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The Internet Of Bodies: Connectivity Enhancing Humans

*By Eleftheria Stefanaki, LL.M**

1. Introduction

In the year 2024, a world without the internet seems unimaginable. Today we take our connectivity for granted; however, it has only been a mere 50 years since the internet appeared. Mark Weiser, a pioneer of computer science, identified the need for connectivity when the internet was making its first commercial appearances. In his article "The Computer for the 21st Century," he referred to "ubiquitous computing" as the transformation of everyday objects into computers.[1] His idea of a room where electronic devices could work as a computer and connect to each other was the forerunner to the Internet of Things (IoT) as we know it.

Weiser's vision sparked the development of the IoT, where the use of the internet allows physical objects to connect with each other.[2] The International Organisation for Standardisation defines the IoT as "an infrastructure of interconnected objects, people, systems and information resources together with intelligent services to permit them to process information of the physical and the virtual world and react."[3] The capabilities of the IoT have transformed daily objects into intelligent tools that make consumers' lives more convenient, efficient and safe.

In other words, the IoT has and continues to revolutionise the way we view the world. Everything is becoming "smart(er)" and digitised. It is estimated that by 2030, the number of IoT devices will reach 30 billion worldwide[4]—3.5 times larger than the projected world population.[5] This connection wave has impacted a multitude of sectors like health, transport and manufacturing.[6] Indeed, it seems that no area has been immune to the advance of connectivity. Even the human body itself is the subject of connectivity developments. This is where the Internet of Bodies (IoB) emerges, unlocking immense possibilities for the present and the future of humanity.

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The significance of the IoB is apparent by the constantly emerging initiatives, projects and investments directed to it. A characteristic example is the funding of pilot projects for the purpose of supporting digital innovation in the healthcare sector (IoT in healthcare) by the European Union, amounting in 2020 to EUR 60 million.[7] In addition, industry players acknowledge the prominence of IoB devices and the considerable influence that they (will) have in life as we know it.[8]

Against this background, this article introduces and explores the Internet of Bodies. It will present several examples of widespread IoB devices as well as their utility. Finally, it will explain the importance of ultra-fast and highly reliable connectivity for the IoB to reach its full potential.

2. The Internet of Bodies Explained: Definition and Taxonomy

a. What is the IoB?

The notions of the cyborg and bionic human have

*The views expressed in this article are those of the author and do not necessarily reflect the opinions of Ericsson.

1. Mark Weiser, "The Computer for the 21st Century" (Scientific American website, 1991) <*https://www.lri.fr/~mbl/Stanford/CS477/papers/Weiser-SciAm.pdf*, accessed 22 March 2024.

2. This connection is possible because of the integration of microcontrollers and smart systems. See Friedemann Mattern and Christian Floerkemeier, "From the Internet of Computers to the Internet of Things" in Kai Sachs, Ilia Petrov and Pablo Guerrero (eds), From *Active Data Management to Event-Based Systems and More* (1st edn, Springer 2010) 242.

3. ISO/IEC JTC 1, "Internet of Things (IoT)" (2014) 1, 3 <*https://www.iso.org/files/live/sites/isoorg/files/developing_standards/docs/en/internet_of_things_report-jtc1.pdf*, accessed 22 March 2024.

4. "Number of Internet of Things (IoT) connected devices worldwide from 2019 to 2023, with forecasts from 2022 to 2030" (Statista, 2023) *https://www.statista.com/statistics/1183457/iot-connected-devices-worldwide/*, accessed 22 March 2024.

5. "Global Issues: Population" (United Nations official website, 2024) *https://www.un.org/en/global-issues/population*, accessed 22 March 2024.

6. "IoT sectors enhanced by cellular standards" (4iP Council website) *https://www.4ipcouncil.com/standards/iot-sectors-enhanced-by-cellular-standards*, accessed 22 March 2024.

7. European Commission, "The Internet of Things in European healthcare | Shaping Europe's digital future" (*europa.eu*), accessed 22 March 2024.

8. See more at "10 Hot Consumer Trends 2030: The internet of senses" (Ericsson official website) *https://www.ericsson.com/en/reports-and-papers/consumerlab/reports/10-hot-consumer-trends-2030*, accessed 22 March 2024.

been attractive to the human imagination for decades, becoming a significant part of pop-culture through literature and cinema.[9] Although the terms "cyborg" and "bionic human" are generally distinguishable, they both refer to any potential improvement or enhancement of the human body through technology.[10] The merging of human and machine is, however, no longer the subject of science fiction, rather it is unfolding in the present. Either for therapeutic reasons or for vanity and convenience, many people are excited to exploit the newest technological inventions for their advantage.

The term "Internet of Bodies" was brought into the legal realm by Professor Andrea Matwyshyn in 2019.[11] In her article *The Internet of Bodies*, she thoroughly explores the IoB, which she defines as a "network of human bodies whose integrity and functionality rely at least in part on the internet and related technologies, such as artificial intelligence."[12] The possibilities enabled by connectivity seem endless, especially when an enhanced person can become a member of a community, communicating with others through in-body devices. This way, the human body is becoming a platform, transmitting data directly to external or internal devices (*e.g.*, a smart ring).[13] In the near future, a connected body might even become a platform capable of transmitting and receiving data from other human bodies (*e.g.*, brain-to-brain interfaces).

This connection between human and machine can be achieved through a palette of diverse technologies and solutions, from a simple smartwatch to more technologically advanced bionic eyes.[14] The future of inter-human connectivity holds unimaginable opportunities. Despite being encompassed by the IoB, the numerous different devices do not necessarily share the same function, application, effect, or interaction with the human body.[15] In the next chapter, we describe the current classifications of the IoB according to their location and their scope.

b. Types of IoB Devices

i. IoB Devices Based on their Purpose

Before delving deeper into IoB-specific categorisation, we will examine the significant dichotomy between medical[16] and non-medical devices. The European legislator has given a broad definition of what constitutes a medical device in Article 2 of EU Regulation 2017/745. In essence, a medical device refers to any device—including implants and software—that has been manufactured with the intention of being used by humans for "specific medical purposes," such as diagnosis, prognosis, monitoring and treatment of disease, injury or disability.[17] Thus, interconnected devices falling within the scope of this definition, such as internet-connected cochlear implants[18] or neural interfaces (*e.g.*, brain implants) for Parkinson's treatment[19] are considered medical IoB devices.

The use and popularity of these devices disseminated during the COVID-19 pandemic. The vitals of people infected with the virus were monitored with the help of these devices in a safe and contact-free manner.[20] In

9. Adam Belloto, "An Early History of Our Cinematic Cyborgs" (Film School Rejects, 2014) *https://filmschoolrejects.com/an-early-history-of-our-cinematic-cyborgs-9707632eef2a/*, accessed 22 March 2024

10. Across the literature, there are several schools of thought and, subsequently, definitions on cyborg and bionic human. According to Sydney Perkowitz, the main difference between cyborg (cybernetic organism) and bionic human is that the former is dominated by its mechanical parts ("a brain in a box"), while the latter maintains its humanity apart from a small number of implants or replacements. *See* Sidney Perkowitz, Digital People—From *Bionic Humans to Androids* (1st edn, Joseph Henry Press Washington DC 2004) 5.

For Woodrow Barfield, the cyborg is more likely to be considered a 'genus,' encompassing any potential improvement or enhancement of the human body through technology.[11] *See* Woodrow Barfield, *Cyber-Humans—Our Future with Machines* (1st edn, Springer 2020) 4.

Adopting a more ontological definition, Donna Haraway in her *Cyborg Manifesto* describes the cyborg as "a hybrid of machine and organism, a creature of social reality as well as a creature of fiction." *See* Donna J. Haraway, "A Cyborg Manifesto: Science, Technology, and Socialist-Feminism in the Late 20th Century" in Joel Weiss, Jason Nolan, Jeremy Hunsinger, Peter Trifonas (eds), *The International Handbook of Virtual Learning Environments* (1st edn, Springer 2006), 117.

11. Andrea Matwyshyn, "The Internet of Bodies" (2019), 61 *William & Mary Law Review* 77. *https://scholarship.law.wm.edu/wmlr/vol61/iss1/3/*, accessed 22 March 2024.

12. Matwyshyn (n 11) 77.

13. Michael Sawh, "Best smart rings: Put a ring on it" (Wareable website, February 7 2020) <*https://www.wareable.com/fashion/best-smart-rings-1340*, accessed 22 March 2024.

14. Muireann Quigley and Semande Ayihongbe, "Everyday Cyborgs: On Integrated Persons and Integrated Goods" (2018) 26(2) *Medical Law Review* 276, 279.

15. Abdulkadir Celik and Ahmed M. Eltawil, "The Internet of Bodies: The Human Body as an Efficient and Secure Wireless Channel" (April 2022), *IEEE Internet of Things Magazine*, 1. *https://www.techrxiv.org/users/663061/articles/677736-the-internet-of-bodies-the-human-body-as-an-efficient-and-secure-wireless-channel*, accessed 22 March 2024.

16. The medical IoB devices are also known as Internet of Medical Things or eHealth devices.

17. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L 117/17, art 2.

18. Celik and Eltawil, (n 15) 2.

19. "iHuman perspective: Neural interfaces" (The Royal Society, 2019) *https://royalsociety.org/news-resources/projects/ihuman-perspective/*, accessed 22 March 2024.

20. World Economic Forum, "Shaping the Future of the Internet of Bodies: New challenges of technology governance" (WEF, July 2020) < *https://www3.weforum.org/docs/WEF_IoB_briefing_paper_2020.pdf*, 8, accessed 22 March 2024.

addition, remote monitoring of carriers and potentially-infected individuals in general assisted with prevention and control of COVID-19.

On the other hand, non-medical IoB devices—as given away by their name—are mostly defined negatively. Any device that is non-medical according to the above definition, or aims to enable self-augmentation might be included into non-medical devices.[21] Another term that could be used is consumer IoB devices (to distinguish with the ones meant for patients).[22] The latter may be used for recreational, educational, communicational or even military purposes.[23] For example, both Apple and Meta have recently marketed their Augmented Reality/Virtual Reality headsets that offer an immersive experience on simple activities such as watching Netflix or playing video games.[24] Another, more eccentric non-medical IoB device is Duo Skin, a tattoo-like on-skin interface developed by the MIT Media Lab in collaboration with Microsoft.[25] This device can control electronic devices (*e.g.*, the user's cell phone) and store data.

Subcategories for medical and non-medical devices have also been proposed.[26] For instance, the U.S. Food and Drug Administration (FDA), believes that some non-medical IoB devices encouraging a healthy lifestyle should be classified as "general wellness" devices. Some examples of such devices would be Fit-Bit, ingestible "smart pills" for health-monitoring[27] or electronic skin.[28] In addition, there are many devices that incorporate both medical and non-medical functions.[29] Some examples include: i) eye lenses measuring the user's glucose levels, whilst being used to translate texts in different languages;[30] and ii) an artificial hippocampus assisting with the restoration and the enhancement of the person's memory.[31] These devices might be the future of the IoB, combining the attributes of medical devices necessary for patients, with the perks and endless possibilities provided by non-medical devices.

ii. Generations of IoB Devices

Apart from the purpose-oriented classification of IoB devices, Matwyshyn introduced a categorization method comprised of three generations based on their interaction with and proximity to the human body. The first generation refers to body external devices,

21. It needs to be noted here that under the scope of Regulation (EU) 2017/745 fall several devices that do not have an intended medical purpose, as listed in Annex XVI of said Regulation. These devices are the following: 1. Contact lenses or other items intended to be introduced into or onto the eye; 2. Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings; 3. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing; 4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty; 5. High intensity electromagnetic radiation (*e.g.*, infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment; 6. Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

For these devices specifically, the European Commission adopted Implementing Regulation (EU) 2022/23461, as amended by Implementing Regulation (EU) 2023/1194, to address the risk management concerns.

22. Andrei Klubnikin, "What is the Internet of Bodies (IoB), and why should you care?" (RItrex, 2022) *https://itrexgroup.com/blog/internet-of-bodies-iob-definition-benefits-examples/*, accessed 22 March 2024.

23. Matwyshyn (n 12) 111; E&T Editorial Stuff, "Darpa funds brain-machine interface project for controlling weapons via thoughts" (*Engineering and Technology website*, May 23 2019) *<https://eandt.theiet.org/content/articles/2019/05/darpa-funds-brain-machine-interface-project-for-controlling-weapons-via-thoughts/*, accessed 22 March 2024.

24. Will Greenwald, "Apple Vision Pro vs. Meta Quest Pro: Mixed Reality Matchup" (*PCmag*, 2024), *https://uk.pcmag.com/comparison/150863/apple-vision-pro-vs-meta-quest-pro-mixed-reality-matchup*, accessed 22 March 2024.

25. Duo Skin, (Duo Skin website), *<https://duoskin.media.mit.edu/*, accessed 22 March 2024.

26. Matwyshyn (n 12) 95; U.S.A Food & Drug Administration, "General Wellness: Policy for Low Risk Devices" (FDA website, Sept 2019) *<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices*, accessed 22 March 2024.

27. Celia Ford, "This pill tracks your vitals from the inside" (*Wired*, 2023) *<https://www.wired.com/story/this-pill-tracks-your-vitals-from-the-inside/>* accessed 22 March 2024.

28. Isabel Pedersen, "Will the Body Become a Platform? Body Networks, Datafied Bodies and AI Futures" in Isabel Pedersen and Andrew Iliadis (eds), *Embodied Computing: Wearables, Implantables, Embeddables, Ingestibles* (1st edn, The MIT Press 2020) 24.

29. Matwyshyn (n 11) 111.

30. Mantik Choy, "New Smart Contact Lenses to Monitor Glucose Levels" (Medical News Bulletin website, 2018) *<https://medicalnewsbulletin.com/new-smart-contact-lensesto-monitor-glucose-levels/*, accessed 22 March 2024; Tekla S. Perry, "Augmented Reality Contact Lens Startup Develops Apps With Early Adopters-to-Be" (IEEE Spectrum, 2021) *https://spectrum.ieee.org/startup-mojo-vision-has-the-earliest-adopters-of-augmented-reality-contact-lenses-in-its-sights*, accessed 22 March 2024.

31. Woodrow Barfield and Alexander Williams, "Law, Cyborgs and Technologically Enhanced Brains" (2017) 2 *Philosophies* 1, 5.

the second generation to body internal devices and the third generation to body melted devices.[32]

A. First Generation

Today, the most popular and familiar to consumers IoB devices are the ones remaining outside of the human body. For example, smartwatches or fitness trackers have become indispensable for millions of consumers, with their initial adoption being comparable to the one of mobile phones.[33] It is estimated that in 2023 there were almost 220 million smartwatch users globally.[34] But, except for the 'must have' fitness watches, there are other smart devices with diverse functions in the market, *e.g.*, Bluetooth-connected breast pumps. These devices can update the user's daily pumping schedule and send the information directly to the connected smart phone.[35] This relatively simple use-case is one step closer to the "platformisation" of the human body.

B. Second Generation

The second-generation devices refer to those that are implanted or integrated either entirely or partly inside the human body. They may also be connected to the human body through the nervous system.[36] Regardless of their exact integration, they run software for the collection, analysis and transmission of data on a temporary or permanent basis.[37] A typical example of such a device is the "modern" pacemaker that utilizes the internet to transmit data and realize the remote management of a delicate heart-assisting device.[38]

Such devices are only the beginning. Patients' needs have led to the connection of the nervous system or bones with more "realistic" prosthetics. The patient can control the prosthetic through brain-machine interface (BMI) and move the limb only with their thoughts with a high degree of accuracy.[39] The advancement of the technology does not stop there. Scientists have aspirations to enable amputees to "feel" through their prosthetics.[40] Moreover, people have chosen to have a chip implanted in their bodies in order to unlock their car.[41] Furthermore, some have had chip implants following a request from their employer (the legality of which is heavily debatable, with the practice being banned in several U.S. states).[42] As technology and peoples' needs—real or made-up—continue to develop, the body internal devices will evolve accordingly.

C. Third Generation

Finally, third-generation IoB devices refer to those that blend the human brain and computer, creating invasive brain-computer or brain-to-brain interfaces that will enable the person to be both a transmitter and receiver of information.[43] Such characterization surely brings to mind pictures of movie-like androids, but these devices are not so far from becoming a reality.

Body-melded technology is the vision of many scientists and entrepreneurs that systematically pursue the creation of an evolved version of a human, the real human-cyborg. A case in point: Neuralink, a neurotechnology company, has created a brain-computer interface for the purpose of improving the life of people with serious medical conditions and, as a next step, to open up limitless possibilities for humans.[44] Indeed, at the beginning of 2024 Neuralink performed its first chip implantation in a human, with the first neural indications being positive.[45] The initial objective of Neuralink is to allow the recipients of the implants to complete easy tasks such as control a computer keyboard using only their thoughts.

Despite the incredible leaps made by neurotechnology scientists, there is a long way to go before achieving cognitive enhancement of the human brain through

32. Matwyshyn (n 11) 94.

33. *The Economist—Technology Quarterly*, "The quantified self—Wearable devices are connecting health care to daily life" (7 May 2022) *<https://www.economist.com/technology-quarterly/2022/05/02/wearable-devices-are-connecting-health-care-to-daily-life*, accessed 22 March 2024.

34. Insightful Smartwatch Statistics For 2024 (DemandSage, 2024) *https://www.demandsage.com/smartwatch-statistics/*, accessed 22 March 2024.

35. Matwyshyn (n 11) 94.

36. Matwyshyn (n 11) 103.

37. Quigley and Ayihongbe (n 14) 279.

38. Celik and Eltawil (n 15) 2; Mary Lee, Benjamin Boudreaux, Ritika Chaturvedi, Sasha Romanosky and Bryce Downing, "Internet of Bodies: Opportunities, Risks, and Governance" (RAND Corporation, 2020) *<https://www.rand.org/pubs/research_reports/RR3226.html*, accessed 22 March 2024.

39. Leslie Nemo, "This New Prosthetic Leg Hooks Into Users' Nervous Systems" (*Discover* website, Oct 4 2019) *<https://www.discovermagazine.com/health/this-new-prosthetic-leg-hooks-into-users-nervous-systems*, accessed 22 March 2024.

40. Claudia Lopez Lloreda, "Nerve-mimicking device gives 'feeling' to prosthetics" (*Science*, 2023) *<https://www.science.org/content/article/nerve-mimicking-device-gives-feeling-prosthetics*, accessed 22 March 2024.

41. *The Economic Times*, "That's handy! Tesla driver implants chip in his hand as car key" (2022) *https://economictimes.indiatimes.com/news/new-updates/thats-handy-tesla-driver-implants-chip-in-his-hand-as-car-key/articleshow/93707020.cms?from=mdr*, accessed 22 March 2024.

42. SHRM, "Another State Bans Employers Microchipping Workers" (April 2021) *https://www.shrm.org/topics-tools/news/technology/another-state-bans-employers-microchipping-workers*, accessed 22 March 2024.

43. Matwyshyn (n 11) 112.

44. Neuralink official website (2024) *https://neuralink.com*> accessed 22 March 2024.

45. *Reuters*, "Elon Musk's Neuralink implants brain chip in first human" (2024) *https://www.reuters.com/technology/neuralink-implants-brain-chip-first-human-musk-says-2024-01-29/*, accessed 22 March 2024.

a computer (*e.g.*, uploading information directly to our brain). In the meantime, the already developed body-melded IoB devices are focused on making everyday life easier for patients or even trying to mitigate some of their symptoms. For example, brain prosthetics are examined to help people with degenerative diseases such as Alzheimer's to regain some of their memories[46] or paraplegic people walk again, without the use of an exoskeleton.[47]

3. Achieving the Full Potential of the IoB

i. Connectivity Standards for IoB

It is natural that the IoB—as with most drastically innovative technologies—carries an avalanche of improvements in the users' health as well as daily life. The use of medical IoB devices allows, for example, for pain-free, non-invasive diagnosis or can improve the quality of life of patients with chronic diseases.[48]

It is worth noting that these cutting-edge IoB solutions and their subsequent benefits are possible thanks to seamless and ubiquitous connectivity.[49] More specifically, connectivity between the users' devices with mobile and wireless networks as well as amongst each other. In order to achieve such connectivity, the devices need to be interoperable and compatible by adhering to a common set of technical rules. And this is where standardisation comes into play.[50]

Technical standards "define how a cellular network operates and communicates with other networks."[51] Examples of standards in the information and communication technology (ICT) field are Bluetooth, Wi-Fi and cellular standards (2G to 5G). All the above technologies are currently used in IoB devices.[52] However, due to their technical characteristics, these connectivity solutions serve different purposes and apply in different use cases.

Bluetooth is a short-range wireless solution with limited data transfer capabilities. For this reason, its application can be less costly.[53] A simple and common use case for Bluetooth is to connect smartwatches, or even cochlear implants, with mobile phones.[54] On the other hand, for more advanced use cases in order to connect the device from wherever it is to the internet, Wi-Fi and cellular standards have been deployed.[55] Wi-Fi has been a constant in our workplaces and homes for years due to its stability and lower cost.[56] However, 5G offers much faster and reliable data transfer as well as increased flexibility and mobility.[57] In a comparison between Wi-Fi and 5G made by Accenture, a multinational IT consulting company, 5G prevails over Wi-Fi in all metrics (*i.e.*, latency, mobility, coverage, bandwidth and security).[58] For this reason, the so-called Cellular Internet of Bodies is expected to become the most popular solution for

46. Carly Cassella, "New 'Prosthetic' Hacks The Brain to Recall Specific Memories" (*ScienceAlert*, February 2024) *https://www.sciencealert.com/new-prosthetic-hacks-the-brain-to-recall-specific-memories*, accessed 22 March 2024.

47. Christine E. King, Po T. Wang *et al.*, "The feasibility of a brain-computer interface functional electrical stimulation system for the restoration of overground walking after paraplegia" (*Journal of NeuroEngineering and Rehabilitation* website, Sept 24 2015) *<https://jneuroengrehab.biomedcentral.com/articles/10.1186/s12984-015-0068-7*, accessed 22 March 2024.

48. *The Economist*, "Wearable technology promises to revolutionise healthcare" (7 May 2022) *https://www.economist.com/leaders/2022/05/05/wearable-technology-promises-to-revolutionise-health-care?giftId=b49c5c00-4b97-4805-a3e7-c512420d57af*, accessed 22 March 2024; "What is the Internet of Bodies (IoB), and why should you care?" (n 23).

49. Eleftheria Stefanaki, "The Internet of Bodies could save many lives but risks failing without standards" (*IAM*, 2021) *https://www.iam-media.com/article/the-internet-of-bodies-could-save-many-lives-risks-failing-without-standards*, accessed 22 March 2024.

50. For more information on standardization see: Dr. habil. Nizar Abdelkafi, Prof. Raffaele Bolla *et al.*, "Understanding ICT Standardization: Principles and Practice" (*ETSI* website, 2021) *<https://www.etsi.org/images/files/Education/Textbook_Understanding_ICT_Standardization.pdf*, accessed 22 March 2024. You can find a summary of this publication here: "Summary: 'Understanding ICT Standardisation: Principles and Practice'" (2023) *https://www.4ipcouncil.com/research/summary-understanding-ict-standardisation-principles-and-practice*, accessed 22 March 2024.

