghassan Kassab, Founder & CEO of 3DT Holdings & California Medical Innovations Institute (USA)

✓ International expert panel chaired by Juergen Graner, Founder and CEO, Globalator (USA)

Register: Event Build-to-Sell Deadline: 29 June 2023 HTB forum: IP strategy and management 30 November 2023, 10:00-12:00 (CET)

✓ Case study presenter: Thomas Nieraad, co-founder and Board Chair, Connect One Digital AG

✓ International expert panel chaired by Prof. Alexander Wurzer, Director IP Management Education, CEIPI

Register: Event IP Strategy and Management Deadline: 30 November 2023

European IP Helpdesk

- Service initiative of the European Commission
- Addressing current and potential beneficiaries of EU-funded projects and EU SMEs
- Free-of-charge first-line support on intellectual property (IP)
- Hands-on IP and innovation management support
- International pool of IP experts from various thematic fields
- Unique cooperation scheme with the Enterprise Europe

Network: 44 ambassadors from 27 EU countries

Visit: <u>www.ec.europa.eu/ip-helpdesk</u>



Keep an eye out for updates





Unitary Patent System

Unifying Europe's market for technology and innovation





ONE patent for a single territory of 17 EU member states **ONE court,** the Unified Patent Court, harmonises case law ONE market 300 million consumers; GDP over €12 trillion **ONE annual fee** paid in euros to the EPO

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Thank you for joining us today!

DISCLAIMER

The European IP Helpdesk provides free-of-charge first-line support on IP-related issues aiming to help current and potential beneficiaries of EU-funded projects, as well as EU SMEs, manage their Intellectual Property assets.

The European IP Helpdesk is managed by the European Commission's European Innovation Council and SMEs Executive Agency (EISMEA), with policy guidance provided by the European Commission's Directorate-General for Research and Innovation (DG RTD).

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