51. 4iPCouncil, "IoT & Cellular Standards," *https://www.4ipcouncil.com/standards/what-are-iot-and-cellular-standards*, accessed 22 March 2024.

52. Bowman Heiden, "The Value of Cellular Connectivity—From Mobile Devices to the Internet-of-Things (IoT)" (August 9, 2020), 9 - available at SSRN: *https://ssrn.com/abstract=3670222*, accessed 12 March 2024; See also Celik and Eltawil (n 15) 5-6. The authors mentioned specifically the IEEE 802.15.6 specification as well as Bluetooth Low Energy (BLE).

53. Heiden (n 52) 9; *Britannica*, "What's the Difference Between Bluetooth and Wi-Fi?" (Britannica official website) *https://www.britannica.com/story/whats-the-difference-between-bluetooth-and-wi-fi*, accessed 22 March 2024.

54. Cochlear, "Cochlear introduces the world's first Made for iPhone cochlear implant sound processor" (Cochlear website, July 2017) *https://www.cochlear.com/ca/en/corporate/media-center/media-releases/2017/cochlear-introduces-the-worlds-first-made-for-iphone-cochlear-implant-sound-processor*, accessed 22 March 2024.

55. Ericsson, "5G and Wi-Fi: Charting a path towards superior indoor connectivity" (Ericsson official website) *https://www.ericsson.com/en/reports-and-papers/5g-and-wi-fi-path-toward-superior-indoor-connectivity*, accessed 22 March 2024.

56. Accenture, "The future is 5G—Frequently Asked questions?" (Accenture official website, 2024) *https://www.accenture.com/us-en/insights/5g-index#accordion-286da373b5-item-ea5eaf3129*, accessed 22 March 2024.

57. *Ibid.*

58. *Ibid.*

the health ecosystem in the near future.[59] Meanwhile, there are examples in China and Italy where surgeons used 5G-powered robots to perform certain procedures and surgeries.[60]

Due to the shortcomings of Bluetooth and Wi-Fi, cellular standards (in particular 5G and 6G) are expected to be used for critical IoB applications in the future. Advanced security protocols, increased flexibility, and low latency[61]—*i.e.*, low response time between sending and receiving data—amount to reliable connectivity for present and future IoB devices.

ii. Standardisation as the Cornerstone of IoB Connectivity

IoB applications raise unique challenges. Given the potential impact on human health and well-being, IoB applications will face rigorous commercial demands for security, privacy, reliability, and ultra-low latency communications. To address these challenges, one could expect development of standards that ensure the safe and effective use of cellular technology within IoB contexts. To achieve the highest performance, these standards will likely be developed in 3GPP.[62]

3GPP is a joint project of seven Standard Development Organisations (SDOs), including ETSI (European Telecommunications Standard Institute).[63] In addition to cellular standards (2G to 5G), 3GPP has introduced various standards that facilitate IoT applications through technologies like NB-IoT (Narrowband IoT) and LTE-M (LTE for Machines). These and other similar standards developed in 3GPP could potentially be applicable to IoB applications due to their focus on low power consumption, wide coverage, and ability to support a vast number of connected devices.

In 3GPP, only the best technologies become part of a collaborative standard. As these technologies are the result of massive investments in research and development, they are typically protected by patents.[64] Patented inventions that are necessary to comply with a technical standard are known as standard essential patents (SEPs). Hence, any standard-compliant device must incorporate them.[65]

To facilitate the widespread dissemination of cutting-edge standards, innovators usually agree to make their SEPs available on fair, reasonable and non-discriminatory (FRAND) terms and conditions.[66] The FRAND commitment allows those implementing the standard to gain access to standardised technologies on reasonable terms. Moreover, the FRAND framework enables technology developers to receive fair and adequate compensation for their innovative contributions of proprietary solutions to the standard.[67] Such compensation

59. A. M. Rahmani, W. Szu-Han, K. Yu-Hsuan and M. Haghparast, "The Internet of Things for Applications in wearable technologies" (*IEEEXplore*, November 2022) *https://ieeexplore.ieee.org/document/9963553*, accessed 4 March 2024; More for the importance of 5G for IoB in: PWC, *5G In Healthcare: PwC* (PWC official website) accessed 22 March 2024; and IHS Markit, "The 5G Economy in a Post-COVID-19 Era: The role of 5G in a post-pandemic world economy" (November 2020) *https://www.qualcomm.com/content/dam/qcomm-martech/dm-assets/documents/qualcomm_5g_economy_in_a_post-pandemic_era_report_2020.pdf* at page 16, accessed 22 March 2024.

60. Krunal Pandav, AG Te, Nir Tomer, SS Nair, AK Tewari, "Leveraging 5G technology for robotic surgery and cancer care" Cancer Rep (Hoboken). 2022 Aug;5(8):e1595. doi: 10.1002/cnr2.1595. Epub 2022 Mar 9. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9351674/*, accessed 22 March 2024.

61. Celik and Eltawil (n 15) 5; see also Ericsson, "Internet of Senses" (Ericsson official website) *https://www.ericsson.com/en/6g/internet-of-senses*, accessed 22 March 2024.

62. About 3GPP (3GPP official website) *https://www.3gpp.org/about-us*, accessed 22 March 2024.

63. About ETSI (ETSI official website) *https://www.etsi.org/about*, accessed 22 March 2024.

64. See Spyros Makris and Haris Tsilikas, "Standard Essential Patents and Injunctions: The Key Role of Good Faith in Major Jurisdictions," *IEEE Communications Standards* Magazine, December 2021, 1. *https://ieeexplore.ieee.org/document/9696261*, accessed 22 March 2024. Companies that contribute to 3GPP devote time and resources for the purpose of technological advancement and increased social welfare. For example, it is reported that since the beginning of the development of the 5G standard, 3GPP has received almost one million written contributions, more than half of which come from specific industry players. The companies with the most contributions are (alphabetically): Ericsson, Huawei, Nokia, Qualcomm, Samsung, and ZTE. *See* Lorenzo Casaccia, Urška Petrovčič & Karyn Vuong, "Understanding the Difference Between Participants and Contributors in a Standard-Development Process" (Competition Policy International Columns, Intellectual Property, February 2024) *Understanding the Difference Between Participants and Contributors in a Standard-Development Process* (*pymnts.com*), accessed 22 March 2024.

65. Jean-Sébastien Borghetti, Igor Nikolic & Nicolas Petit (2021) "FRAND licensing levels under EU law," *European Competition Journal*, 17:2, 206, DOI: 10.1080/17441056.2020.1862542. Also available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3532469*, accessed 22 March 2024.

66. See Section 6.1 of the ETSI IPR Policy at: *https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf*, accessed 22 March 2024.

67. This is illustrated in the Policy Objectives of the ETSI IPR Policy (Section 3.1 and 3.2). For more information see: ETSI IPR Policy at: *https://www.etsi.org/images/files/IPR/etsi-ipr-policy.pdf*, accessed 22 March 2024.

Regarding the investments in R&D see: Georgios Effraimidis and Kirti Gupta, "5G standards and the stark divide between innovators and implementers," *IAM*, 8. June 2022, *https://www.iam-media.com/article/5g-standards-and-the-stark-divide-between-innovators-and-implementers* and *https://www.4ipcouncil.com/research/5g-standards-and-stark-divide-between-innovators-and-implementers*, accessed 22 March 2024.

Jean-Sébastien Borghetti, Igor Nikolic & Nicolas Petit (2021), "FRAND licensing levels under EU law," *European Competition Journal*, 17:2, 206, DOI: 10.1080/17441056.2020.1862542. Also available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3532469*, accessed 22 March 2024.

acts as a strong incentive for them to continue investing in research and development (R&D) for the next generation of the standard, closing the cycle of innovation.[68]

iii. IoB at Risk

The use of cellular technologies in IoB applications will allow consumers and patients to benefit from a variety of secure end products that will have been attained through vigorous downstream competition.

In order to ensure that the much-needed standardization efforts will be pursued in the IoB field, the current successful standardisation (FRAND) ecosystem needs to be maintained, from the open collaboration in standards development to the efficient technology sharing through FRAND licensing. Any attempt to disrupt the delicate balance of interests between contributors and implementers should be avoided. This includes an appropriate IP framework that makes it possible for industry players to obtain a fair return on their investment to encourage them to invest in IoB innovation.[69]

In this context, a regulatory proposal made last year by the European Commission for a new licensing framework for SEPs[70] may diminish the success of the IoB. The European Parliament has recently adopted its position on the proposal for regulation and is now waiting for the position of the Council of the European Union before the legislative process can move forward.[71] In brief, the newly introduced measures pertain to SEP registration and essentiality checks, FRAND determination and SEP aggregate royalty rates, all within the auspices of a new Competence Centre. This Centre will be under the European Union Intellectual Property Office (EUIPO).[72]

According to the Commission, the main objective of said proposals is to establish a transparent SEP licensing framework that balances the interests of both SEP owners and implementers.[73] This will allegedly increase the competitiveness of European companies and boost the EU single market.

From its publication, this regulatory proposal has faced strong criticism. Some of the many concerns raised are that the proposed regulation:

(i) is based on the premise that the status quo in FRAND licensing is inefficient and needs to be fixed,[74] while the evidence on this aspect is "inconclusive."[75] To the contrary, the current landscape proves that any potential challenges have not discouraged contributions to and development of standards, nor the implementation thereof in the market.

(ii) breaches EU Fundamental Rights and the TRIPS Agreement,[76]

68. Alexander Galetovic and Stephen Haber, "SEP royalties: What theory of value and distribution should courts apply?," *The Ohio State Technology Law School Journal*, Vol 17.2 (2021), 208 at *https://www.law.berkeley.edu/wp-content/uploads/2021/05/Galetovic_Haber.pdf*, accessed 22 March 2024.

69. For more information on the value of patents for innovation see Maureen K. Ohlhausen, "Patent Rights in a Climate of Intellectual Property Rights Skepticism," *Harvard Journal of Law and Technology*, Vol. 30 (2016)*https://jolt.law.harvard.edu/assets/articlePDFs/v30/30HarvJLTech103.pdf*, accessed 22 March 2024.

70. European Commission, Standard Essential Patents (European Commission official website) *https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/standard-essential-patents_en*, accessed 22 March 2024.

71. Mathieu Klos, "Under no circumstances should the EU create a regulatory SEP monster," *JUVE Patent*, 4 March 2024 *https://www.juve-patent.com/legal-commentary/under-no-circumstances-should-the-eucreate-a-regulatory-sep-monster/*.

72. European Commission, Standard Essential Patents (European Commission official website) *https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/standard-essential-patents_en*,accessed 22 March 2024.

73. *Ibid.*

74. See indicatively IPEurope, "LIVE BLOG: Third-party comments on the European Commission's proposal to regulate standard-essential patents (SEPs)," *https://ipeurope.org/blog/live-blog-third-party-comments-on-the-european-commissions-seps-proposal/*, accessed 22 March 2024.

75. According to a study financed by the European Commission, "[e]xisting empirical evidence on the causal effects of current SEP licensing conditions is largely inconclusive. Empirically observable outcomes do not indicate the existence of pervasive "opt-out" from standards-related innovation as a consequence of SEP licensing conditions; *i.e.*, it does not appear that the observed challenges in SEP licensing are sufficiently severe as to systematically discourage potential contributors from participating in standards development, or discourage potential implementers from creating products that use technology standards subject to potential SEPs." At Justus Baron *et al.*, Empirical Assessment of Potential Challenges in SEP Licensing (*LexisNexis* website, May 2023), at pg. 185, *https://www.lexisnexisip.com/wp-content/uploads/2023/09/Empirical-Assessment-of-Potential-Challenges-in-SEP-Licensing.pdf*.

See also Justus Baron, "The Commission's Draft SEP Regulation—Focus on Proposed Mechanisms for the Determination of 'Reasonable Aggregate Royalties'." 4iPCouncil, 10 August 2023, *https://www.4ipcouncil.com/research/commissions-draft-sep-regulation-focus-proposed-mechanisms-determination-reasonable-aggregate-royalties*.

76. Mohammad Ataul Karim, "The Proposed EU SEP Regulation: Checking Balancing Incentives, and compatibility with EU Fundamental Rights, and the TRIPS Regime," 4iPCouncil, 04 July 2023, *https://www.4ipcouncil.com/research/proposed-eu-sep-regulation-checking-balancing-incentives-and-compatibility-eu-fundamental-rights-and-trips-regime*; Wayne Chinembiri, "EC Draft SEP Regulation and the TRIPS Agreement Compatibility Assessment," 4iPCouncil, 4 July 2023, *https://www.4ipcouncil.com/research/ec-draft-sep-regulation-and-trips-agreement-compatibility-assessment*.

(iii) interferes with the requirements established by Court of Justice of the EU in *Huawei v ZTE*,[77]

(iv) risks weakening EU's global competitiveness,[78]

(v) grants the EUIPO authority for essentiality checks, FRAND determination, and SEP aggregate royalty rates although the Center lacks sufficient resources and expertise,[79] and

(vi) has not given an opportunity for new market solutions (like Avanci)[80] or the new Unified Patent Court system[81] to address any potential challenges raised by the European Commission.

Should this new framework be adopted in Europe, the existing well-functioning FRAND licensing regime will likely be distorted to the benefit of implementers.[82] Compliance with the newly introduced measures will require SEP owners to invest additional resources to fulfil the requirements of the new and often duplicative system, creating additional bureaucracies without achieving the stated goal of facilitating SEP licenses. In addition to this, SEP owners will probably lack timely compensation on FRAND terms. If so, contributors will not be incentivised to invest in standardisation.

As a result, the consequences are expected to negatively affect European technology leaders, European standardisation institutions as well as the European market.[83] Furthermore, the IoB sector would likely be equally impacted, since the relevant industry players will be devoid of incentives to invest in R&D towards its advancement.

Conclusion

Several years ago, the IoT revolutionised our daily lives; now many consider owning a smart car the obvious choice. Technological development though pushes the boundaries, introducing the next frontier: the Internet of Bodies. IoB devices are expected to profoundly impact the lives of consumers and patients alike. Electronic devices connected to the internet reside around, on and within the human body, creating a massive network where data is transmitted every passing second. This seamless connectivity is made possible primarily through ICT standards such as 5G, which are crucial in the communication between IoB devices and the human body. For this reason, the continuous development and improvement of connectivity standards, and especially cellular standards, is considered a key variable for the future of the IoB. Towards this goal, technology developers are willing to devote a great number of resources, provided that they can be rewarded fairly for their endeavours. The FRAND licensing framework currently in place allows such fair remuneration. Therefore, it is indispensable to maintain this well-functioning system; any ill-considered efforts to alter it, such as the recent proposal of the European Commission to regulate standard essential patents, could lead to a disruption of the balance among stakeholders and market inefficiencies, ultimately affecting end-users globally. ■

77. These concerns were raised by the European Intellectual Property Judges Association (IPJA) in a letter to the European Commission on 29th October 2023, *https://www.linkedin.com/posts/joff-wild-6a80bb8_former-england-and-wales-court-of-appeal-activity-7125581578033840133*.

78. Claudia Tapia, "Building the house from the roof down: The Standard Essential Patent (SEP) Draft Regulation," 2023, *The Patent Lawyer*, *https://patentlawyermagazine.com/building-the-house-from-the-roof-down-the-standard-essential-patent-sep-draft-regulation/*.

79.Joff Wild, "The European Commission's SEP licensing plans are terrible on every level," *IAM*, 30 March 2023, *https://www.iam-media.com/article/jw-column-30th-march-2023-ec-sep-licensing-plans*.

80. Avanci, *https://www.avanci.com/*.

81. Unified Patent Court, *https://www.unified-patent-court.org/en*.

82. European Commission, SWD(2023)124—Impact assessment accompanying the proposal for a regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001, *https://single-market-economy.ec.europa.eu/publications/com2023232-proposal-regulation-standard-essential-patents_en*, pg. 114.

83. Patrick McCutcheon, "The European Commission's SEPs proposal is an own goal. It should be rejected." (*IAM*, 24 February 2024) *https://www.iam-media.com/article/the-european-commissions-seps-proposal-own-goal-it-should-be-rejected*, accessed 22 March 2024.

Navigating The New European Patent System Through Properly Drafted Agreements

By Mariella Massaro, Suvi Julin, Jennifer Burdman and Robert Alderson

Introduction

We are now well past the one-year anniversary of the new European patent system which notably includes a new type of patent, a European patent with unitary effect, also known as a Unitary Patent, as well as a new court system, the Unified Patent Court (UPC). The new European system provides opportunities for patent prosecution strategies which can be agreed upon in advance and which are covered in the first section below. In conjunction with those prosecution strategies, patent owners should be mindful of the nuances in how the Unified Patent Court is interpreting the right to enforce those Unitary Patents. Recent interim orders and decisions from the Unified Patent Court provide guidance on how various stakeholders can control risk and uncertainty through the use of properly drafted agreements. This article addresses key aspects of license and joint ownership agreements relating to patent prosecution and litigation, including standing to sue of licensees as well as joint owners. The article also includes brief comparative information on United States law relating to standing to sue of licensees and joint owners, important for patentees seeking to engage with third parties in both jurisdictions.

Transitional Period and Patent Filing Strategies in Europe

Since 1 June 2023, when the UPC started to operate, and for the duration of what is referred to as the "transitional period" stipulated by Art. 83(1) UPCA, owners of European patent applications have the option of either validating the patent in the countries of interest participating in the European Patent Convention or to request unitary effect in the countries participating in the UPC system. Therefore, the transitional regime offers a number of possibilities on filing and prosecution strategies that should be considered in view of managing patent portfolios, building strong licensable patent portfolios, and drafting licensing agreements with the intended enforcement rights.[1]

Filing and Prosecution Strategies Utilizing Divisional Applications

From the patentee's point of view, the transitional regime offers a relatively long window of time during which different filing and prosecution strategies are available. Certain strategies extend beyond the transitional regime as well. One of the potentially useful strategies, which enables risk balancing in view of the Unitary Patent System, is to use a divisional application strategy shown in Figure 1, on page 130.

Based on divisional application strategy 1, the applicant can obtain a "parent" European patent application with a wider scope of protection and the granted European patent will be validated nationally in the selected EPC member states. The "parent" European patent will be opted out of the jurisdiction of the UPC. The divisional application(s) are strategically filed with claims targeting a narrower scope of protection to avoid a double patenting objection and when granted, the unitary effect will be requested for the divisional(s).

Divisional application strategy 1 enables building a potentially stronger patent portfolio where the risk of central attack against the "parent" European patent can be effectively mitigated (because it was opted out of UPC jurisdiction) and the UPC can still be utilized,

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1. Filing and prosecution strategies in connection to the Unitary Patent System have been discussed in different contexts. See, for example, Hutterman, "Unitary Patent and Unified Patent Court, 2nd Edition," 2023, p. 436-437, and Hoffman-Eitle, "The Unified Patent Court and Unitary Patent: A Practitioner's Handbook, 2nd Edition," 2022, p. 24-30

Fig. 1: Divisional Application Strategy 1

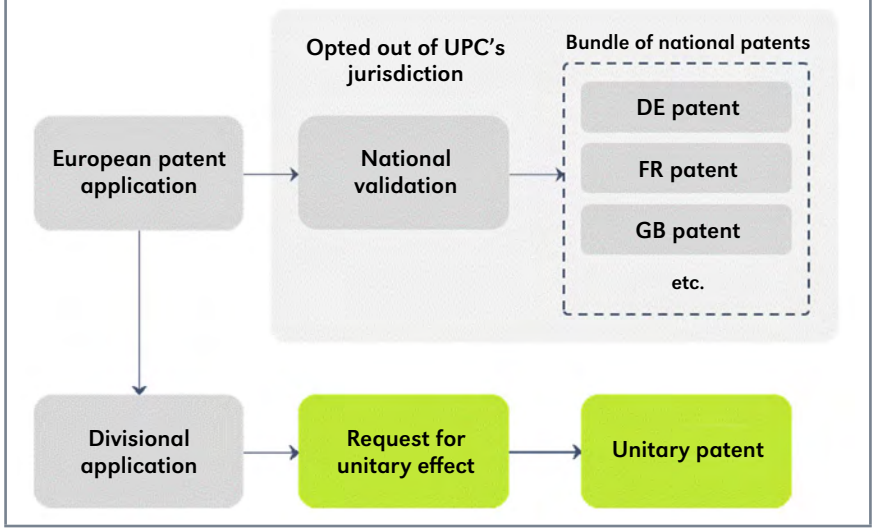
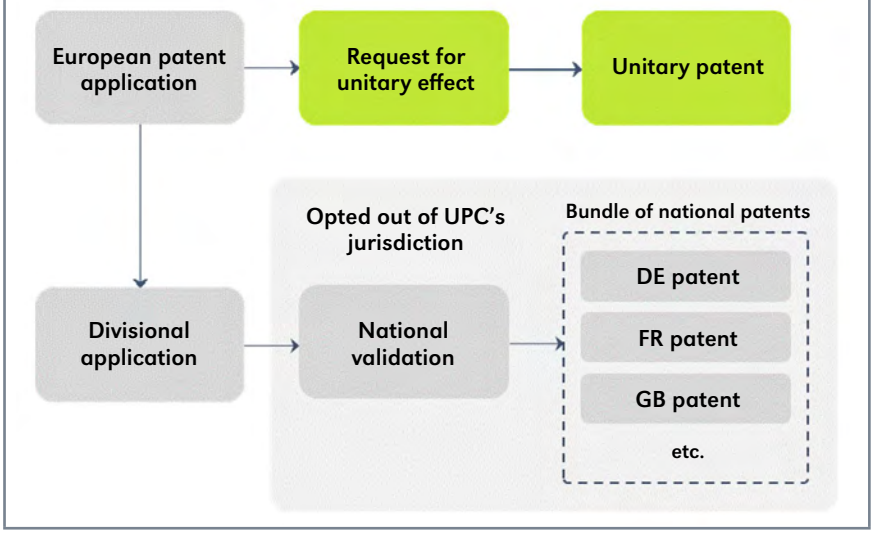


Figure 2: Divisional Application Strategy 2



if needed, with the divisional patent(s). As discussed in more detail below, this may be beneficial from a licensing point of view but requires well-defined license management clauses in licensing agreements, and in the case of joint ownership, attention must be paid to managing decision-making contractually between joint owners. This strategy also may be beneficial, for example, if the wider scope of protection provided by the "parent" European patent may have some weaknesses (from a patentability standpoint) in comparison to the narrower divisional(s).

Divisional application strategy 2 as described in Figure 2 is, in practice, the inverse of the strategy presented in Figure 1. In this case, the "parent" European patent is a Unitary Patent and the divisional patent(s) are nationally validated in EPC member states. The divisional patent(s) have a narrower scope of protection to avoid any double patenting objection and are opted out of the UPC's jurisdiction.

This strategy may be useful in various situations if the risk of central attack against the "parent" European patent can be accepted and the divisional(s) provide a preferable scope of protection in certain countries, for example. Similar to divisional application strategy 1, this option also enables the creation of a potentially stronger patent portfolio and requires well-defined license management clauses in license and joint-ownership agreements. It may also be beneficial, for example, if the wider scope of protection provided by the "parent" European patent may have some weaknesses (from a patentability standpoint) in comparison to the narrower divisional(s) and certain countries even with a narrower scope of protection are more important for the patentee than others.

Filing and Prosecution Strategies Utilizing National Applications

Certain EPC and UPC member states such as Germany, France, Italy, the Netherlands, Austria, Denmark, Sweden and Finland allow literal double patenting. While the opt out-based divisional strategies 1 and 2 described above remain useful for the duration of the transitional regime, national applications based on combination strategies remain applicable after the transitional regime as well. Figures 3 and 4, on page 131, provide examples of combination strategies where a European patent application/Unitary Patent is combined with national patent applications/patents by utilising a PCT application and entering the regional phase before the European Patent Office and selected national offices in parallel within the time limits of the PCT (where such route is not blocked).

Figure 3: Combination Strategy 1

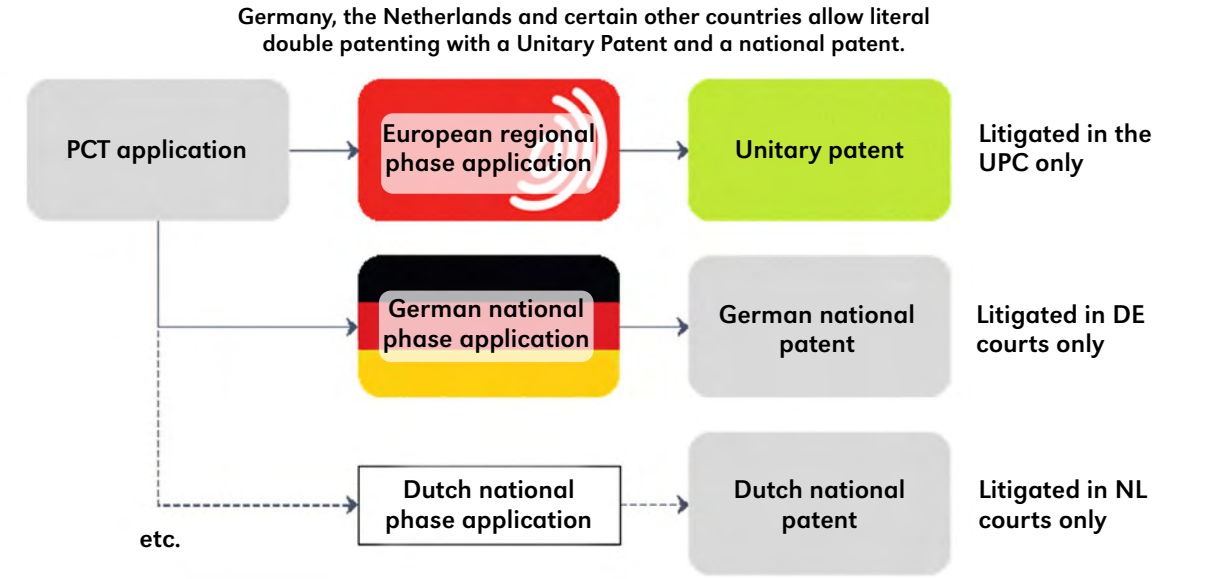
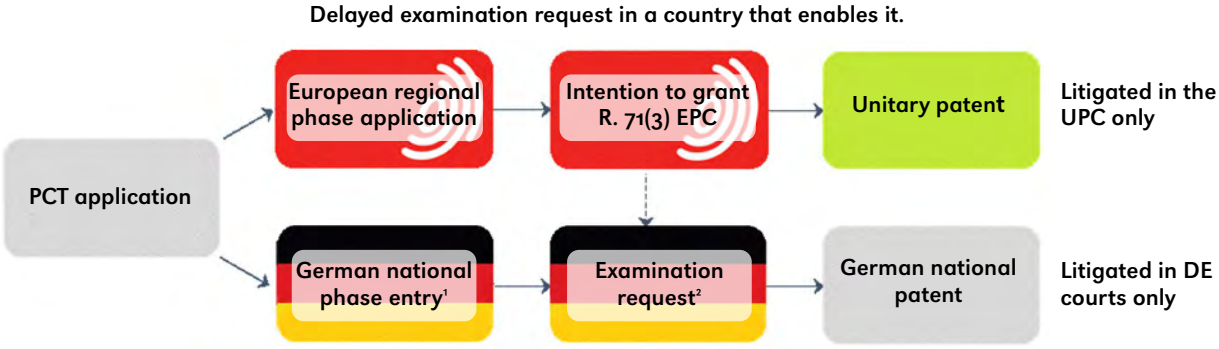


Figure 4: Combination Strategy 2



[1] Without examination request.
[2] Term for filing examination request: 7 years from filing date.

Generally, combination strategies utilising national patent application filings may be beneficial for building stronger portfolios and balancing risks but require particular attention to relevant contract provisions in license and joint ownership agreements, as discussed above. Utilising national patents in combination with Unitary Patents is especially beneficial if there are certain countries that are particularly commercially important for the patentee and where double patenting is permitted. Also, if variation in the scope of protection possibly resulting from national patents can be accepted, national patents in combination with a Unitary Patent can be an alternative that may increase the value of licensable patent portfolios. Of particular note, in Germany, delaying examination requests up to seven years from the date of filing is also possible and would allow optimization of prosecution and scope of protection in view of the claims already granted in the European patent application (Fig. 4).[2]

Transitional Period and Shared Jurisdiction in Europe

During the transitional regime as stipulated by Art. 83(1) UPCA, an action for infringement or for revocation of a European patent may still be brought before national courts in case of European patents validated traditionally in UPC member states. Further, Art. 83(3) and 83(4) UPCA establish so-called opt-out and opt-in procedures together with Rule 5 of Rules of Procedure ("RoP").

2. See also, for example, Hutterman, "Unitary Patent and Unified Patent Court, 2nd Edition," 2023, p. 436-437, and Hoffman-Eitle," The Unified Patent Court and Unitary Patent: A Practitioner's Handbook, 2nd Edition," 2022, p. 25-28.

Unless an action has already been brought before the UPC, a proprietor of or an applicant for a European patent granted or applied for prior to the end of the transitional period shall have the possibility to opt out from the exclusive competence of the UPC by notifying the Registry by the latest one month before expiry of the transitional period (Art. 83(3) UPCA). Rule 5 of the Rules of Procedure for the UPC stipulates that the proprietor of a European patent (including a European patent that has expired) or the applicant for a published application for a European patent who wishes to opt out that patent or application from the exclusive competence of the UPC can lodge an application to opt out with the Registry.

Art. 83(4) UPCA further stipulates that unless an action has already been brought before a national court (of a UPC member state), proprietors of or applicants for European patents who have made use of the opt-out procedure in accordance with Art. 83(3) UPCA shall be entitled to withdraw the opt out at any moment by notifying the Registry accordingly. Opting out and withdrawing an opt out ("opting back in") can only be done once pursuant to Rule 5(10) RoP. Further, where an application for a European patent that has been opted out proceeds to grant as a European patent with unitary effect, the opt out shall be deemed to have been withdrawn. At the end of the transitional period, the European patents that have opted out will remain opted out, and thus they will be subject to the jurisdiction of the respective national courts.

The UPC has already issued orders related to the validity of opt outs and withdrawals of opt outs and, although not specifically related to joint ownership, certain aspects should be considered. In the matter *Mala Technologies v Nokia Technology* (UPC_CFI_484/2023) the Paris Central Division as a first instance held that there is no general principle within the UPCA that precludes the UPC from asserting jurisdiction in revocation proceedings merely because other proceedings relating to the same patent are pending before other courts. The Court indicated that the interests of claimants filing revocation lawsuits before and after the entry into force of the UPCA are distinct. The Court stated that a party which filed a lawsuit in a national court before the entry into force of the UPCA should not be barred from filing a lawsuit before the UPC because, at the time of filing the national lawsuit, the UPC was not yet operational. The Court reasoned that at that time a claimant could not make a choice between the UPC and a national court. In contrast, a claimant which files a lawsuit during the transitional period can make such a choice.[3]

It should be noted that a previous decision by the Helsinki Local Division in the matter *AIM Sport Vision v Supponor* (UPC_CFI_214/2023) as a first instance court determined that withdrawal of an opt out was ineffective due to the national infringement and invalidation proceedings before the German courts and, as a result, the UPC lacked competence. The Court considered that reading of Art. 83(4) UPCA and Rule 5.8 RoP causes a withdrawal of an opt out to be irrespective of whether the national action is pending or it has been concluded, and in this case the German national action was still pending on the date of withdrawal of the opt out.[4]

Presumably, the different approach taken by these two courts will be resolved by subsequent UPC jurisprudence.

Patent Litigation and Licensing Considerations: A Comparison between the United States and the Unified Patent Court

This section will provide some basic information regarding the legal principles governing patent licensing and the ability to bring infringement actions in the United States and Europe before reviewing recent cases of the Unified Patent Court relating to similar issues.

Standing to Sue of the Licensor and Licensee under United States Law

In order to sue for patent infringement in the U.S., the plaintiff must meet jurisdictional requirements to show that it has been injured by the defendant's alleged infringement (referred to as standing under Article III of the U.S. Constitution) and that it has the right to exclude the use of the technology as the "patentee" (35 U.S.C. § 281).[5] The U.S. Patent Act defines a "patentee" here as

3. *Mala Technologies v Nokia Technology*, Paris Central Division, UPC_CFI_484/2023, order of 2 May 2024, points 58-59.

4. *AIM Sport Vision v Supponor*, Helsinki Local Division, UPC_CFI_214/2023, decision of 20 Oct 2023, section 1.6 federal courts' requirement that a plaintiff possess sufficient exclusionary rights in the patent to bring suit, and the Commission's rule that the complainant must be an owner or exclusive licensee.

5. *Alfred E. Mann Found. for Sci. Rsch. v Cochlear Corp.*, 604 F.3d 1354, 1358–59 (Fed. Cir. 2010); *Ridge Corp. v. Kirk National Lease Co.*, No. 2024-1138 (Fed. Cir. Aug. 1, 2024) citing *Univ. of S. Fla. Research Found., Inc. v. Fujifilm Med. Sys. U.S.A., Inc.*, 19 F.4th 1315, 1320 (Fed. Cir. 2021). The requirements to bring a patent infringement action at the US International Trade Commission do not require Article III standing. "Certain Active Matrix Organic Light-Emitting Diode Display Panels and Modules for Mobile Devices, and Components Thereof, Inv." No. 337-TA-1351 Comm'n Op. at 13 (May 15, 2024) ("Insofar as the Commission has previously applied a constitutional standing requirement in the past or suggested that it applies to section 337 investigations, that precedent is hereby overruled."). The ITC has recently reaffirmed that at least one complainant in every case must be an owner or exclusive licensee of the asserted patent and that "it is appropriate to consider precedent as to whether [complainant] is a 'patentee' who can bring a patent infringement action under 35 U.S.C. § 281." Although the Commission noted that "[t]he terms 'owner or exclusive licensee' *have been interpreted* to be the same as the term 'patentee' in 35 U.S.C. § 281" by the federal courts, it left unanswered whether there is any difference between the federal courts' requirement that a plaintiff possess sufficient exclusionary rights in the patent to bring suit, and the Commission's rule that the complainant must be an owner or exclusive licensee.

the party to whom the patent was issued and the successors in title to the patentee, but it does not include mere licensees. Nevertheless, it is recognized that "[a] patent owner may transfer all substantial rights in the patents-in-suit, in which case the transfer is tantamount to an assignment of those patents to the exclusive licensee," who may then maintain an infringement suit in its own name.[6] In many cases, the analysis of "injury by defendant" has been collapsed into the discussion of whether the plaintiff has the right to exclude the use of the technology by that defendant as an exclusive licensee/"patentee" under § 281.

In order for an "exclusive licensee" to be able to sue for infringement (without having the patent owner licensor joined in the lawsuit), the licensee must have "all substantial rights" including the "exclusionary right" to sue for alleged infringement. If a license does not explicitly transfer the right to sue to the licensee, the licensee may not have the right to sue on its own. This necessarily impacts how patent owners structure and phrase their license agreements that include the U.S. territory, particularly where, as discussed above, patent owners may choose to reserve key rights to their licensed patents for strategic reasons.

While the U.S. courts have not established a brightline rule for language that must be included in the contract to provide an exclusive licensee with sufficient rights to bring an infringement action (without including the licensor in the suit), they have provided the following criteria to be examined under the "totality" of the license agreement. That list of criteria includes: (1) the scope of the licensee's right to sublicense, (2) the nature of license provisions regarding the reversion of rights to the licensor following breaches of the license agreement, (3) the right of the licensor to receive a portion of the recovery in infringement suits brought by the licensee, (4) the duration of the license rights granted to the licensee, (5) the ability of the licensor to supervise and control the licensee's activities, (6) the obligation of the licensor to continue paying patent maintenance fees, and (7) the nature of any limits on the licensee's right to assign its interests in the patent. Among these factors that are to be considered, the exclusive right to make, use, and sell, as well as the nature and scope of the patentee's retained right to sue accused infringers are the most important considerations in determining whether a license agreement transfers sufficient rights to render the licensee the owner of the patent and confer standing to sue in U.S. federal court.[7]

6. *Alfred E. Mann Found. for Sci. Rsch. v Cochlear Corp.*, 604 F.3d 1354, 1358–59 (Fed. Cir. 2010).

7. *Ridge Corp. v Kirk National Lease Co.*, No. 2024-1138 (Fed. Cir. Aug. 1, 2024) citing *Univ. of S. Fla. Research Found., Inc. v Fujifilm Med. Sys. U.S.A., Inc.*, 19 F.4th 1315, 1320 (Fed. Cir. 2021).

Standing to Sue of the Licensor/Patent Owner before the Unified Patent Court

The licensor's entitlement, as the patent owner, to file suit and to join actions started by its licensee is expressly provided for by Article 47 (Parties) of the Unified Patent Court Agreement (UPCA):

1. The patent proprietor shall be entitled to bring actions before the Court.

   (…)

4. In actions brought by a license holder, the patent proprietor shall be entitled to join the action before the Court.

In the now well-known case *10X Genomics and Harvard v Nanostring*, which resulted in the first preliminary injunction granted based on a Unitary Patent, the Munich Local Division addressed the issue *"whether the formal legal position according to the entry in the register is sufficient for entitlement under Article 47(1) UPCA, or whether the substantive entitlement is ultimately decisive,"* affirming that this question can remain open for decision in the proceedings on the merits, while the formal entitlement was deemed sufficient in the urgent proceedings (*10X Genomics and Fellows of Harvard College v NanoString Technologies*).[8]

This approach was upheld in the appeal phase, where the UPC confirmed that

> *"The concerns raised in the Appeal against the entitlement of Applicants 2 [Harvard] to file the application are not justified. Due to their corresponding entry in the Register for Unitary Patent Protection, Applicants 2 are to be treated as the proprietor of the patent at issue, in accordance with R. 8.4 RoP. As such, they are entitled to apply for provisional measures in accordance with Art. 47(1) UPCA."*[9]

In this regard, the Court of Appeal referred to Rule 8.4., which provides:

For the purposes of proceedings under these Rules in relation to the proprietor of a European patent with unitary effect, the person shown in the Register for Unitary Patent protection [Regulation (EU) No 1257/2012, Article 2(e)] as the proprietor shall be treated as such.

A subsequent decision of the Düsseldorf Local Division in the *10X Genomics v Curio Bioscience* case clarified that

8. *10X Genomics, Inc and President and Fellows of Harvard College v NanoString Technologies Inc., NanoString Technologies Germany GmbH and NanoString Technologies Netherlands B.V.*, Munich Local Division, UPC_CFI_2/2023, order of 19 September 2023

9. *NanoString Technologies Inc, NanoString Technologies Germany GmbH, NanoString Technologies Netherlands B.V. v 10X Genomics, Inc., and President and Fellows of Harvard College*, Court of Appeal of the Unified Patent Court, UPC_CoA_335/2023, order of 26 Feb 2024

"If in the case of a European patent a person is registered as the patent proprietor in the respective national register, there is a rebuttable presumption that the person recorded in the respective national register is entitled to be registered (R. 8.5(c) RoP). The result of such a legal presumption is to reverse the burden of explanation and proof with regard to the presumed fact. If the Applicant can refer to his listing in the registers relevant to the respective dispute, it is up to the Defendant's side to set out and, if necessary, prove that the Applicant is not entitled to be registered." [10]

Standing to Sue of the Licensee before the Unified Patent Court

Article 47 UPCA also recognizes the entitlement of the licensee to file suit, but makes a distinction between the position of an exclusive and a non-exclusive licensee:

2. Unless the licensing agreement provides otherwise, the holder of an exclusive license in respect of a patent shall be entitled to bring actions before the Court under the same circumstances as the patent proprietor, provided that the patent proprietor is given prior notice.
3. The holder of a non-exclusive license shall not be entitled to bring actions before the Court, unless the patent proprietor is given prior notice and in so far as expressly permitted by the license agreement.

Notwithstanding the default position of Article 47 UPCA, it is important to understand that the licensor and the licensee are free to negotiate additional or different contractual requirements. In particular, the license agreement can include an obligation for the exclusive licensee to request the licensor's consent before bringing an infringement action at the UPC.

In the dispute involving *10X Genomics and Harvard University v Nanostring* before the Munich Local Division, referenced above, the defendant Nanostring contested the exclusivity of 10X Genomics' license, and thus its right to bring actions before the Court. In particular, the defendant pointed out that Harvard's research that resulted in the patent at issue was financed by the NIH and that the funding was subject to certain contractual obligations under the Bayh-Dole Act, including the obligation to grant non-exclusive licenses to third parties to the results of the funded activities. However, notwithstanding this obligation, Harvard University granted two exclusive licenses to 10X Genomics covering different territories.

The Munich Local Division decided that

"In the event that Claimant 2) [Harvard University] has made a commitment to the NIH to grant non-exclusive patent licences with respect to the patent at issue, the Local Division cannot be convinced with sufficient certainty in the summary proceedings that it was possible to grant an exclusive licence contrary to this commitment; this question is therefore reserved for a detailed examination of the relevant US law in the proceeding on the merits in the event that it is relevant for a decision."

However, this issue did not have any practical impact on the proceedings, because, as the Munich Court pointed out

"According to Article 47(3) UPCA, the holder of a non-exclusive licence is also entitled to file a request if the patent proprietor has been informed of the seizing of the court by said holder and the licence agreement expressly allows the request to the court. The court is convinced that both are the case here: Claimant 2) [Harvard University] was informed of the seizing of the court by Claimant 1) [10X Genomics]; the request was filed together with Claimant 1). According to the submission in the written statement of 11 August 2023, both Claimants also agree that there is at least a non-exclusive licence agreement between them concerning the patent at issue, which allows Claimant 1) to bring the matter before the court in the sense of the asserted request. It is also neither apparent nor submitted by the Defendant side that any infringements of NIH funding conditions resulting from the grant of an exclusive licence prevent a later agreement on a simple licence."

These principles were upheld by the Court of Appeal and are currently under the consideration of the judges in the proceedings of the merit.

Counterclaim for Revocation by the Defendant in UPC Infringement Actions brought by the Licensee

In the framework of a UPC litigation including a counterclaim for revocation, Article 47.5 of the UPC Agreement provides the following:

"The validity of a patent cannot be contested in an action for infringement brought by the holder of a licence where the patent proprietor does not take part in the proceedings. The party in an action for infringement wanting to contest the validity of a patent shall have to bring actions against the patent proprietor."

This provision along with Rule 25.2 of the RoP appears to force the defendant to bring a separate revocation action before the Central Division, unless the patent owner joins the original infringement proceedings brought by the licensee.

If this interpretation is confirmed by UPC case law, it would be preferable to allow some flexibility in license agreements so that the licensor and licensee are not

10. *10x Genomics Inc. v Curio Bioscience Inc.*, Düsseldorf Local Division, UPC_CFI_463/2023, order of 30 April 2024.

bound to bring infringement actions jointly but are free to evaluate the litigation strategy based on the concrete circumstances of the case.

First FRAND Issues at the Unified Patent Court

In 2023, Panasonic filed a number of SEP infringement actions against Xiaomi, OPPO and other parties before the Mannheim LD. Although these proceedings have not yet reached a decision on the merits, the UPC has already issued several orders concerning the submission of evidence which gives some indication of how it will evaluate these cases.

The Mannheim LD followed the principles set forth by FRAND case law of the Court of Justice of the EU (CJEU), in particular the leading case *Huawei v ZTE*, which defined the *"negotiation program that outlines the steps that the parties must take on the path to result-oriented negotiations of a fair, reasonable and non-discriminatory license agreement."* [11]

Referring to the CJEU's ruling, the Court noted that the patent owner is required, under EU law, to *"submit a specific written license offer on FRAND terms and, in particular, to specify the license fee and the method of calculating it (ECJ Huawei v. ZTE, ECLI: EU:C: 2015 :817 para. 63)."*

With respect to the latter requirement, the UPC also clarified that

> *"For the explanation of the manner in which the license fee is calculated, as required by the ECJ, it is not sufficient to simply state the mathematical factors on which the calculation is based. Rather, the ratio on which the ECJ is based must be made transparent as to why the SEP holder believes that the offer it is making to the alleged infringer complies with FRAND conditions. The necessary justification can be provided, for example, by reference to a licensing practice already established in the market in the form of a standard licensing program. If no such program exists, specific individual license agreements can be used as a benchmark if it is explained why the SEP holder believes that they can use these as a suitable reference point in comparison with the alleged infringer."* [12]

Another issue addressed by the UPC, in relation to the submission of SEP license agreements by Panasonic as the SEP holder, was how to reconcile the requirements set forth by EU antitrust law with confidentiality provisions typically drafted under U.S. law, which subject the disclosure of the license content only upon the consent of the contractual party, compelling legal reasons or a court order. In this respect, the Court noted that *"as a result, the corresponding clauses only incompletely take into account the mutual transparency obligations of the parties arising from EU antitrust law."*

On a separate note, the Court also pointed out the conflict between U.S. style confidentiality provisions and UPC procedural law, in particular

> *"when disclosure is only permitted to the respective party representatives, but not to a natural person of the party concerned (attorneys' eyes only confidentiality club)"* and thus concluded that *"in this respect, the party's obligation under EU antitrust law to behave transparently when negotiating a FRAND license and enforcing patent rights from an SEP outweighs the conflicting clause and its application by the contracting party concerned. This is because anyone who includes confidentiality clauses in a contract that also concerns standard-essential patents that are enforceable in the European Union, which are in conflict with the EU antitrust law requirements for transparency, cannot generally refuse consent on sufficiently worthy legal grounds."* [13]

Standstill Agreements and Jurisdiction of the Unified Patent Court

The effect of a standstill agreement on UPC jurisdiction was discussed in a recent decision issued by the Paris Central Division (CD) in proceedings including both a revocation action and an action for declaration of non-infringement.[14]

In particular, the defendant argued that the Court lacked jurisdiction to decide the case due to the breach by the plaintiff of a standstill agreement between the parties according to which a party has to give notice to the other party of its intention to file a lawsuit at least 90 days before any lawsuit is filed.

The first issue addressed by the Court was whether the standstill clause actually concerned the court jurisdiction or related only to the use of confidential information received from the other party. The Court decided that the wording of the clause at issue included an obligation to provide the other party with a prior written notice in relation to any "proceeding arising from or relating to a dispute over intellectual property" and

11. *Panasonic Holdings v Xiaomi Technology France, Beijing Xiaomi Mobile Software, Xiaomi Communications, Xiaomi H.K., Shamrock Mobile GmbH, Xiaomi Technology Netherlands, Xiaomi Technology Italy, Odiporo GmbH, Xiaomi Technology Germany*, Mannheim Local Division, CFI_219/2023, CFI_218/2023 and CFI_223/2023, orders of 30 April 2024.

12. *Panasonic Holdings v Guangdong OPPO Mobile Telecommunications*, OROPE Germany, Mannheim Local division, CFI_216/2023, orders of 16 May 2024 (Machine translation from original in German language).

13. *Panasonic v Xiaomi*, cited in note 11.

14. *Tandem Diabetes Care, Inc., Tandem Diabetes Care Europe B.V. v Roche Diabetes Care GmbH*, Paris Central Division, UPC_CFI_589997/2023, decision of 10 May 2024.

thus rejected the plaintiff's interpretation according to which the standstill clause applied only to proceedings using the other party's confidential information.

The plaintiff also contested the validity of the standstill clause itself, claiming that it was contrary to the right of access to court and to a fair trial. The UPC disagreed with this argument providing a list of all the elements that were favorably considered when evaluating its legitimate purpose:

> *"it is aimed at giving the parties a 'cooling-off' period in order to enhance and enable an out-of-court settlement, is proportionate, as it is limited in time and appropriate to verify if an out-of-court settlement is possible, and does not undermine the rights of the parties (and of the claimants, in particular), as the wait for the lapse of the 90-days period does not appear to be detrimental to its interests and, in any case, no allegation has been made by the claimant on that point."*

Finally, the Court considered how a lack of jurisdiction can only occur

> *"when a different court or a different body (as an arbitration board) which is part of a different judicial system have the power to address the dispute ('relative' lack of jurisdiction) or when the situation brought to courts is not even abstractly configurable as a protectable right, pertaining to the administrative or the legislative power ('absolute' lack of jurisdiction)."*

Based on these considerations, the Paris CD affirmed that *"none of these situations is present in the situation at hand"* and therefore concluded that *"the violation of a standstill agreement does not constitute grounds for challenging the jurisdiction of the Unified Patent Court."*

Joint Ownership

Basic Principles of Jointly Owned Patents under United States Law

In contrast to certain UPCA provisions and/or European national law when the UPCA may not apply (according to the criteria set forth by Article 7 of Regulation (EU) No 1257/2012), in the United States the rights of joint owners of a patent are governed by 35 U.S.C. § 262 which provides that *"[i]n the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners."* Subsequent and well-settled case law extends this right to allow joint owners to license the patent to third parties without obtaining the consent of or accounting to other joint owners.[15]

There is also substantial case law in the United States concerning the need to join all joint owners in patent litigation.[16] Under such case law, a joint owner acting alone lacks standing to sue. As a result, by not joining a litigation one joint owner can disrupt the plans of another joint owner seeking to enforce a jointly owned patent against an infringer. U.S. courts have noted that the rule against involuntary joinder is well-established, and a contrary decision would upset the expectations of the parties.

Indeed, the requirement that all joint owners must join a patent infringement action trumps Rule of Civil Procedure 19 concerning required joinder of parties. In the *Ethicon v U.S. Surgical* case a joint owner of the patent did not consent to the suit against U.S. Surgical and as such Ethicon's complaint did not include one of the joint owners of the patent.[17] Thus, the Federal Circuit in a 2 to 1 decision dismissed the suit for lack of standing. Interestingly, Judge Newman in her dissent indicated that she would have applied Rule 19 to the facts of the case.

In light of the above, licensing and litigation issues related to jointly owned patents in the United States can and should be governed by agreement, so the wishes of all parties can be agreed upon in advance.

Joint Ownership of Unitary Patents

The Unitary Patent System has significant implications on jointly owned patents and certain aspects need to be considered at the time of filing an application for a European patent as significant issues extend beyond the grant procedure for European patents. Joint ownership, or co-ownership, is relatively common in many jurisdictions and also across jurisdictions especially in various types of research collaborations and publicly funded research and development programs.

The Unitary Patent System provides which national laws will apply to a Unitary Patent as an object of property. However, joint owners can contractually establish the specific rights and obligations they prefer. Joint ownership agreements, of course, have been an essential tool to manage co-ownership of European patents before the start of the Unitary Patent System but their role have become even more critical now.

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15. *Schering Corp. v Roussel-Uclaf SA*, 104 F. 3d 341 (Fed. Cir. 1997).

16. *STC.UNM v Intel Corp.*, 767 F.3d 1351 (Fed. Cir. 2014).

17. *Ethicon Inc. v U.S. Surgical Corp.* 135 F.3d 1456 (Fed. Cir. 1998).

Representation of Joint Owners before the European Patent Office and the Unified Patent Court

In case of representation before the European Patent Office, if no common representative is appointed by joint applicants or proprietors, the first-named applicant or proprietor is considered to be the representative (Rule 151 EPC). Thus, the order of the listed joint applicants may become decisive early in the patent prosecution process.

It also should be noted that during the grant procedure, a formal request for unitary effect for obtaining a Unitary Patent must be filed by the proprietor of the European patent before the European Patent Office. In the case of joint ownership, the joint owners should have agreed on a common representative and whether to obtain a Unitary Patent. Even if the joint owners have agreed on a common representative, all the patent proprietors must duly sign the request for unitary effect.

Also, representation of joint owners in any proceedings before the UPC should be taken into account in agreements involving joint ownership. There are extensive rules on representation of the parties provided by the UPC Rules of Procedure under Chapter 3, which also apply to joint owners.[18]

Laws Applicable to European Patents as an Object of Property

The laws applicable to a Unitary Patent as an object of property is defined so by Art. 7(1) and 7(3) of EP-UE Regulation,[19] which defines which national law shall be applied to a Unitary Patent as follows:

i. If the applicant of a European Patent as recorded in the European Patent Register had their residence or principal place of business in a UP/UPC member state on the date of filing of the European patent application, the national laws of that UP/UPC member state will apply.

ii. If i. above does not apply, but the applicant of a European Patent as recorder in the European Patent Register had their non-principal place of business in a UP/UPC member state on the date of filing of the European patent application, the national laws of that UP/UPC member state will apply.

iii. If i. or ii. above does not apply, then the German laws regarding a patent as an object property will apply (as the headquarters of the European Patent Office is located in Munich, Germany).

The order in which the joint applicants are listed is decisive beyond the grant procedure in terms of Unitary Patents. Namely, the order of in which the joint applicants are listed determines which national law is applicable to the Unitary Patent as an object of property according to Art. 7(2) of EP-UE Regulation.

The national law will then determine how the Unitary Patent can be assigned to other proprietors, what requirements and effects granted licenses will have, and what rights and obligations the joint owners have. Specifically, the firstly listed applicant is important. The firstly listed applicant in the European Patent Register in conjunction with its residence or place of business at the filing date will determine the applicable national law, which will impact all other joint applicants in accordance with Art. 7(2) of EP-UE Regulation. If neither the first nor any of the further applicants (in their listed order) are domiciled within the territory of the states participating in the Unitary Patent System nor have any place of business in the UPC territory, then German law will apply.

By the wording of Art. 7(2) of EP-UE Regulation, the applicable national law as determined on the date of filing cannot be changed. It will stay the same even if the order of joint applicants would for some reason be altered, if the applicant transfers the Unitary Patent to a third party or to an already listed joint applicant with residence or place of business in a different country, or later changes its place of business. Therefore, attention should be paid to the order of listing the joint applicants already at the time for filing a European patent application in order to avoid potential issues related to the applicable national law relating to a European patent as an object of property.

Opt Out from the UPC Jurisdiction by All Joint Owners

As discussed above, Art. 83(3) and 83(4) UPCA together with Rule 5 of the RoP, during the transitional period, establish so called opt out and opt in procedures enabling proprietors of European patents validated nationally in the UPC member states to choose whether or not their European patents remain in the competence of the UPC. Rule 5 RoP also stipulates that where the patent or application is owned by two or more proprietors or applicants, all proprietors or applicants must lodge the application to opt out.

The UPC Court of Appeal has already issued a decision confirming that a valid opt out application must be filed by or on behalf of all proprietors of all national parts of a European patent to be effective in *Neo Wire-*

18. Regarding representation, in a recent decision by the Paris Central Division UPC_CFI_164/2024 on 2 July 2024, the court noted that *"the fact that a party's representative also carries out active administration tasks on behalf of the represented party and that he may be directly interested in the outcome of the case is not decisive in order to consider that the representative is not independent for the purposes of the application of Rules 290, 291 and 292 'RoP'."*

19. Regulation (EU) No 1257/2012 regarding implementing enhanced cooperation in the area of the creation of Unitary Patent protection.

less v Toyota.[20] In this case Neo Wireless LLC was the owner of European application EP 3 876 490 for all designated states. The German part of the application was transferred to Neo Wireless GmbH & Co KG in February 2023. Neo Wireless LLC filed an opt out for "all EPC states" in March 2023. The opt out application was not filed on behalf of Neo Wireless GmbH & Co and no consent was provided by Neo Wireless GmbH & Co in connection with the opt out application.

Toyota filed a revocation action against the German part of EP 3 876 490 before the Paris Central Division of the UPC. Neo Wireless GmbH & Co KG filed a preliminary objection on the grounds that EP 3 876 490 had been validly opted out from the jurisdiction of the UPC, and the UPC therefore lacked jurisdiction and competence to decide on the revocation action. The Paris Central Division as the first instance court held that the opt out filed by Neo Wireless LLC was invalid, because not all proprietors of all national parts had lodged the application as required by Article 83(3) UPCA and Rule 5.1(a) RoP.

Neo Wireless GmbH & Co KG argued that, according to the wording of Art. 83(3) UPCA, an opt out by any one applicant for a European patent should be sufficient. The UPC Court of Appeal found that Art. 83(3) UPCA required interpretation and determined that the object and purpose of Art. 83(3) UPCA make clear that the opt out application must be lodged by or on behalf of all proprietors of all national parts if there are more validations. Thus, the appeal by Neo Wireless GmbH & Co KG was rejected by the Court of Appeal, which held that the patent had not been validly opted out from the competence of the UPC as required by Article 83(3) UPCA and Rule 5.1(a) RoP.

Contractual Implications of Joint Ownership in Europe

It is obvious from the above that joint ownership of European patents whether traditionally validated or with the unitary effect raises a number of issues that must be considered in relevant agreements. Great variation regarding national laws and relevant caselaw applicable to joint ownership exists between different UP/UPC member states, which, if not understood early enough, can cause complexity in joint ownership and exploitation of jointly owned European patents.

At an early stage, joint owners should agree on the order that they will be listed as applicants on the European patent application, on appointing a common representative and how decisions regarding applying for national patents, a classical European patent with national validations and/or requesting unitary effect are made. It is also advisable to contractually set forth in detail matters related to prosecution and maintenance of patent applications including, for example, who will control prosecution and, if this is managed by one of the joint owners, how the other joint owners are informed and consulted and their rights and options related to prosecution and how costs are shared. It is also recommended to agree on what happens and what are the conditions that must be met in the event that one of the joint owners wishes to leave the joint ownership and/or wishes to assign its rights to a third party.

Rights regarding use and exploitation of the patent should be agreed upon as well including, for example, rights to grant licenses and sub-licenses, possible exclusivities and agreeing on fields and/or territories of use as well as potential revenue sharing. In terms granting licenses and sub-licenses, it should be agreed if a consent of the other joint owner(s) is needed as well as possible conditions that must be met when granting any licenses.

Finally, rights and obligations to enforce, in particular jointly owned Unitary Patents but also classical nationally validated European patents, should be agreed upon including decisions to opt out and opt back in classical nationally validated European patents, keeping in mind that an application to opt out (and also the application to opt back in) must be done by all joint owners. In terms of enforcement, attention should be paid to who has a right to enforce, how the joint owners will cooperate in enforcement, how the burden of costs is carried, and how the possible damages will be shared.

Conclusion

The early case law of the Unified Patent Court is still based mainly on decisions and orders issued in the context of preliminary proceedings. While significant guidance can be gleaned already, future decisions on the merits will provide more specific information about how patent related agreements should be drafted in order to navigate the new European patent system effectively. ■

20. *Neo Wireless v Toyota*, Court of Appeal of the UPC, UPC_CoA_79/2024, order of 4 June 2024.

Intellectual Property Rights And Antitrust: The Distribution Agreements And Technology Transfer Agreements[1]

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In the academic landscape and in Italian and international case law, the relationship between Intellectual Property Rights (IPRs) and antitrust rules presents a partially contradictory relationship. The former aim to encourage innovation and investment by giving the IPR owner the right to exclude third parties (for a certain period of time) from exploiting a new and original solution to a technical problem that can be realised and applied in the industrial field (the patent), an industrial design (the drawings and models), a distinctive sign (the trademarks) or an original work or database (copyright). The latter, on the other hand, are a set of regulatory provisions whose primary objective is to maximise consumer welfare through a system of rules facilitating companies' access to the market or, according to the most accredited economic theories, the attainment of economic efficiency through an efficient allocation of resources (so-called allocative efficiency); it is therefore widespread opinion that antitrust law strives to keep markets open. This imperative was in the past equally commonly opposed to the prerogative of IPRs to create reserved market areas.

Such an approach, which was considering these two areas of law to be in radical conflict with each other, may now be considered outdated on both sides of the Atlantic. In the United States as in Europe, it is now generally recognised that the so-called dynamic competition brought about by intellectual property rights plays a fundamental role in the protection and enhancement of competition. By incentivising the introduction of innovative products and processes, intellectual property rights contribute to improve consumer welfare by satisfying consumers' needs more efficiently or by satisfying new needs.

According to this approach, it is now an accepted principle that both disciplines pursue the same goal, *i.e.*, maximising consumer welfare and promoting efficient resource allocation. As acknowledged by the European Commission in the *Transfer Technology Guidelines* (TTGL) on the application of Article 101 TFEU to technology transfer agreements of 2014, *"Innovation is dynamic and essential for an open and competitive market economy. Intangible property rights foster dynamic competition, as they encourage enterprises to invest in the development or improvement of new products and processes; competition acts in a similar way, as it pushes enterprises to innovate. Therefore, intangible property rights and competition are both necessary to foster innovations and to ensure their competitive exploitation."* [2] The same principle can be found in the antitrust guidelines for IPR licensing agreements in the U.S. where it is stated that *"The intellectual property laws and the antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare. The intellectual property laws provide incentives for innovation and its dissemination and commerce by establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression.* [...] *The antitrust laws promote innovation and consumer welfare by prohibiting certain actions that may harm competition with respect to either existing or new ways of serving consumers."* [3]

*The opinions expressed by the authors in this contribution are personal and do not represent the official position of their respective companies.

1. This article is the English translation with some amendments and updates of a contribution of the same authors published as part of the "Intellectual property: new perspectives for sustainable growth" edited by LES Italy and Netval, 2023 available at *https://les-italy.org/pubblicazioni/proprieta-intellettuale-nuove-prospettive-per-una-crescita-sostenibile*.

2. OJEU L89, 28.3.2014, pp. 3-50, §7.

3. DOJ and FTC, "Antitrust Guidelines for the Licensing of Intellectual Property," §1, p. 2, available at *https://www.justice.gov/atr/guidelines-and-policy-statements-0/2017-update-antitrust-guidelines-licensing-intellectual-property* (last accessed 17.3.2023). For an in-depth discussion of the U.S. discipline, see G. COLANGELO, "The Innovation Market: Patents, Standards and Antitrust, in *Quaderni di Giur. Comm.*," 397, 2016, pp. 123 *et seq.* and A. DEVLIN, "Antitrust and Patent law," OUP, 2016, pp. 407 *et seq.*

Although it may be considered unquestionable today that these two disciplines pursue the same objective, this is done from different perspectives and in different ways such that in the practical application of the regulatory provisions, situations may occur in which these two areas of law may enter into conflict. However, this conflict most often appears to be solvable by means of the legislator or by the judges that apply the two sets of rules in a way that both reach the common goal in a coordinated way.

The first step in the antitrust field is the acknowledgement that the notion of anti-competitive agreements or concerted practices between undertakings is a restrictive one. This interpretation clearly emerges from the principle expressed by the Court of Justice in the *Groupement des cartes bancaires* case, whereby the EU supreme court clarifies the principle that only agreements and practices that by their nature are *"detrimental to the proper functioning of normal competition"* [4] fall under this prohibition of Article 101 TFEU. Commercial practices involving the exploitation of IPRs are often exempt from the antitrust prohibition since, although they entail restrictions of competition, they generate efficiencies that are sufficient to offset any anti-competitive effects in compliance with the requirements set out in Article 101.3 TFEU, provided that they do not contain hardcore restrictions of competition or excluded restrictions.

In today's antitrust law, the IPR licensing agreements, while they entail the restrictions of competition which by their nature are necessary for their implementation (*e.g.*, the granting of one or more exclusivities), are in the vast majority considered to have pro-competitive effects because they support the dissemination of technologies, the consequent creation of value, and ultimately help to promote competition by removing obstacles to the development and exploitation of new and/or improved technologies. In particular, in sectors characterised by the existence of numerous patents, *"licensing often occurs in order to create design freedom by removing the risk of infringement claims by the licensor"* (§17 and §4.1.3 TTGL).

A similar approach is taken in the field of rules prohibiting the abuse of a dominant position. In this case, it is a well-established principle both in the U.S. and Europe that the granting of IPRs does not in itself lead to the creation of a monopoly in the economic sense and, therefore, to market power that makes the IPR holder dominant. Notwithstanding the fact that IPRs constitute legal monopolies, their exercise is very often a source of competitive pressure both on those who do not have these rights—because they are incentivised to create alternative ones—and on the IPR holders—who are incentivised to improve their own IPR-protected products and processes to keep their competitive advantage. What is caught by the prohibition of Article 102 TFEU today is the improper use of the exclusive right, *i.e.*, when it is exercised in a way that entails an exclusion of competitors or an extension of the exclusivity beyond what is legitimately necessary to guarantee the remuneration of the investments made for the creation of innovation and, more generally, the role of the innovation incentive.

The economic and legal fields in which intellectual property rights and modern antitrust law interact are manifold and heterogeneous. For instance, in the field of cooperation among companies, although there is no precise legal definition of agreements pursuing a cooperative objective in pro-competitive terms, it can be said in general that this notion encompasses all agreements primarily aimed to achieve the objectives of rationalising the functioning of the participating companies at the level of research and development, production, procurement, marketing of products or provision of services (*e.g.*, distribution agreements) and finally at the specific level of technology transfer (*e.g.*, licensing of IPRs).

In line with the aims of LES Italia, the focus of the therein contribution is on the antitrust assessment of two specific categories of agreements at the European level: distribution agreements and technology transfer agreements. The former are vertical agreements, *i.e.*, agreements where each contracting party operates at a different level of the production or distribution chain. The latter, on the other hand, may be concluded both between undertakings that are competitors on the market for products and/or services incorporating the technology being transferred and on the technology market, as well as agreements between non-competitors.

1. Vertical Agreements Between Companies for Distribution

One of the objectives of the Treaties of Rome establishing the European Economic Community, which subsequently permeated all legislation up to the Treaty on the Functioning of the European Union, is the establishment of a common (and then single) European market. The objective of economic integration, based on the free movement of goods, services and productive factors (capital and labour), could not disregard the adoption of a unitary European regulation, which could not be derogated from by national regulations, aimed at eliminating and preventing those barriers potentially capable of altering the economic parity between operators on the European market, which also include anti-competitive conduct by companies.

Article 101 TFEU represents one of the founding

4. European Court of Justice, judgment 11 September 2014, C-67/13, available at *www.curia.eu* (last accessed 17.3.2023), para. 50.

bases of the legislation that, within the European Union, is deputed to strictly regulate those practices that must allow economic operators to act in full respect of equal opportunities for development in the market and, therefore, also of competition, while allowing the necessary flexibility to supervisory authorities to assess conduct that could even potentially damage the completion of the single market.

It is based on three fundamental directives: (i) the prohibition (foreseen in the first paragraph) of a series of commercial practices that the European legislator has already identified as being detrimental to trade between Member States by affecting competition between undertakings operating in the single market; (ii) the outright nullity of agreements or decisions prohibited by Article 101 TFEU; and finally, (iii) the exemption of those decisions, conducts and practices of undertakings that are likely to contribute to improving the production or distribution of goods or to promoting technical or economic progress.

Agreements or decisions whose purpose is to make the market behaviour of competitors more pre-visible and, therefore, governable, are void as of right. It is an irremediable nullity, not subject to a statute of limitations, *ex tunc*, which can be detected *ex officio* and by anyone who considers himself harmed by an anti-competitive agreement or practice. The distinction that Article 101.1 TFEU makes between restrictions 'by object' and 'by effect' is substantial: if an agreement has as its object the restriction of competition, it has by its nature such a high potential to produce negative effects on competition that it is not necessary, for the purposes of application[5] of Article 101.1 TFEU demonstrate the existence of specific effects on the market, as well as the parties' intention to restrict competition (although this is an important element of the assessment). There are also agreements whose object is not to restrict competition; however, their anticompetitive effects, even potential ones (as long as they are appreciable), are assessed for the application of Article 101 TFEU.

However, not all agreements between undertakings, especially those between undertakings at a different level of the supply chain, are to be considered as having an anti-competitive object or as having negative impact on competition, since some of them are, on the contrary, capable of developing significant economic potential in EU markets. It is in this light that the third paragraph of Article 101 TFEU must be read, which explicitly admits the possibility that the provisions of the first paragraph may be declared inapplicable to certain agreements, decisions or concerted practices that have as their object the improvement of production or distribution of goods, or the promotion of technical or economic progress, and that—by reserving a fair share of the profits to consumers—do not impose on the undertakings concerned restrictions that are neither indispensable nor constitute a means of eliminating competition in respect of a substantial part of the products. Such agreements (whether individual or categories of them, or concerted practices) which, although restrictive, have the potential to create economic benefits that outweigh the anti-competitive effects, are thus exempted from the prohibitions of Article 101 TFEU, provided they fulfil the four cumulative conditions mentioned above.

The Commission may issue a number of general exemption regulations for certain categories of agreements which, because they do not contain restrictions on the blacklist of severely and objectively anti-competitive restraints and are concluded between undertakings without significant market shares, have the potential to produce positive economic and competitive effects.

Precisely in this respect, agreements between companies operating at different levels of the supply chain (so-called vertical agreements) have been viewed more favourably by the Commission. The latest general exemption[6] regulation of vertical agreements (VBER)[7] entered into force on 1 June 2022 together with the new Guidelines on Vertical Restraints (VGL),[8] and establishes a so-called "safe harbour" for those vertical agreements whose parties do not exceed certain market share thresholds (30 percent) (Article 3), provided that these agreements do not contain hardcore restrictions (Article 4), *i.e.*, all those practices that are considered to be serious restrictions of competition.

5. § 21, Communication from the Commission, "Guidelines on the application of Article 101.3 TFEU," OJEU no. C 101 of 27/04/2004 pp. 97 - 118.

6. As for the motor vehicle sector, the Commission opted for a special regulation whereby the general exemption regulation applies only to agreements related to the distribution of new motor vehicles, while agreements related to aftermarkets are covered by both the general exemption regulation and specific exemptions set out in Reg. (EU) No 461/2010, which includes a complementary list of prohibited hardcore restrictions (Article 5) justified by certain peculiarities of the aftermarkets and which is accompanied by additional specific guidelines for the sale and repair of motor vehicles and for the distribution of spare parts (OJEU C138, 28.5.2010, p. 16). This regime has been extended until 31 May 2028 by Reg. (EU) 2023/822 (OJEU L 102I, 17.4.2023) amending the 2010 regulation. For a more detailed exam of this specific regime see A. FRIGNANI M. NOTARO, "Il Regolamento 461/2010 di esenzione per categoria degli accordi verticali nel settore automobilistici: la saga dei pezzi di ricambio non sembra aver fine," in Dir. Comm. Int., 2010, 4, p. 715 and A. PAPPALARDO, "Il diritto della concorrenza dell'Unione Europea - profili sostanziali, II ed," UTET, p. 441 *et seq.*

7. Regulation (EU) No 2022/720, 10.5.2022, OJEU L 134, 11.05.2022.

8. OJEU C 248, 30.6.2022, pp. 1-85.

The VBER, in addition to redefining the safe harbour, updated the entire antitrust discipline in the light of the exponential development of electronic commerce, which had only been partially regulated by the previous Regulation No. 330/2010.

In particular, in view of the growth of online sales compared to physical sales channels, dual pricing is no longer considered a hardcore restriction (§209 VGL), as it is seen as a legitimate way to incentivise greater investment between on- and offline channels (provided that this differentiation does not have the effect of preventing the actual use of the internet for the sale of goods or services). Similarly, the new GLPs allow that (as part of a selective distribution system) the provider may impose different criteria for on- and offline sales, provided that this solution does not restrict competition.

According to the most recent conclusions of the Court of Justice, in particular the principles set out in the judgments *Pierre Fabre*[9] and *Coty Germany*,[10] only those restrictions on online sales are considered hardcore that effectively prevent, even if indirectly, the use of the internet as a channel for the commercialisation of goods and/or services, as well as those that prevent the use of an entire online advertising channel. Accordingly, limitations tout court of price comparison sites (which are deemed a genuine advertising channel) are prohibited, unless the limitations result from the application of specific and objective quality standards. Similarly, sales using marketplaces may be restricted, as they are deemed to be only one of the online sales methods that may be used by the distributor.

Another novelty of the new VBER is the confirmation of the block exemption of the so-called dual distribution (which occurs when the supplier is also a distributor of its own goods, in competition with its own distributors—Article 2.4), but above all the attention that the European legislator has paid to the critical nature (from an antitrust point of view) of information exchanges at a horizontal level. Abandoning a technical solution based on specific market thresholds, the Commission has specified that in cases of dual distribution between supplier and distributor, exchanges of information are excluded from the benefit of the exemption if they are neither necessary to improve the production or distribution of the goods/services covered by the contract, nor directly related to the implementation of the vertical agreement.[11]

As requested by some stakeholders during the several rounds of public consultations for the review of the 2010 VBER,[12] the Commission confirmed its position on "resale price maintenance" (RPM) clauses, which continue to be considered as a hardcore restriction, although with some openings in cases where *de facto* RPM clauses may be eligible for an individual exemption under Article 101.3 of the Treaty.

RPMs are (Article 4 (a)) agreements requested by an upstream supplier to a downstream buyer (typically a distributor, or a retailer) which, directly or indirectly, have their object of restricting the buyer's ability to determine its resale prices. This may happen because of contractual provisions specifically preventing the buyer from selling at a price which is below a certain price level determined by the seller.[13]

But there may be also contractual provisions that do not directly set the retail price, yet they have the indirect effect of influencing the self-determination of the buyer to freely set its resale price, *i.e.*, by granting incentives only to those resellers who conform to a certain price level suggested by the seller, or to a certain resale margin. Several cases of indirect RPM agreements are listed in §187 VGL, but they serve just as an example of any agreement which, although apparently neutral pricewise, in fact influences the ability of the buyer to determine the resale price of any purchased good (see Table 1, on page 143).

Contrary to the U.S.,[14] RPM is seen negatively by the European antitrust national authorities and the European Court of Justice, as it may both limit (or prevent, as the case may be) the intra-brand competition and facilitate anti-competitive inter-brand agreements between suppliers and/or distributors.

9. European Court of Justice, judgment of 13 October 2011, "Pierre Fabre Dermo-Cosmétique," C-439/09, cited above.

10. European Court of Justice, judgment of 6 December 2017, "Coty Germany," C-230/16, cited above.

11. See §99 VGL indicating a list of information to which the exemption applies and §100 containing a list to which it does not apply.

12. The public document can be found here *https://competition-policy.ec.europa.eu/system/files/2021-11/contributions_summary_draft_revised_VBER_and_VGL.pdf*, page 9-10.

13. For a more detailed exam of the new RPM rules in the VBER 2022, see B. ROHRßEN, "VBER 2022: EU Competition law for Vertical Agreements," Springer 2023.

14. An interesting approach to RPM, which differs from both the U.S. and EU law is the one adopted by Australia.While *per se* illegal, the Australian Competition law contains processes which can provide legal immunity to practices including RPM. Prior to recent amendments to the Australian Competition & Consumer Act (ACCA), parties could only seek authorisation for RPM conduct on public benefit grounds. Recent amendments to the ACCA allow parties to also seek RPM immunity through a notification process, which is a significantly simpler process than the authorisation process. For both authorisation and notification processes, the Australian Competition & Consumer Commission (ACCC) will consider whether the public benefits of the RPM conduct outweigh any public detriments. For more details about the ACCC approach to RPM, see ACCC, "Resale Price Maintenance Notification Guidelines," 2022, available at *https://www.accc.gov.au/about-us/publications/resale-price-maintenance-notification-guidelines* (last accessed 06.8.2024).

Table 1 – RPM (VGL §187)	
Direct measures	**Indirect measures**
Fixing the resale price—here and below always including fixing price minimum resale prices or price levels	Fixing the resale margin
Allowing the supplier to fix the resale price	Fixing the maximum level of discount that the distributor can grant from a prescribed price level
	Making the grant of rebates or the reimbursement of promotional costs by the supplier subject to the observance of a given price level
	Imposing minimum advertised prices (MAPs), which prohibit the distributor from advertising prices below a level set by the supplier
	Linking the prescribed resale price to the resale prices of competitors
	Threats, intimidations, warnings, penalties, delay or suspension of deliveries or contract terminations in relation to the observance of a given price level

RPM conducts are one of the most sanctioned vertical restrictions by EU Competition State Authorities by far. However, similarly to the 2010 version of VBER,[15] the Commission still does not consider a provision containing a maximum resale price, or the recommendation of a resale price, as unlawful *per se*. It may turn into one if combined with other provisions that have the effect of holding back the buyer from freely fixing the price of the products.

Although the EU Commission takes a strict approach to RPM enforcement, there may be cases when RPM clauses enhance efficiency. Following the suggestions of some national competition authorities during the targeted consultation for the impact assessment of the review of Regulation (EU) No 330/2010, the Commission exemplifies in par. §197 VGL several instances of pro-competitive RPM clauses, mainly related to: i) the launch of new products on the market; ii) short-term promotions (up to six months maximum) and iii) provision of additional pre-sales services by retailers to avoid free riding. Suppliers intending to claim the pro-competitive effect of an RPM clause still have to provide evidence of such effect and prove that all the conditions of Article 101.3 are fulfilled in the individual case. Furthermore, in the new VGL there is another case in which RPM may be exempted, *i.e.*, where *"A minimum resale price or MAP can be used to prevent a particular distributor from using the product of a supplier as a loss leader. Where a distributor regularly resells a product below the wholesale price, this can damage the brand image of the product and, over time, reduce overall demand for the product and undermine the supplier's incentives to invest in quality and brand image. In that case, preventing that distributor from selling below the wholesale price, by imposing on it a targeted minimum resale price or MAP may be considered on balance pro-competitive"* (§197 lett. (c)).

The Commission's position in the new VGL confirms a somewhat more relaxed interpretation in respect to price clauses, despite the different outlook on the subject held by many national authorities and the European Court of Justice, that in several cases considered RPM to be a restriction of competition by object within the meaning of Article 101.1 TFEU. Interestingly though, in one of the most recent cases, the ECJ also[16] seems to have softened its approach to RPM conducts, and it decided that hardcore restrictions (the case dealt precisely with an RPM clause) cannot be automatically considered as restriction of competition by object, thus reinforcing the interpretation that the two definitions of hardcore restrictions listed in Article 4 of VBER and the concept of "restriction by object"[17] do not overlap.[18] The aim of a hardcore restriction, although in principle could raise suspicions given its capability to restrict competition, is only to exclude certain vertical restrictions from the

15. *See https://competition-policy.ec.europa.eu/document/download/71915692-b99a-4206-839d-29e58872a10f_en?filename=VBER_IA_summary_contributions_from_NCAs.pdf* page 5 (last accessed 06.8.2024).

16. European Court of Justice, judgement C-211/22, "Super Bock Bebidas SA, AN, BQ v Autoridade da Concorrencia," dated 23 June 2023 *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62022CJ0211* (last accessed 06.8.2024).

17. A "restriction of competition by object" is either a conduct or an anti-competitive practice that is intrinsically damaging competition to the point where no further assessment in regard to their impact or effect on competition is deemed necessary.

18. "*(..) as the Commission observed in its written observations before the Court, the concepts of 'hardcore restrictions' and of 'restriction by object' are not conceptually interchangeable and do not necessarily overlap.* It is therefore necessary to examine restrictions falling outside that exemption, on a case-by-case basis, with regard to Article 101(1) TFEU." (ECJ, Judgement C-211/22, "Super Bock Bebidas SA, AN, BQ v Autoridade da Concorrencia," dated 23 June 2023 § 41).

scope of a block exemption. However, a vertical agreement fixing minimum resale prices must also be evaluated in respect to the context of its formation (legal and economic alike) of its content and other consideration (such as *"the nature of the goods or services affected, as well as the actual conditions of the functioning and structure of the market or markets in question"*)[19] to assess whether in fact it constitutes a harm to competition. If it does, given the specifics of the case which must be analysed on a case-by-case basis, then a RPM included in a vertical distribution agreement can be found to be a restriction of competition by object.

The ECJ clarified that the classification of RPM as hardcore restriction does not imply a stigma on its being always a restriction by object. Therefore, national courts cannot just rely on the mere presence of an RPM in a vertical agreement to state that such clause is restrictive of competition beyond any doubt—and beyond any further assessment.

2. Technology Transfer Agreements (TTAs)

In antitrust law, technology transfer agreements are agreements concluded between two or more undertakings concerning the licensing (or, in some cases, the assignment)[20] of IPRs relating to a technology, often covering patent rights, know-how and, in this phase of exponential growth of digital markets, increasingly also software copyrights. Complex contracts combining licences of several IPRs also fall within the same scope.

While licensing agreements are now considered to have multiple pro-competitive effects as mentioned above, there may be particular situations in which such agreements may have anti-competitive effects, *e.g.*, when two competing undertakings use a technology transfer agreement to share a certain market (§169 TTGL) or when the undertakings have a high market share (see below) both in the market for products incorporating the licensed IPR and in the market for licensed technology rights and their substitutes.

Since in European antitrust law a cartel is not irretrievably prohibited and void if four cumulative conditions, two positive and two negative, provided for in Article 101.3 TFEU are met, the Commission, in order to allow operators to identify which TTAs can be exempted, has also adopted a regulation for this specific category of agreements: Reg. (EU) no. 316/2014 (*Transfer Technology Block Exemption Regulation*, TTBER)[21] accompanied by Guidelines (TTGL) in which the Commission sets out the principles it applies in assessing when TTAs fall within the scope of 101.1 TFEU and in recognising the exemption of the aforementioned regulation.

After setting out the relevant definitions (Article 1) and an article acknowledging the exemption for TTAs containing restrictions of competition falling within the scope of Article 101.1 TFEU (Article 2), the TTBER contains a safe harbour threshold expressed as a percentage of market shares below which it is presumed that the participating undertakings do not have sufficient market power to cause serious risks to competition when they engage in TT agreements (Article 3), then lists a series of hardcore restrictions which, if present in the agreement, irrespective of the market shares of the parties,[22] render the exemption in any event inapplicable (Article 4) and, finally, a series of excluded restrictions[23] from the benefit of the block exemption (Article 5). For exemption to be granted, agreements must fulfil certain specific requirements.

First, they must be agreements concluded between two undertakings.[24] Multilateral agreements, therefore, are subject to individual assessment by analogy with the same principles set out in the TTBER. Similarly, the Regulation also does not apply to agreements establishing patent pools, *i.e.*, agreements whereby two or more undertakings create a technology package that is licensed to pool participants and/or third parties;[25] in addition to being multilateral agreements (§56 TTGL), they do not

19. ECJ, judgement C-211/22, "Super Bock Bebidas SA, AN, BQ v Autoridade da Concorrencia," dated 23 June 2023, § 35.

20. Article 1.1 lett c. (ii) Reg. no. 316/2014.

21. Reg. (EU) No 316/2014, 21.5.2014, OJEU L 93, 28.3.2014, p. 17-23. The current regulation is due to expire on 30 April 2026 and the Commission has started the consultation process ahead of this deadline see *https:// ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13636-EU-competition-rules-on-technology-tran-sfer-agreements-evaluation_en* (last accessed 06.8.2024).

22. See Com. Commission "De minimis," OJEU C 291, 30.8.2014, pp. 1-4, §13.

23. The inclusion in a licence agreement of one of the restrictions set out in the article does not prevent the application of the block exemption to the remainder of the agreement, if that remainder is severable from the excluded restrictions. Only the individual restriction is not covered by the block exemption, which requires an individual assessment (§3.5 TTGL).

24. In antitrust law, in particular European antitrust law, the notion of undertaking is reconstructed in functional terms so that it "encompasses any entity engaged in an economic activity, regardless of the legal status of that entity and the way in which it is financed" (See Court of Justice, judgment of 23 April 1991, C-41/90, *Höfner and Elser v. Macrotron*, §21). For a more detailed discussion of the concept of undertaking see A. FRIGNANI S. BARIATTI, "EU Competition Law, in Trattato di dir. Comm. and Dir. Pub. Econ." (edited by F. GALGANO), Vol. LXIV, 2016, Cedam, pp. 83 *et seq.*

25. As recognised by the Commission itself, technology pools can be either simple arrangements between a limited number of parties or complex organisational arrangements whereby the organisation of the licensing of the pooled technologies is entrusted to an independent body. In both cases, the pool may allow licensees to operate on the market on the basis of a single licence. For an in-depth discussion of the European regulation of patent pools, see A. FRIGNANI, "Patent pools after EU Reg. no. 316/2014 providing for a block exemption of categories of technology transfer agreements," in Dir. Comm. Int., 2016, no. 2, p. 343.

provide for the grant of a particular licence to produce contract products (§247 TTGL). Technology pools, however, have an entire subsection of the TTGL (§4.4).

The TTGLs firstly recognise that pools (and in some cases standards related to them) generate undoubtedly favourable effects for competition and market efficiency: reduction of transaction costs, setting a limit for cumulative royalties (thus avoiding the problem of double marginalisation and the creation of a one-stop shop), and greater efficiency in the management of joint production phases. Afterwards, there can be possible restrictions of the competition that such collaborative instruments between companies may generate, including price fixing cartels, reduction of innovation, foreclosure of alternative technologies, and barriers to entry for new technologies. The main points on which the Commission has focused its regulatory intervention concern the formation (in particular, the selection of the technologies included in the technology pool), establishment and functioning of the pool, as clarified in paragraph 248 *et seq.*[26]

Secondly, the TTAs must relate to the IPRs listed in Article 1.1(b), from which list are excluded contracts having as their exclusive object a trade mark or copyright licence which do not relate to software.[27] Thirdly, licence agreements must be concluded between undertakings holding a combined share of no more than 20 percent or 30 percent in the two relevant markets indicated above, depending on whether they are more or less in competition with each other.

Fourth, Article 4 of the TTBER lists the always prohibited restrictions by making a distinction between the case where the parties are competitors and the case where they are not competitors. In the first case, where anti-competitive effects are more likely to occur, hardcore restrictions are those clauses that: (i) affect the ability of a party to decide on the prices charged for the sale of products incorporating the licensed technology; (ii) concern the limitation of production (with the exception of those imposed in a non-reciprocal agreement);[28] (iii) have the sole purpose of sharing markets and/or customers (see Table 2); and (iv) inhibit both

TABLE 2

Allowed restrictions under Article 4.1 (c) TTBER—agreements between competitors	Permitted in mutual agreement?	Permitted in non-reciprocal agreements?
Prohibition of production in one territory or of active/passive sales in one territory or to a customer group reserved for the other (licensor or licensee)	NO	YES
Prohibition of active sales in the territory or to a customer group reserved for another licensee	NO	YES—insofar as the licensee was not a competitor of the licensor at the time of the conclusion of the agreement
Prohibition of passive sales in the territory or to a customer group reserved for another licensee	NO	NO
The licensor restricts the licensee from using the technology to produce components to be incorporated into its own products and prohibits the sale to third parties.	YES—to the extent that it can sell the components as spare parts	YES—to the extent that it can sell the components as spare parts
The obligation imposed on the licensee, in a non-reciprocal agreement, to produce the contract products only for a particular customer	NO	YES—if the licence was granted for the creation of an alternative source of supply for the customer

26. The Commission draws two basic distinctions, between: a) complementary technologies, both of which are necessary for the production of the product, and substitute technologies, which individually allow the holder to produce the product; b) essential and non-essential technologies, depending on whether or not there are no substitutes, inside or outside the pool, for the production of the product or are an essential element to meet the standard followed by the pool (technologies essential to the standard). While pools of complementary technologies generally have positive effects for competition, the massive inclusion of substitute technologies in pools makes an exemption unlikely.

27. A trademark licence agreement will only be assessed under the TTBER if it relates to goods or services obtained from technologies covered by agreements falling within Regulation No 316/2014. When, on the other hand, such agreements are part of a distribution agreement (*e.g.*, a commercial affiliation such as a franchise agreement) or selective distribution agreement, they will be assessed in light of the provisions set out in VBER.

28. For the definition of reciprocal and non-reciprocal TTAs, see Article 1.1(d) and (e) TTBER.

parties to the agreement from carrying out research and development (R&D)[29] or the licensee from exploiting its technological rights.

In contrast, when the undertakings concerned are not competitors, the prohibited clauses are less stringent and are:[21] (i) the imposition of a minimum resale price (not the mere recommendation or indication of a maximum price as is the case with vertical agreements); (ii) restrictions of the territory (or customers) within which the licensee may make passive sales (except for a number of restrictions which are in practice necessary for the functioning of a licence agreement; see table 3);[30] (iii) the prohibition of active and passive sales to end-users imposed on the licensee member of a selective distribution operating at the retail market level.

TABLE 3

Allowed restrictions under Article 4.2 (b) TTBER —agreements between NON-competitors	Allowed?
Prohibition of passive sales in the exclusive territory or to a customer group reserved for the licensor	YES
Restrictions on passive sales in the exclusive territory or to a customer group reserved for another licensee	NO—in Reg. 2004 this restriction was exempted for two years after the beginning of the sale of the product today in the TTGLs recognised that it does not fall under 101 TFEU—see text
The licensor restricts the licensee from using the technology to produce components to be incorporated into its own products and prohibits the sale to third parties.	YES—insofar as it can sell the components as spare parts
The obligation imposed on the licensee, in a non-reciprocal agreement, to produce the contract products only for a particular customer	YES—if the licence was granted for the creation of an alternative source of supply for the customer
Restrictions on sales to end-users	YES—when the licensee operates as a wholesaler
Restrictions on unauthorised distributors within a selective distribution system	YES—unless the licensee is a wholesaler, the licensee must be free to sell to end users

Whereas in the VGL they represent a hardcore restriction, in the TTA restrictions on passive sales by licensees into an exclusive territory or to a group of customers assigned to another licensee may fall outside the scope of Article 101.1 TFEU, and thus are permissible, if limited to a certain period[31] and if they are objectively necessary for the protected licensee to enter a new market by making substantial sunk investments.

Finally, Article 5 lists the restrictions excluded from the TTBER for which a case-by-case assessment is required:[32] (i) grant backs (exclusive grant backs) whereby the licensee of a "basic" technology undertakes to assign to the licensor, or to grant under exclusive licence, rights to improvements or new applications developed subsequently, whereas non-exclusive grant back clauses fall under the TTBER exemption;[33] (ii) no challenge clauses whereby the licensee undertakes not

29. This is except where such a restriction is 'indispensable to prevent disclosure of the licensed know-how to third parties.'

30. Unlike in the case of vertical agreements, in the case of licence agreements not only restrictions on active (*i.e.*, solicited) sales are permissible, but also certain restrictions on passive (*i.e.*, unsolicited) sales.

31. The TTGLs indicate that in most cases two years are sufficient to recover the investment, but also recognise that in certain cases, the licensee may need a longer protection period to recover the costs incurred (§ 126).

32. In the consultation process concerning the evaluation of TTBER 2014 LES Italy expressed the view that in the new TTBER *"should be clarified that being the co-owner of the improvements is not an exclusive grant-back. Often when two companies cooperate and the IP under license (i.e., trade secrets protecting data) is used to create further technical results which are eligible for IP protection in many cases the licensor and licensee agree to be co-owners of the IP rights insisting on such improvements. LES Italy also suggests to clarifying what consideration for exclusive grant back is able of offsetting procompetitive effects as stated in the current §130 of TTGL or, in case, to provide more guidance in order to allow companies to assess what is the level of consideration that is the relevant factor in the context of its individual assessment under Article 101."* For more detail please see the full contribution at the following link *https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13636-EU-competition-rules-on-technology-transfer-agreements-evaluation/public-consultation_en* (last accessed 06.8.2024).

33. In the 2004 Rules it was different: exclusive grant back obligations on non-separable improvements were exempted in the same way as non-exclusive grant back clauses. Exclusive grant back obligations on severable improvements, on the other hand, were already excluded from the exemption. See J. MARKVART, "The Treatment of Exclusive Grant Backs in EU Competition Law," in *Journal of European Competition Law & Practice*, 2018, Vol. 9, No. 6, p. 361. It is important to point out that the grant back obligation is essential for the operation of a patent pool as it precludes holders of fundamental rights from benefiting from the single licence offered by the pool's administrator and at the same time from engaging in hold-up practices to the detriment of the other pool members. Without an obligation of retrocession on the part of all breeders, the patent pooling agreement would hardly be concluded. On this point see O. BORGOGNO, "Il contratto di patent pooling: tra antitrust e proprietà intellettuale," 2015, pp. 191 available at the following link *https://www.studiotorta.com/tesi-contest/* (last accessed 6.8.2024).

to challenge the validity of the licensed IPRs;[34] (iii) restrictions on R&D when the agreement is entered into between non-competing undertakings.

Exclusive retrocessions require a case-by-case assessment because it is argued that insofar as they prevent licensees from exploiting realised improvements, they deprive the licensee of the incentive to innovate. Some clarifications are needed on this point: (i) exclusive grant back clauses do not always have an overall negative impact on innovation because the licensor, without a contractual mechanism to counterbalance future competition or a strong grant back clause, would not fully license a state-of-the-art technology;[35] in such cases, therefore, the benefits that can be achieved in terms of inter-technology competition through the agreement should be weighed as carefully as the possible negative effects in terms of intra-technology competition; (ii) the risk of disincentives to innovation is very low in situations of strong inter-technological competition and multiple competing research poles; (iii) in view of the rationale of the exclusion it can reasonably be argued that the licensor's co-ownership of improvements is normally not an excluded clause;[36] (iv) the payment of a royalty by the licensor makes it less likely that an exclusive grant back obligation leads to a disincentive for the licensee to innovate, even if the legislator does not give any indication as to the extent to which this correspondent must have (§130 TTGL).

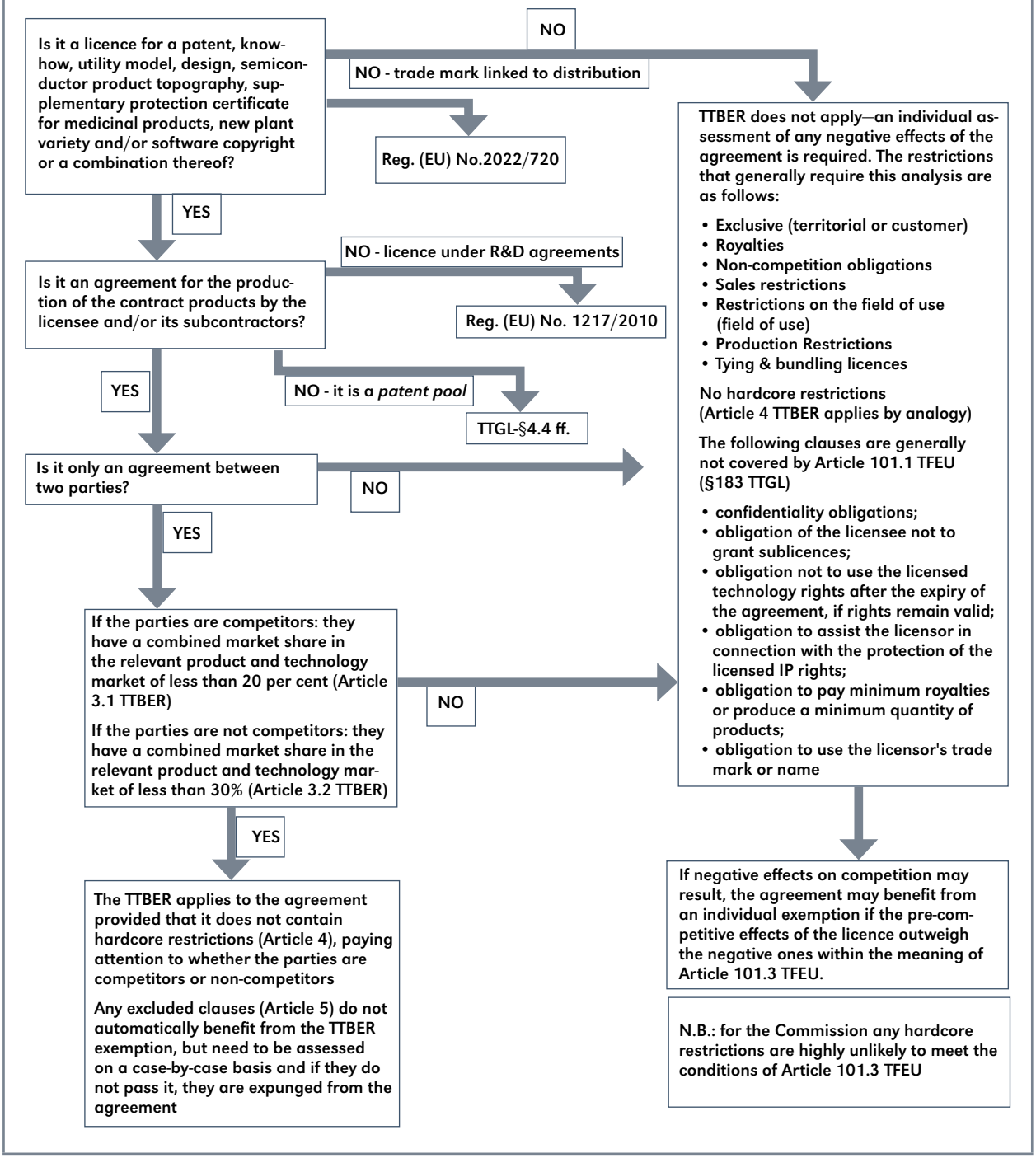
In conclusion, both exemption regulations should mark the transition from a legalistic and formalistic European approach to a more economic one. However, on the evidence of the facts, this desirable objective does not seem to be adequately achieved. In the regulation of vertical agreements, in fact, even in the last regulation, apart from a deserving effort to provide more clarification in several crucial areas (such as for instance on the positive effects on competition generated by fixed price policies; §197 VGL), it may be perceived a certain "basic rational of hesitation" in not recognising the positive effects in terms of increased inter-brand competition gathered by certain restrictions on online sales, especially the ones aimed at preserving the value of brands and the substantial investments necessary to face the competition of a digital market. The same can be alleged for TTBER, which needs some important adjustments, especially with a view to favouring those clauses that, while constituting restrictions within the same technology, are nevertheless functional to the development of robust inter-technology competition. ■

34. This is not an absolute prohibition. Article 5.1(b) itself states that it is *"without prejudice to the possibility, in the case of an exclusive licence, to terminate the technology transfer agreement if the licensee contests the validity of any of the licensed technology rights."* For a more detailed discussion of the scope of the exclusion see §133 *et seq.*

35. In this case, the licensor would at most license a 'slightly obsolete' technology. The licensor would then have to spend resources to develop technologies that bridge the gap between the licensor's cutting-edge technology and the licensed technology before being able to develop new technologies. In this scenario, therefore, an exclusive grant back clause can contribute to the dissemination of innovative knowledge and accelerate the overall innovation process of the system, especially in cutting-edge technology sectors.

36. Provided that the by-laws governing the community do not provide for mechanisms that effectively exclude the exploitation of the improvements also by the licensee.

Flow Chart: Application (TTBER)-REG No 316/2014



Latest Case Decisions Affecting Patent Licenses In U.S., Europe And Japan

By Yorikatsu Hohokabe, Hideaki Kobayashi and Dirk Schüßler-Langeheine

Abstract

Global IP practitioners need to know what is happening in major market segments to protect and enforce their IP rights for their business activities or their clients' business activities, given the most recent case decisions. They may need to change their IP strategy for better accommodation in such a legal environment to increase present and future business competitiveness.

This workshop session, which was scheduled as **Workshop No. 11** at the LESI Annual Conference 2024 (Madrid) on April 30, 2024, provided information regarding the latest case decisions in the U.S., Europe and Japan. This panel was originally planned to be moderated by Dr. Yorikatsu Hohokabe, but was actually run as jointly moderated by Yorikatsu, followed by Dr. Dirk Schüßler-Langeheine.

Panel:

- Dr. Yorikatsu Hohokabe, Senior Advisor, OBLON - co-moderator
- Dr. Dirk Schüßler-Langeheine,[1] Attorney, Hoffman Eitle - co-moderator
- Mr. Hideaki Kobayashi, Attorney, OHNO & Partners

U.S. Case Decisions

Importance of Inventorship—Significant impact on patent infringement litigation learned from U.S. case decisions

Three recent case decisions were addressed:

1. *HIP, Inc. v. Hormel Foods Corp.*, Fed. Cir. No. 2022-1696; May 2, 2023

Background

Hormel was working on a project to improve its microwave cooking process for precooked bacon. Hormel employees met with David Howard, an employee of Unitherm, the predecessor of HIP, to discuss the potential processes and HIP's cooking equipment. Eventually, HIP and Hormel entered into a joint agreement to develop an oven having a two-step cooking process; the first step to preheat the meat and then a higher temperature cooking step.

Hormel conducted testing on its own that eventually resulted in a two-step cooking process; the first step involving preheating the meat in a microwave oven and the second step involved cooking the meat in a superheated steam oven.

Hormel filed a patent application on this two-step cooking process that named only its own employees as inventors. The claims of the issued patent recite the use of a microwave oven, infrared oven or hot air for the preheated step.

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District Court

HIP sued Hormel, asserting that Howard was a joint inventor, and that HIP was a co-owner of the patent. Among other reasons, HIP asserted Howard was a co-inventor based upon the contribution of the idea of using an infrared oven in the preheating step. Howard alleged that during the collaboration he suggested the use of an infrared oven in the preheating step.

The district court found that Howard was an inventor solely based upon the contribution of the infrared preheating step, and that Howard's conception of that idea was confirmed by a Hormel inventor.

Federal Circuit

Hormel appealed, arguing:

- the infrared preheating step was well known and part of the state of the art;
- the contribution of the infrared preheating step is insignificant when measured against the scope of the full invention; and
- there was not sufficient corroboration of Howard's contribution.

1. Special thanks to Dr. Maximilian Konrad, German Attorney-at-Law, Hoffmann Eitle, for his support of the European part of the presentation at the workshop and of this manuscript.

HIP argued:

- While infrared preheating may have been disclosed in a prior patent publication, the publication was obscure and not widely known and therefore did not form part of the state of the art.
- The district court found that Howard's contribution was significant enough to warrant him being a joint inventor.

The Federal Circuit found:

- That Howard's contribution was insignificant when compared to the full scope of the invention, and he was not an inventor because:
- Infrared preheating is only mentioned once in the specification as an alternative to the use of a microwave oven.
- It is only mentioned once in a single dependent claim as an option in a Markush group for preheating.
- Preheating in microwave ovens is extensively disclosed and claimed and all figures and examples only disclose the use of a microwave oven in the preheating step.

Lessons Learned

Contribution insignificant in comparison to full invention

- While a court may correct inventorship after issuance, the procedure is adversarial and expensive.
- The scope and quality of the alleged contributions in comparison to the scope of the claimed subject matter will influence the inventorship determination.
- During prosecution, to avoid claims of joint inventorship, the applicant should carefully draft claims to exclude the contributions of others. Alternatively, as here, claims of co-inventorship may be diminished by making the potential contributions of others to be optional limitations that do not feature prominently in multiple claims or the specification.
- Note the Federal Circuit made its decision solely on the basis of the significance of the contribution and did not rule on Hormel's arguments regarding whether Howard's contributions were merely a recognition of the state of the art or whether there was insufficient corroboration.
- While the panel did not rule on these specific arguments, the facts alleged may have influenced the panel's decision regarding the significance of the contribution.

2. *Blue Gentian LLC v. Tristar Products*, Fed. Cir. No. 2021-2316; June 9, 2023

Background

Blue Gentian sued Tristar for infringement of design and utility patents related to an expandable water hose.

Tristar was a licensee of patents owned by Ragner Technology Corporation and counterclaimed to correct inventorship of all patents-in-suit to name the owner of Ragner Technology Corporation, Mr. Ragner, as an inventor of all of Blue Gentian's asserted patents.

Ragner Technology Corporation had been seeking investors to bring an expandable hose to the market. Mr. Ragner met with Mr. Berardi, the founder of Blue Gentian and the sole named inventor on all the patents-in-suit, to seek investment.

Mr. Ragner has a BS in physics and a MS in aerospace engineering and had designed many expandable hose prototypes and was a named inventor on patents for expandable hoses. Mr. Berardi has a degree in sociology and at the time of the meeting had no experience designing or constructing hoses.

Before the meeting, Mr. Berardi watched a video demonstrating Mr. Ragner's expandable hose product. He testified that after watching the video he conceived of his invention. During the meeting, Mr. Ragner also provided a document detailing the manufacturing process for his expandable hose and its internal components. Mr. Ragner also demonstrated a prototype at the meeting.

Mr. Ragner testified that Mr. Berardi asked whether a wire spring in the hose could be replaced with elastic and Mr. Ragner responded by saying that his first two prototypes were constructed using inner surgical tubing for the retracting force rather than a spring.

Shortly after that meeting, Mr. Berardi went to Home Depot to buy supplies to build his first prototype similar to the prototypes described by Mr. Ragner having an inner elastic tube to provide a retracting force and an outer tube that water ran through.

Mr. Berardi filed his first patent application within three months of the meeting and listed himself as the sole inventor.

District Court

After an evidentiary hearing where this information was disclosed, the district court granted judgment in favor of Tristar and ordered that Mr. Ragner should be listed as an inventor on all patents-in-suit, effectively nullifying Blue Gentian's claims of infringement since Tristar was a licensee of Mr. Ragner's patent rights to expandable hoses.

Federal Circuit

The Federal Circuit affirmed the district courts' finding that Mr. Ragner should be listed as an inventor because he had contributed to the conception of at least one claim in each asserted patent, and that Mr. Ragner's contributions were what permitted Mr. Berardi to overcome prior art rejections.

The Federal Circuit further found that his testimony

was sufficiently corroborated by his knowledge of expandable hoses and documentary evidence predating the meeting.

The Court further found that the detailed information communicated during the meeting were sufficient to show that he conceived at least part of the claimed invention(s) and communicated those aspects of the invention to Mr. Berardi.

Lessons Learned

Inventor need not have contributed to every claim or to all aspects of claims

- It is possible to challenge inventorship/ownership as a strategy to negate infringement allegations.

3. *Dana-Farber Cancer Inst., v. Ono Pharmaceuticals Co. et al.*, Fed. Cir. No. 2019-2050; July 14, 2020

Background

Ono Pharmaceuticals obtained six patents related to a method of treating cancer by administering antibodies targeting specific receptor-ligand interactions on T cells. Ono Pharmaceuticals' application only listed a professor at Kyoto University, Dr. Honjo, and other researchers in Japan, as inventors.

Dana-Farber filed suit alleging that one of its employees, Dr. Freeman, and an employee of the Genetics Institute, Dr. Wood, who had shared information from its investigations on similar subject matter with Dr. Honjo, should also have been named as inventors on Ono Pharmaceuticals' patents.

District Court

The district court found that Drs. Wood and Freeman had made significant contributions to all six of Ono Pharmaceuticals' patents and that they should have been named as inventors on all six patents.

Federal Circuit

The Federal Circuit found that Dr. Wood and Dr. Freeman did not participate in all experiments that led to the conception of the claimed invention, but that does not negate their overall contributions.

Ono's argument that Dr. Wood's and Dr. Freeman's contributions were speculative because the experiments were not *in vivo* is misplaced.

Inventorship is determined by conception which occurs when an idea is definite and permanent enough that POSITA would understand the invention.

The inventor need not know if the invention will work for the intended purpose for conception, that is part of reduction to practice.

The non-obviousness of Ono's patent claims over Dr. Wood's and Dr. Freeman's provisional application is not relevant to whether they made significant contributions to the claimed inventions in the Ono patents.

Joint invention is not negated by a public disclosure of less than the complete invention. Complex inventions are often the result of partial contributions to conception over a period of time and there is no reason to discount genuine contributions because a portion of the work was disclosed prior to the complete conception of the invention.

The documentary record corroborates Dr. Wood's and Dr. Freeman's contributions and communication of those contributions to Dr. Honjo.

Dr. Wood and Dr. Freeman are joint inventors.

Lessons Learned

Not every inventor contributes equally

- Informal collaboration between researchers at different organizations may unintentionally result in joint inventions.
- Public disclosure of less than the complete invention does not nullify an inventor's contributions.
- Joint inventors need not contribute equally to the conception of the invention.

Comments in Summary

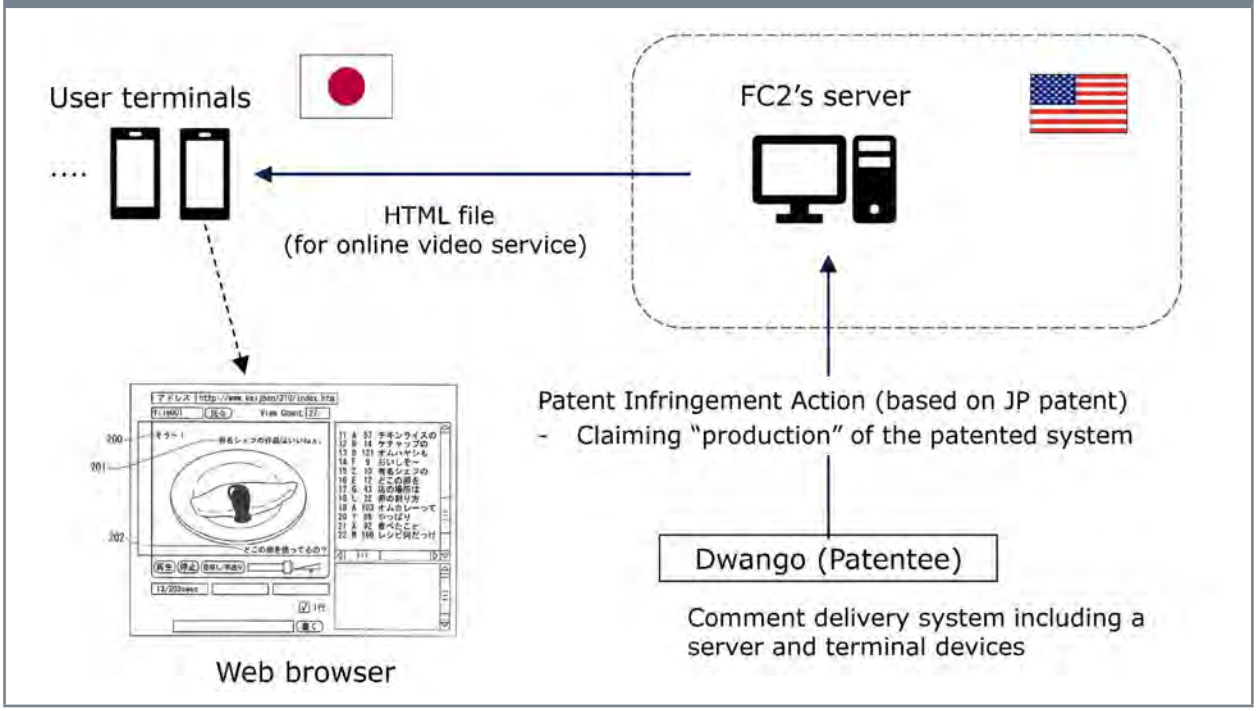
- Inventorship in the United States is very important and must be accurately assessed at the time a patent application is filed.
- U.S. inventorship determination requires an understanding of the scope of the invention under U.S. law and the significance of the contribution of each alleged contributor.
- Improper inventorship may result in unnecessary and expensive litigation that could invalidate the patent, nullify claims of infringement, create co-ownership issues, and result in awards of damages.
- Communicating information regarding the state of the art or other information well known in the art is not an inventive conception entitling one to be an inventor.
- Claims of joint inventorship must be corroborated and proven by clear and convincing evidence.
- It may be possible to avoid claims of joint inventorship by limiting the scope of claims and the disclosure in a specification.

Japanese Case Decisions

1. "Comment Delivery System" case (IP High Court, May 26, 2024)

This case relates to cross-border infringement. The patented claim recites a comment delivery system comprising a server and a user terminal. In the accused system, the server located in the U.S. sends

Figure 1: Comment Delivery System



HTML files to user terminals in Japan. The Tokyo District Court found that the whole system satisfies all elements of the patented claim, but dismissed the patentee's claim because the "comment delivery system" is not produced in Japan. The district court held that, in order to qualify as "production" of the system, it is necessary to create a new product in Japan that satisfies all the constituent requirements of a patented invention.

In appeal, the IP High Court reversed TDC's judgment and granted injunction and damage compensation. IP High Court held that, in the case wherein the server exists outside Japan, the following factors should be considered in finding "production of the system" in Japan: (i) specific manner of said act; (ii) the function and role played by the elements, which exist in Japan, from among the elements constituting said system; (iii) the place where the effect of said invention can be obtained from the use of said system; and (iv) the effect of such use to the economic interests of the patent holder of the invention. In this particular case, the IP High Court found "production" in the territory of Japan at the time when a HTML file is transferred to the user terminals in Japan.

In the event of including activity outside Japan, the court recently tends to consider circumstances to decide whether or not they constitute infringement of a JP patent (*e.g.*, IP High Court, 2022/7/20 [Video delivery program]; Tokyo District Court, 2020/9/24 [Monosodium glutamate]). In a network-related invention, it is not easy to avoid infringement by simply providing a server outside of Japan, so it may be necessary to consider licensing of network-related patents even if the server is not located in Japan.

2. "Excluding Claim" case (IP High Court, Oct. 5, 2023)

This case is an appeal to JPO's decision of invalidating all claims, rejecting a claim amendment request. The independent claim provides "A composition comprising HFO1234yf, HFC-254eb, and HFC-245cb (except for a composition comprising 1 percent by weight or more of HCFC-225cb)." (underline amended). JPO held that the specification has no description (including the amount) of HCFC-225cb, so the claim amendment introduces a new technical matter (thus not allowed under JP patent law).

The IP High Court reversed JPO's decision, holding that the claim amendment request is allowable, holding that claim amendment excluding a composition comprising 1 percent by weight or more of HCFC-225cb cannot be deemed to cause any change in the technical matters (*i.e.*, a new technical matter is not added). The IP High Court further held that JP patent law does not require to exclude only a portion identical to the invention of the prior application.

Lessons Learned

It is possible to easily overcome a rejection if the "excluded" feature is an essential component of the

prior reference, and such "excluded-type" claims are increasing in Japan. The requirement for claim amendment after issuance is not so strict in Japan, so claim amendment is an effective method to overcome prior references for a patentee.

European Case Decisions

1. Unified Patent Court: *10xGenomics v. Nanostring Technologies*—Cloud-computing outside the UPC Territory

In September 2023 the Unified Patent Court issued one of its first decisions in provisional injunction proceedings, which also touched upon an element of cross-border infringement. In the *10xGenomics v. Nanostring Technologies* case,[2] the defendant raised the non-infringement argument that part of the contested analytical method was performed by cloud-computing outside of the UPC territory.

The UPC Munich Local Division however, rejected this defense, stating that the data analysis steps conducted by cloud-computing abroad were merely additional analytical steps for the sake of the commercial product offered by the defendant, but not part of the patent protected method. Insofar as the patent claim described these further steps as part of the purpose of the patent protected analytical method, this description of mere purpose was irrelevant for determining a patent infringement.

While the case continued at the appeal stage and was decided by the UPC Court of Appeal, it did not (have to) deal with the impact of the extraterritorial cloud-computing element as the requested PI was already denied by the Court of Appeal for other reasons.

Lessons Learned

While the UPC has not decided on the scope of liability for acts (partly) conducted outside the territory of patent protection thus far, the first instance decision of the Munich Local Division seems to suggest that cloud-computing abroad as such does not present infringement, at least if the cloud-computing step is not material for the question of patent infringement.

2. German Federal Court of Justice: Ultrasonic Transducer—Liability for patent infringement by acts (partly) conducted abroad

In the *Ultrasonic Transducer* case decided by the German Federal Court of Justice[3] the defendant supplied ultrasonic transducers from Taiwan to numerous customers worldwide, including a Renault/Dacia production facility in Morocco.

The plaintiff informed the defendant by an authorization request that Renault/Dacia vehicles produced in the Morocco factory with the transducers supplied by the defendant are offered and supplied in Germany. After the receipt of this letter by the defendant, vehicles containing the transducer continued to be offered and supplied in Germany.

In general, liability for patent infringement does not require that the defendant performs one of the patent infringing acts specified in Section 9 sentence 2 of the German Patent Act by itself.[4] Rather, a party can be held liable for (contributing to) patent infringement when it merely causes the infringement of the IP right by not preventing an infringement of IP rights by a third party which they have facilitated, although such act to prevent infringement could have been expected from them.[5]

A foreign-based supplier of a product protected by a domestic patent who supplies a product to a customer who is also based abroad is not automatically obligated to check or monitor the further use of the supplied goods by the customer. However, such an inspection or monitoring obligation may arise if there are specific indications for the supplier that an onward delivery to the domestic market appears likely.[6]

Such specific indications may arise, for example, from circumstances such as:

- The supplier has obtained knowledge of an actual or imminent delivery in Germany,
- The quantity purchased is so large that it can hardly be distributed exclusively on markets without intellectual property rights,
- The purchasing behaviour correlates conspicuously with a perceptible and potentially infringing activity of the purchaser on the domestic market.

In the *Ultrasonic Transducer* case, the specific indications for the defendant were

- The plaintiff's letter to the defendant, stating that the converters are used for Dacia Lodgy vehicles in Germany, and
- The geographical location of the production facility in Morocco, which made it obvious that Renault/Dacia would supply vehicles with the transducers to the EU.

In this context, it is irrelevant whether the initial letter sent to the defendant was a request for authorization or a warning letter. It is rather only important that the information triggering the legal obligation to take further action is transmitted.

2. UPC CFI 2/2023, for a detailed case report see also *https://www.hoffmanneitle.com/ja/news/2024-01-03-case-report-cfi-2-2023*.

3. German Federal Court of Justice, X ZR 47/19.

4. German Federal Court of Justice, X ZR 53/8 –Ethofumesat.

5. German Federal Court of Justice, X ZR 156/97–Räumschild.

6. German Federal Court of Justice, X ZR 120/15–Abdichtsystem.

The scope of the injunction (and the liability for infringement) is limited to recipients of the infringing products domiciled abroad for whom there are specific indications for the supplier that the relevant products are delivered onward to Germany. In the case at hand, the Federal Court of Justice therefore considered the extension of the injunction to deliveries to all Renault/Dacia group companies as too broad, as there may also be group companies manufacturing parking systems or cars which are not supplied to Germany.

Lessons Learned

If a foreign-based supplier delivers a patent-infringing product to a foreign-based customer, who then puts the product on the market in Germany, the foreign-based supplier may still be liable for patent infringement in Germany if the supplier has obtained positive knowledge of the onward delivery to Germany or if this onward delivery is highly likely based on the circumstances of the case.

3. Higher Regional Court Dusseldorf: Cup Dispenser—Patent exhaustion by hand-over to a waste disposal (recycling) company

In the *Cup Dispenser* case,[7] the Higher Regional Court (HRC) Dusseldorf had to address questions of patent exhaustion for a patent protected cup dispenser, which was part of a beverage vending machine that was first leased to an operating company and then taken out of service and handed over to a waste disposal (recycling) company, which instead of destroying it sold it to the defendant.

According to the standing case law of the German Federal Court of Justice, exhaustion occurs for embodiments of the patent protected product which are put on the market by the patent proprietor or with their consent.

The putting on the market of the beverage vending machine by way of leasing (*i.e.*, without a transfer of ownership) did not exhaust the patent rights, as a temporary transfer of use rights does not realize the market value of the invention.

The operation of the machine could in theory cause exhaustion if the technical condition of the entire device has deteriorated to such an extent that it can no longer be used. The full economic value of the patent would then have been obtained by the patent holder, which justifies exhaustion. In the case at hand the beverage vending machine was however still fully functional and only taken out of use due to signs of wear.

The patent proprietor then handed the beverage vending machine over to the waste disposal company, which sold it to the defendant. In principle the transfer of a patent-protected embodiment to a third party leads to exhaustion as the patent proprietor no longer has any control over its fate. In this case, an exception might however apply if it had been contractually agreed upon that the waste disposal company had to destroy the machine. The waste disposal company would then only act as an "extended workbench" of the patent proprietor, destroying the machine in place of the patent proprietor.

However, there was no such contractual agreement to destroy the machine, and the waste disposal company was therefore free to recycle the still fully functional beverage vending machine by selling it. The buyer of the machine and defendant in the *Cup Dispenser* case could therefore invoke the principle of exhaustion and was not liable for patent infringement. To prevent exhaustion, the patent proprietor should have contractually ensured that the machine would be destroyed.

Lessons Learned

In case of a hand-over of a patent-protected machine to a third party (such as a waste disposal company), it has to be contractually made sure that the machine will be destroyed. Otherwise, the hand-over will cause patent exhaustion, and the third party will be free to resell the patent-protected machine. ■

7. Higher Regional Court Dusseldorf, 2 U 39/21, GRUR 2023, 394.

The Confluence Of Gastronomy And Intellectual Property: A Journey With The Basque Culinary Center

By Raquel Martin Rodriguez

At first glance, intellectual property in a field like gastronomy and culinary arts might not ring a bell. However, conversations with the Basque Culinary Center ecosystem and our network have revealed the multifaceted role of Intellectual Property (IP) in the gastronomic world.

Needless to say, I am far from an IP expert. Still, during my time in the food industry and academia, my exploration of the IP landscape has been both enlightening and inspiring, especially since I joined the Basque Culinary Center, working on its new expansion project: GOe (Gastronomy Open Ecosystem), which will open its doors in Q3 2025 in San Sebastian-Donostia, Spain.

The Intersection of IP and Gastronomy

The world of IP in the food industry is rich with examples: strong trademarks like McDonald's and Starbucks, patents such as Nespresso's Original Lines, and the industrial design and trade secrets behind the iconic Coca-Cola bottle and its closely guarded recipe. Geographical Indications, such as DOP or IGP, play a crucial role in regions like the Basque Country, underscoring the cultural and regional significance of food products.

Yet, in the realm of gastronomy, IP's presence is most palpable in the copyrighting of cookbooks. The protection of recipes remains a contentious and evolving area, with notable instances like "Las croquetas de Pedroche" by renowned Michelin Star chef Dabiz Muñoz sparking discussions on the extent to which culinary creations can be safeguarded.

Now, the question is, what about gastronomy itself? What about the creativity and the unique experiences that chefs bring to the table—those intangible yet unforgettable elements that every artist aspires to replicate? Beyond the protection of individual recipes, we see a growing recognition of the broader scope of innovation ecosystems, where diverse agents collaborate to co-create solutions for future challenges.

With this short article, I will highlight the role that IP plays in the vibrant world of flavors and innovation at the Basque Culinary Center (BCC) and how we deal with certain aspects of IP in our day-to-day operations.

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The BCC Ecosystem: A Hub of Innovation and Talent that Evolves

Established as a non-profit foundation, BCC has emerged as a leading food and gastronomy faculty, grounded in a profound belief in the transformative power of gastronomy. What began as a local initiative by eight chefs, supported by public and private institutions and an academic body, has grown into a dynamic force for professionalizing and elevating gastronomic education and innovation across the Basque Country.

Fourteen years of growth have also inspired the Basque Culinary Center to embrace and explore the world of IP across every aspect of our organization.

Education is at the core of the Basque Culinary Center offering a wide range of educational programs from a four-year university degree to 12 master's programs, professional courses, and PhD opportunities. All the knowledge generated through these programs is protected with IP, and due to the international scale and momentum of food and gastronomy, we are experiencing a great opportunity for collaboration across different regions and actors to either adapt our content or design new programs for them. New opportunities entail negotiations on IP rights. Already having an IP protocol in place, we tend to analyze those protocols case by case in order to keep the door open for collaboration. Ultimately, the educational programs attract a diverse mix of international and national talent, with students from 38 different countries enriching our campus, so an open mind is required to nurture all the new talent and keep the ecosystem evolving.

Now, the question goes beyond all certified training because how would you approach areas such as cooking courses for amateurs? The objective of these programs is to enjoy the culinary experience and learn specific techniques or cuisines without having to be a profes-

sional to join them. Gastronomy should be accessible to everyone; that is our vision. This is a different model, yes, but it also requires creativity and ideation to design these programs, so should they be protected? I leave the question open for reflection.

Talking about gastronomy and food, we must not forget that both are naturally linked to celebration and bringing people together. A neutral space around the table becomes a key connecting and interaction element and, for this reason, events and promotion are another key area at the Basque Culinary Center with a dedicated team that organizes high-profile events such as the Basque Culinary World Prize and Zinemaldi, showcasing our commitment to celebrating culinary excellence with over 140 annual events.

Those gatherings of people and the passion present in the restaurants and R&D centers have led over the years to several culinary inventions in which intellectual property in all its formats has played a role. Examples such as "Molecular Gastronomy Techniques" by Ferran Adrià, or The Anti-Griddle by Chef Grant Achatz have put the importance of intellectual property legal advisors into the gastronomy scheme.

This is why the Basque Culinary Center, as an innovative institution, established the first **Research & Development Center in Gastronomy**, working with external institutions (public and private) while fostering entrepreneurship through initiatives like Culinary Action and its international program Culinary Action On The Road. A total of 35 researchers working in key research lines such as nutrition and health, culinary innovation, sensory analysis, digital transformation, and sustainability collaborate and understand that the role of IP is more important than ever. This is because all research projects may have intellectual or industrial property implications associated with developing possible process or product patents or simply the need for copyrights when developing manuals and other publications.

Culinary Action: A Catalyst for Internationalization

Culinary Action, BCC's entrepreneurship program, has been instrumental in the international expansion. The Culinary Action OTR program, alongside a series of startup events, brings together a wide array of stakeholders—venture capitalists, entrepreneurs, scientists, and public institutions—creating a fertile ground for innovation. We initiate startup calls, select candidates, and connect them with a network of partners, culminating in research and development support from our R&D Center, BCC Innovation. Through mentoring, funding, and collaborative projects, we empower entrepreneurs to develop and scale their ventures.

Here, it is important to highlight our contribution to intangible assets, from idea generation during brainstorming sessions to the hedonistic experiences offered through showcasing and networking dinners. While these may not always translate directly into traditional IP assets, they are invaluable in sparking innovative concepts.

Navigating the Future: The Food Industry's Evolution

The food industry is on the cusp of significant transformation, with predictions indicating it will reach a market value of $1.4 trillion in the coming years. This growth is driven not only by economic factors but also by the social, cultural, climate, and health impacts of food—issues that are increasingly central to our daily lives amid challenges like food insecurity, digitalization, and climate change.

However, innovation at top food companies is quite limited with approximately 0.4 percent of revenues spent in R&D between 2015 and 2020, according to top investors, versus the 10 percent of revenue spent in R&D of software companies.

One might argue that food is not about disruptive innovation, but we live in a constantly evolving world that, coupled with the climate crisis and a growing population, will require collaboration and a certain degree of innovation to face the future.

The Gastronomy Open Ecosystem: Embracing Openness and Creativity

As we look to the future, we at the Basque Culinary Center are working on further developing our gastronomic ecosystem with collaboration and innovation as the north star.

The Gastronomy Open Ecosystem (GOe) aims to be the epicenter of food innovation, community engagement, and culinary excellence in San Sebastian, next to the Basque Culinary Center. This unique talent ecosystem will connect a diverse range of stakeholders, primarily corporations across the globe, expanding the concept of gastronomy to include disciplines such as architecture, design, arts, sciences, and anthropology. The transdisciplinary collaboration facilitated by GOe will be key to addressing the systemic challenges in the food sector. But these collaborations with multiple actors once again highlight the role of IP in these new models, which may present unique challenges and opportunities for legal professionals.

GOe will pursue four key objectives:

1. Creating a Reference Innovation Ecosystem in gastronomy and food tech to tackle global food challenges.
2. Nurturing and Attracting Multidisciplinary Talent to foster a vibrant community of innovators.
3. Building a Community of Innovation with a Gastronomy 360-degree approach, promoting innovative solutions across the gastronomic sector.

4. Facilitating Interaction and Synergies Among Companies in a creative space, leveraging diverse talent to develop unique value propositions through prototyping and other initiatives.

Our approach will involve strategic "glocal" alliances, presenting new opportunities for our legal partners, as we navigate issues of intellectual property rights and commercialization in an open, collaborative environment. At GOe, we will embark on various projects that emphasize transparency and shared innovation rather than exclusivity. We anticipate that new models of exploiting IP might need to be in place to foster and continue developing these ecosystems. So, this is an open call to collaborate, exchange ideas, and keep building the future together.

The GOe initiative embodies our vision of openness and creativity. It will be a space where diverse talents converge, fostering spontaneous, serendipitous encounters that often lead to groundbreaking innovations. Whether through physical spaces, such as prototyping kitchens, labs, media studios, the coworking space, or the café and restaurant that will be present at GOe, or exploring the GOe Digital Community, we aim to create an environment where the best ideas can flourish from unexpected interactions.

To conclude, let us remember that IP in the context of gastronomy and at GOe serves as a tool to incentivize and protect innovation, with collaboration at its core. As we embark on this journey of culinary innovation, we invite all of you to join us in exploring the limitless possibilities where creativity knows no bounds, and the law protects the fruits of our collective efforts. Welcome to GOe! ■

Driving Innovation Through IP: Three EPO SME And Technology Transfer Case Studies

By Thomas Bereuter, Adéla Dvořáková, Bowman Heiden, John McManus, Ciaran O'Beirne and Ilja Rudyk

Still at the early stages? Looking for funding? No proof of concept? Struggling to secure freedom to operate? Three EPO case studies review how intellectual property (IP) can lay a foundation for business ventures in one of the most complex fields of innovation: cancer.

Finding cures for cancer is one of the toughest challenges in innovation. Novel ideas for treatments and diagnostics are hard to establish and slow to develop. Their effects, however, can be far-reaching for both society and the economy.

Providing a clearer indication of whether breast cancer is likely to recur, for instance, could save up to 1.5 million women from undergoing the ordeal of chemotherapy each year. Or, as the World Health Organization argues, it could save up to 2.5 million lives by 2040.

At an individual level, anyone worried about having skin cancer can now obtain a diagnosis from a 3D probe in almost real time, instead of waiting 15 days for the results of an invasive biopsy. This adds up to a major saving in the efficiency and cost of medical treatments too.

Such improvements can only be achieved by a complex network of inventors, implementers, partners, users and funders. Intellectual property is what holds them all together at each delicate stage of an idea as it evolves and matures, enabling them to retain control and ultimately defining everyone's input and return.

In the early, inspired stages of discovery, most concepts are usually far from market with little funding, no proof and a diffuse outlook in terms of ownership. IP creates a solid basis by establishing the rights of the inventors and founders and how they can engage with business partners or users. In terms of cancer treatments, a core or platform patent is usually the first step, establishing exclusivity and securing time to develop and test the technology while exploring the market.

Options for the most promising uses are subsequently investigated, often resulting in more specific product patents down the value chain, as well as the accumulation of a portfolio around trade secrets, materials, prototypes and designs. As a product evolves between technology push and market pull, a new treatment will coalesce as a brand underpinned by a trade mark. Extra value is created at this stage too, with artificial intelligence used to track metrics on how a treatment performs and what can be improved next.

An overarching IP strategy will provide guidance and filter where, when and which IP rights to pursue, based on the venture's overall objectives. As it grows, a set of IP policies will be put in place and someone will take responsibility for overseeing the portfolio to make sure that the IP is proactively managed. Protocols around confidentiality and non-disclosure will be established early on, as well as how these requirements are communicated to fellow researchers.

At each funding stage, investors will check the robustness of an IP portfolio to protect their investment and whether the business is ready to scale-up. Ultimately, it is the IP that will determine the venture's success and constitute its main source of value as an asset.

This article introduces three case studies from the EPO that show the path of three promising concepts to combat cancer. The case studies highlight how

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these concepts were managed over a cycle of ten to twelve years to create treatments and diagnostics that are already in use—or close to adoption—and starting to give genuine hope to millions of people at difficult moments in their lives. A more in-depth look at each of these case studies follows.

As we will see, many inventors face a series of dilemmas as they progress. Should they bring in an additional partner or co-founder early on? What is the best stage to seek venture capital without diluting control or giving away too much? To what extent can the new treatment be adapted in the light of what may subsequently be discovered? How can inventors structure their venture to serve different markets? How can a venture stay independent and invest in the challenges of building its own sales? Is a trade sale the best way to ensure faster adoption of a new treatment? Leveraging IP gives inventors the agility to make all of these choices effectively and realise the full value of their innovation.

Damae Medical: Building an IP Culture

Detection of skin cancer is about to change. To date, doctors have first inspected any abnormalities with their own eyes, followed by a surface scan and a biopsy that can take up to 15 days to yield results. Most abnormalities are healthy, although delays in receiving the results can fray a patient's nerves and lead to higher medical costs. In some cases, however, cancerous abnormalities are missed altogether because they are hard to spot on the surface.

Now, a French spin-out is launching a diagnostic probe to scan 3D images of the skin that immediately reveal the full extent of the patient's condition. This will give patients immediate results and enable their doctor to offer more personalised care. In the worst-case scenario of surgery being required, only the affected tissue is removed, and a follow-up operation is only carried out if absolutely necessary.

The technology for this probe originated at the Institut d'Optique in Palaiseau, where its potential was spotted by two students in photonics in their entrepreneurship programme in 2013. Together with the inventor, they launched a start-up called Damae Medical the following year with an exclusive licence for the core patent family from their three partner institutions. Such a licence, while supportive in the short term, can give rise to challenges in terms of control later on. In 2019, Damae exercised its right to buy this foundational patent in return for equity.

It has since started several additional patent families and is extending its range of IP as it moves from technology push to market pull. Damae Medical has also registered the design rights in its probe, along with several trade marks, and has safeguarded the copyright in its digital solutions.

With Damae's team now totalling 30 staff, its inventions are recorded and disclosed under the watch of a lead research engineer, who spends 25 percent of their time on IP. Procedures are also followed to maintain confidentiality and care is taken to co-ordinate with Damae's active programme of scientific communication managing disclosures to promote the technology and support freedom-to-operate by defensive publications in non-core areas.

Damae makes all of its own products, although it has two partners, which are at liberty to maintain and improve their own IP. Any improvements to the core technology, however, belong to Damae, which retains control over it.

By 2017, Damae was in a position to raise €2 million in seed funding, followed by a further €5 million in 2021. It also won a €2.4 million EU grant to develop novel approaches to the non-invasive, personalised diagnosis of skin cancer.

In 2018, shortly before the launch of its 2D system, Damae found the agility of its IP put to the test with the discovery of a game-changing system for 3D stacking of images. Could it afford to pivot? How costly would a delay be?

It took the decision to switch all of its efforts to the 3D probe. Twelve months later, a protocol was ready and a patent filed. So far, Damae's probe, DeepLive, is being used in 40 hospitals worldwide, with more expected to follow.

Research in dermo-cosmetics is the other market that has emerged for Damae as a test for reactions to skin products. Up until recently, dermo-cosmetics accounted for half of Damae's total sales.

As a side effect of operating in more consumer-facing markets, Damae found itself using artificial intelligence (AI) to track the metrics for all these projects, giving users a series of invaluable insights and creating a flow of ideas for Damae to pursue. It also plans to use AI to track the diagnosis of skin cancer, adding to the value that Damae can offer dermatologists and potentially identifying areas for further improvement to its diagnostic capabilities. (See case study beginning on page 162.)

OncoQR: Multi Modal IP

As a platform for stimulating the immune system to combat cancers and allergies, S-TIR has proved to be OncoQR's core technology platform supported by IP. The company OncoQR is now using S-TIR to map out several different treatment paths and has formed a joint venture for some cancer types, such as pancreatic cancer. While OncoQR is pursuing its own research in breast cancer, it is licensing S-TIR for use in neoepitopes generated by mutant cancer genes.

Essentially, S-TIR solves one of the outstanding challenges in immunology: how antibodies can attack unhealthy cells without provoking an over-reaction. For Geert Mudde, originally an immunologist at Novartis,

the solution was modular: create a "warhead" to carry the immunogen to the target cell, whether it be cancerous or allergic.

He was lucky enough that Novartis decided to abandon the technology in its infancy, which allowed him to develop it further. Originally, he filed a patent in 2006 after leaving Novartis. In 2010, he spun out the IP into a separate venture, S-TARget therapeutics, and brought in a biotech engineer with business experience, Christof Langer, as a co-founder to develop the venture. They have since been granted two further patents on the platform.

The first tests on allergies were highly promising. At this point, the founders decided to pursue a twin track for the venture: in cancers and in allergies.

At OncoQR for cancer, they have used their IP in a combination of models to recruit partners that will research S-TIR's use for different cancer types. This has led to two product patents to date: for pancreatic cancer as a joint venture and for breast cancer as OncoQR.

In their partnerships, know-how about the most efficient production techniques is included in any agreements as trade secrets. Any improvements in the platform technology are then licensed back to OncoQR, effectively creating a mechanism for open innovation, which has resulted in several improvements to the warhead that are also made available to all licensees. The flexibility of these different models has allowed OncoQR to fund much of its own research through IP licensing revenues, alongside public national grants. So far, its founders have sought to retain full control over their IP and have been wary of talking to venture capitalists too early. For now, although they remain open to all options, they prefer to use their IP to talk to pharmaceutical companies about building on their progress and moving into clinical trials. (See case study beginning on page 173.)

OncoMark: Serial IP Entrepreneurs

Better diagnosis and prognosis of cancer was the inspiration for creating OncoMark, a spin-out company established at University College Dublin (UCD). In 2021, OncoMark was acquired by a leading US molecular diagnostic company. The management and investors in OncoMark have now re-invested some of the proceeds from the acquisition to set up a start-up to investigate further use of biomarkers with other cancers, such as prostate cancer and melanomas. As seen with other ventures, this follow-on combines the talents of a UCD professor of biology, William Gallagher, and a veteran of the diagnostics industry, Des O'Leary.

After starting his career at a French pharmaceutical company, Rhone-Poulenc, now Sanofi-Aventis, Prof Gallagher brought an interest in translational research to the university. He set up his original venture, OncoMark, in 2007 where he built up a team to explore biobanks for diagnostic purposes.

The potential for using biomarkers to make better informed treatment decisions for breast cancer emerged from Gallagher's research with a colleague at Trinity College Dublin. If we can better predict the likely recurrence of cancer, they asked, can we avoid chemotherapy and the associated side effects for two-thirds of women who are diagnosed with a specific subtype of breast cancer and who do not require and/or benefit from chemotherapy?

Research into this question generated interesting findings and the two universities were sufficiently convinced to file a priority patent with the EPO to protect the invention. To de-risk and validate the patented technology, the universities licensed the invention to OncoMark. It, in turn, applied for a €2.7 million grant from the EU and raised a further €2.1 million from an Irish investment syndicate. In 2015, Des O'Leary joined as chief executive, switching the company's strategic focus from research to development. The prognostic test gained a CE mark and was trademarked. Terms were also agreed with a manufacturing partner and the packaging was prepared for the product launch.

In the meantime, Cepheid, a leading molecular diagnostics company, had spotted the test, which it thought could strengthen its own existing oncology portfolio. The dilemma for OncoMark's owners was whether to invest in the challenges of building their own sales and distribution channels or opt for rapid adoption with Cepheid. In the end, they decided to accept Cepheid's offer of a significant investment to further develop and clinically validate the test on Cepheid's GeneXpert platform before the acquisition was completed in 2021.

For Gallagher and O'Leary, the cycle of commercialising IP is now starting all over again. They have decided to invest the proceeds from their share of the sale in a new diagnostics start-up, OncoAssure, to investigate the potential of biomarkers with other cancers. (See case study beginning on page 182.)

IP Pointers

Each of these case study summaries draws on the insights and experiences of multiple actors in turning cancer discoveries into treatments and diagnostics for patients. Taken together, their experiences and insights give a series of IP pointers about what matters in practice when creating ventures that can make an impact in the clinic. These options and lessons are covered in depth by each of the EPO's case studies. Here are some of the highlights:

- IP gives you the agility to adapt your business strategy as you improve your invention and explore how it is going to be used.

- Founders who combine a background in both research and industry often set their sights early on creating an IP venture by engaging with users and collecting test data.
- A core patent establishes priority for your invention and gives you time to explore its use before deciding how and where to extend the patent protection.
- A spin-out or start-up consolidates the IP in one place. It can then capture any more IP that is created, guarding against its undue dilution when engaging with partners or funders.
- A co-founder is often involved to help build the commercial case either in the early stages or as the treatment moves beyond proof of concept.
- Ventures often begin by exclusively licensing their core inventions from their parent institutions, whether academic or corporate. In the short term, it has advantages of continuing cooperation, but can cause challenges with control later, so an option to purchase the IP is often exercised.
- As innovations move from technology push to market pull, the range of IP broadens to include trade secrets protecting know-how, designs and copyright. As a brand strengthens, trade marks become one of the principal sources of a venture's value.
- Artificial intelligence is opening up insights into a much wider range of metrics about how treatments are being used. Any resulting new and inventive solutions with a technical effect can be patented.
- An IP strategy, often under the direction of the Chief Science Officer, allows you to prioritise which IP rights to pursue and where.
- Tracking and recording further inventions and improvements usually becomes the responsibility of someone in or close to the research team, who will also keep a watch on confidentiality and disclosure.
- All this IP creates the potential for several different commercialisation models: you can continue your own research and development, collaborate, license, form a joint venture or sell the technology. For a platform technology, you may well combine a version of all of these models in different niches.
- You can opt for three main types of licence for your technology: for the platform, for a product or for non-commercial research. Your licence will have more value when you can include a rich mix of IP, including know-how and additional support.
- With your partners, you might decide that you will each be free to create your own IP, but encourage a culture of open innovation to improve the core technology, often through back licences. In any case, securing freedom-to-operate is essential.
- Early on, research grants are a significant source of funding. Licensing your technology to secondary markets or for different fields of application is often an effective way to fund ongoing research too.
- For venture capital, it is worth getting your timing right. It is usually best after proof of concept but before you lose momentum when running out of money or patent lifetime becomes an issue.
- If a pharmaceutical company takes a serious interest in your IP, it is likely to fund some clinical proof first. If it then offers to acquire the technology, you will have to decide whether the offer is worth accepting or if it is better to invest in building your own sales operation.
- Advisory boards with views from both science and business can help to map out the series of IP and financing decisions that ventures will face. ■

Disclaimer

Any opinions expressed in this article are those of the authors and not necessarily those of the European Patent Office or the authors' respective organisations.

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A New Dimension To Skin Cancer Diagnosis

By John McManus

Abstract

The company was spun out from Institut d'Optique Graduate School, Palaiseau, France in 2014 by a team of photonics researchers. They have taken a patented technology with applications in biological and medical imaging and used it to create a new medical device for real-time diagnosis of lesions from all types of skin conditions, including skin cancer.

The technology is a new advanced medical imaging system, which is protected by a suite of six patent families and other IP rights. It is currently making a high impact in over 40 centres around the world including onco-dermatology clinics. Close collaboration with key opinion leaders in the world's top dermatology centres is driving new developments to provide dermatologists with artificial intelligence (AI) algorithms for diagnostic support.

Founding Damae Medical

Damae Medical can trace its origins back to over 20 years of cutting-edge research in the field of optical coherence tomography (OCT) by Professor Arnaud Dubois and a patent application filed by him in 2013 for an invention relating to an optical tomography apparatus for the visualisation and examination of biological tissues arising from his research in the Biophotonics group at Charles Fabry Laboratory, a research unit of Institut d'Optique Graduate School.

During 2013, Professor Dubois began collaborating with two graduate students to develop a commercial application for his OCT-based technology. The students, Anaïs Barut and David Siret, were specialising in biophotonics with a major in entrepreneurship. They singled out Professor Dubois' technology from several innovative ideas and technologies presented as non-confidential information to the entrepreneurship group by researchers and companies, as potential options for a final year project to create a business proposition for a start-up company.

They engaged with Professor Dubois at both the technical and business level to develop the idea and explore possibilities for the technology in the biomedical field. After rigorous research and analysis of the medical imaging market, they were convinced that the technology held tremendous potential for clinical applications in dermatology. It appeared to offer the best product/market fit, promising to achieve a significant level of clinical impact, as well as offering a commercial opportunity for a new medical imaging device.

Line-field Confocal Optical Coherence Tomography (LC-OCT) Device—DeepLive

Professor Arnaud Dubois
Chief Scientific Officer at Damae Medical

"Our job as engineer-entrepreneurs was to develop the technological proofs-of-concept while performing medical imaging market research to identify the most relevant clinical applications and target markets for the technology. We pinpointed the dermatology market as the best product-market fit for a first application in terms of unmet medical needs, the technical capabilities and clinical potential of the technology, level of impact and benefits of the innovation, business opportunities and market-entry barriers."

Professor Arnaud Dubois

Confident in the feasibility of the business proposition—confirmed by validation of both the business and technical opportunities—Professor Dubois initiated a priority patent filing at the end of 2013. The three partners subsequently decided to create a start-up and in 2014 they established Damae Medical.

The patent application, which became the cornerstone for this new start-up, was filed and owned by a consortium of three partner institutions that supported the research and commercialisation of the technology, namely Institut d'Optique Graduate School, Paris-Saclay University and Centre National de la Recherche Scientifique (CNRS). As joint owners, the mandate to commercialise the IP rests with the technology transfer office CNRS Innovation, whose goal was to find partners, negotiate exploitation contracts and ensure effective implementation of the IP rights. Damae entered into negotiations with CNRS Innovation and obtained an exclusive licence to the core patent family in return for royalties on sales.

However, depending on a licence agreement for a business's core IP can prove risky in the long term, as potential future differences may arise surrounding the interpretation of the licensing terms, patent costs and prosecution decisions, inventorship and ownership issues. It can make more sense to acquire the patent family, as this gives a company full control over managing all aspects of its IP. So Damae subsequently–and with increasing business success–acquired outright ownership of this patent family in 2019 through a purchase agreement in return for equity.

Revolutionising the Management of Skin Cancer

Skin cancer is one of the most common cancers globally and its number of cases has risen sharply in recent decades. Today, the dermatologist examines a patient's skin abnormalities with the naked eye (clinical examination) and then with a dermoscope. In case of doubt, the dermatologist takes a sample called a biopsy. The biopsy is sent to a laboratory for microscopic histology examination, which provides a diagnosis within 15 days. This process gives rise to anxiety and leaves the patient with a scar. The majority of biopsies turn out to be healthy and have resulted in avoidable costs for healthcare systems. However, some melanomas are not diagnosed at the earliest stage because surface signs are not obvious enough to perform a biopsy.

Damae is reinventing skin imaging by revolutionising the detection, management and follow-up of skin cancers (melanoma and carcinoma) with its optical biopsy solution. Its equipment, which trades under the brand of deepLive, is a Class IIa medical device complying with EC regulation 2017/745.[1] The deepLive probe

Figure 1: Hand-held deepLive probe[2]

1. This EU Directive applies to medical devices and their accessories. Such devices are typically used for the diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury or handicap, or investigation, replacement or modification of the anatomy. You can consult the Directive online at *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01993L0042-20071011*.

2. Presentation video of deepLive: *https://youtu.be/29MCBEzgLgQ*.

is a non-invasive imaging system comprising a unique imaging modality adapted to capturing 3D "optical histological images" to analyse multiple skin conditions. See Figure 1.

Visualisation of suspect tissue is at the cellular level, with a depth of penetration down to the dermis. deepLive allows easy imaging of a patient's entire lesion. By using deepLive dermatologists can detect malignant tumours early, increasing patient survival statistics while reducing the number of benign biopsies and healthcare costs. Accurately identifying tumour margins prior to surgery allows maximum tissue preservation while avoiding possible revision surgery.

Offering Multiple Business Models

Damae is responsible for manufacturing the deepLive product. However, some of the fabrication is outsourced to two different manufacturing partners in France, each responsible for different sub-assemblies of the product. Damae completes the final integration, quality control and product release.

Damae is cautious about entering into joint IP agreements. Every possible research cooperation that may give rise to an IP claim by a third party is reviewed and evaluated by the research team led by Dr Jonas Ogien. The majority of existing research collaborations allow both parties to maintain and improve their own IP and avoid complex management of joint IP. All strategic subcontracts also include a clause protecting Damae's IP rights by stipulating that all IP arising from the subcontracted work conducted becomes the property of Damae.

Takeaway: IP and Supply Partners

Exercise caution in agreeing to joint IP arrangements with supply partners, which can dilute value for both parties and create unnecessary dependencies.

Currently, the marketing and sales functions are mostly integrated within the Damae organisation, selling directly to its customers. The company offers a user training program, as well as maintenance and service contracts to access the latest innovations developed by the company.

The main market for Damae's medical imaging device is dermatology, which focuses on the diagnosis, treatment and management of skin conditions relating to cancer and other skin pathologies. Damae adopts different business models to generate revenue depending on its customers—mostly hospitals, clinics and liber al practices—and their needs, which range from purchase, rental, leasing and revenue sharing to services such as maintenance and image analysis services (3D segmentation and quantification).

Another key market that has emerged for Damae comprises companies in the cosmetics and pharmaceutics sectors that invest heavily in researching and evaluating the benefits and impact of new products for skincare and skin treatment respectively. Companies in these sectors recognise the high-performance imaging capabilities of deepLive and the benefits of this non-invasive application for analysing the cellular structures and physiological mechanisms of skin in clinical studies. Damae either rents or sells the equipment to these companies, while supporting them in defining their studies and acquiring images from the study volunteers.

Finally, Damae applies AI algorithms to the captured images in order to derive relevant metrics and interpretations. The study protocols of these clients frequently cover a broad range of objectives, from optimising preclinical research, developing or characterising the benefits of the active ingredient or molecule, or improving the efficacy of formulations to evaluating products to support marketing claims and assessing and improving the safety of their products.

Damae's first revenues were generated in 2019 from clients in the cosmetics market when the LC-OCT 3D device was launched. Since then, revenues have been divided equally between the dermatology and cosmetics/pharmaceutics markets, with sales doubling year-on-year. However, sales from the dermatology business are beginning to exceed those generated by the cosmetics and pharmaceutics business.

Since the commercial launch of the deepLive trade mark in 2020, there has been strong demand from European dermatologists, particularly in the German, Italian and French markets. To date, the company has a market presence in more than ten countries in Europe, the United States and Asia. In the United States, the first systems are being installed mainly in the context of clinical research. Damae's patent filing strategy has ensured protection for all of these territories from the outset.

Takeaway: Strategic Alignment

Align the geographical scope of patent protection with your long-term marketing strategy.

Innovative technology

Traditional visualisation and analysis of skin tissue and cells relies on the preparation of histology slides from biopsy material and inspection using advanced microscopy techniques applied by a specially trained anatomical pathologist or histologist. It is a technique that provides a two-dimensional image of a sample sec-

tion. The process is slow, complex and potentially risky, particularly during surgery where speed is crucial and tissue excision can have consequences.

The initial innovation that led to a device for non-invasive medical imaging adapts and combines state-of-the-art optical coherence tomography (OCT—used by ophthalmologists to detect retinal pathologies) and confocal microscopy (CM—used in research for high-resolution imaging of biological samples). It gave rise to a completely new method of real-time imaging and the new term *Line-field Confocal Optical Coherence Tomography* (LC-OCT).

LC-OCT lies at the heart of Damae's innovative approach to dermatological diagnostics and was first protected by a French priority patent application *(FR 136324)* filed by CNRS and partners in 2013. The application describes an optical tomography apparatus, in which both the illumination and detection optics of a microscope are coupled with dynamic focusing of the lens over a site on the skin to enable the capture of a two-dimensional image of a biological tissue.

The patent filing strategy for broad international protection, was to establish a priority date nationally, followed by a PCT application within one year *(PCT/EP2014/078867)*. This provided a timeframe of 30 months (or 31 for an EPO regional application) before decisions with respect to designating international territories had to be made, giving Damae more time to build prototypes, test the technology and ascertain the best market fit. The patent has since been granted in nine international territories and is now validated in eleven European countries covered by the EPO.

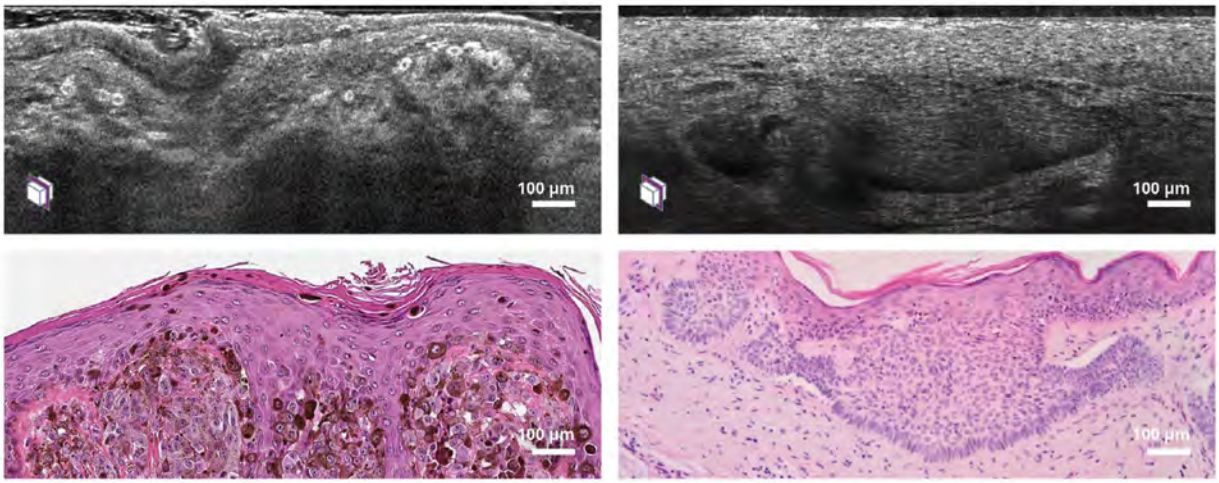
The Importance of Agility

In 2014, Damae first began work on developing a commercial product according to the system described in the patent it had just licensed. The company was initially located in a laboratory space at Institut d'Optique Graduate School and carried out all its research there, before eventually moving to incubator premises in Paris. In the ensuing period, Damae developed a 2D system for vertical section analysis and integrated it into a hand-held probe. The probe was clinically evaluated on patients by their clinical dermatology partners in 2018. Compared to conventional OCT, the technology had the main advantage of achieving higher image resolution down to single cell level. It was thus able to provide similar images to those produced by histology. See Figure 2.

Parallel research into another approach led to a significant technological breakthrough with a lab-scale model for a new configuration of the LC-OCT system that enabled 2D images to be captured in both vertical and horizontal sections of the sample site. This enabled the stacking of images in a 3D format, providing dermatologists with a 3D visual of the skin section being analysed. This was hailed as "revolutionary and a game-changer with major clinical advantages" according to the key opinion leaders of Damae's clinical partners. See Figure 3.

Figure 2: LC-OCT Vertical Images Of A Melanoma (Left) And A Superficial Basal Cell Carcinoma (Right) With Corresponding Histology Images

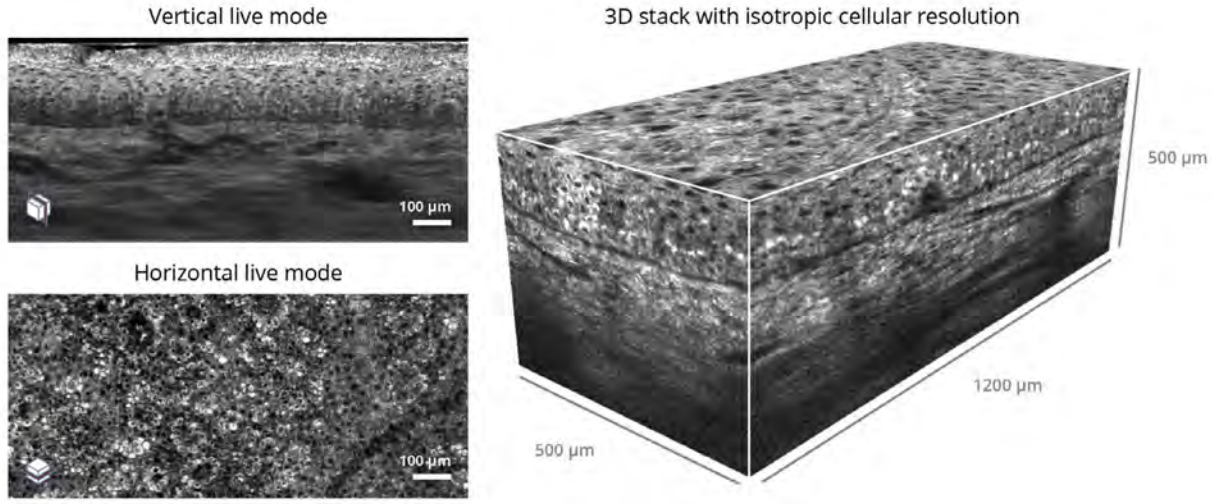
Image taken from the Journal of Biomedical Optics publication—*https://doi.org/10.1117/1.JBO.23.10.106007*



Images courtesy of Prof. Perrot, University Hospital of Saint-Etienne, France and Prof. Suppa & Prof. del Marmol, Hopital Erasme, Universite Libre de Bruxelles, Belgium. Journal of Biomedical Optics (2018): "Line-field confocal optical coherence tomography for high-resolution noninvasive imaging of skin tumors."

Figure 3: LC-OCT Vertical (Top Left), Horizontal (Bottom Left) Images And 3D Stack (Right) Of Healthy Human Skin In Vivo

Image taken from the Journal of Biomedical Optics publication—*https://doi.org/10.1117/1.JBO.23.10.106007*



Biomedical Optics Express (2020): "Dual-mode line-field confocal optical coherence tomography for ultra high-resolution vertical and horizontal section imaging of human skin in vivo."

The huge potential of this new innovation presented a business strategy dilemma for Damae. Should it proceed with commercialisation of the near-complete 2-dimensional imaging system or change tack at this late stage and take a step back to develop the lab-scale 3-dimensional imaging system? A fortuitous injection of fresh finance swayed Damae's decision towards the 3D option. Its R&D team had grown by that stage and the entire team was tasked with developing the lab-scale proof-of-concept to full-scale commercial development, clinical testing and product launch. Twelve months later, a first prototype of the 3D-LC-OCT medical device was ready for evaluation and a patent application quickly followed to secure protection for this new business-critical innovation *(EP4070144A1)*.

Takeaway: Value of Patient Capital

Appropriate funding can open up opportunities to prioritise long-term strategies with high potential over short-term gains with lower risk.

This new technology from Damae adds a "third dimension" to the inspection of skin tissue. Application of the deepLive probe allows a non-invasive visual inspection and analysis that far exceeds traditional histological methodology. Simultaneous vertical and horizontal imaging of the skin at a depth of down to 500 micrometres is possible, enabling a 2D profile of the examination site with a resolution of one micrometre to be captured in real-time as a "digital-optical biopsy," dispensing with the need for often awkward, unpleasant or risky excision of a tissue sample. These 2D images may subsequently be stacked to provide a 3D "optical histology," which generates a more accurate and informative visualisation of skin layers, lesions and cells. This, in turn, enables diagnosis of various skin conditions and enables differentiation between carcinoma types such as basal cell carcinoma, squamous cell carcinoma and melanoma.

Takeaway: Optimal Filing Strategy

Filing a patent application too soon can lead to a set of claims that do not provide cover for the final product. Filing too late can result in the invention being superseded by the competition.

"We strive to maintain an agile and iterative development process. In fact, finalisation of our 2D and 3D systems arose from eleven different versions that were developed, prototyped and tested with end-users over a period of four years. Building on user-feedback, market responses and new ideas from the R&D

team, each version was an improvement on the previous and new patent applications were filed to capture the major innovations that solved the technical setbacks."

David Siret

David Siret
Chief Technology Officer at Damae Medical

Takeaway: Strategic Patenting

Product development paths can change, so think strategically about when and what to patent along the way. Adapt your IP strategy to the innovation process and identify the best stage at which to build or revise the patent claims.

Securing Funding

Since its creation, the company has invested more than €20 million in its activities. In 2017, an initial investment of €2 million seed funding was closed with a consortium of VC firms, including Kurma Partners and Eurazeo, and private investors. This was followed by a round of Series A financing in 2021, with a further injection of €5 million led by BNP Paribas Développement joining the original consortium. Additional funding came in the form of an EU grant in 2019. Under the Horizon 2020 research and innovation programme Damae was awarded €2.4 million towards a €3.5 million SME instrument project to develop a novel approach to non-invasive and personalised skin cancer diagnosis.

Takeaway: Strategic Patenting

For technology start-ups, IP rights are key assets for securing funding.

The company's patent portfolio clearly reflects its R&D success. However, as a start-up company, Damae's technology and IP were the main intangible assets on offer to investors and played a key role in influencing their decisions. During both the seed and Series A funding rounds, investor due diligence focused on an audit of Damae's complete IP portfolio. This was performed by an independent IP firm that delivered a report on the status of patents, trade marks, know-how, domain names and copyright in software and databases. It also examined how IP rights were managed in contracts and provided a freedom-to-operate statement. The strength of the business proposition lay in the business plan. However, the section of the report on IP strategy was closely studied by investors and played a key role in their decision. It remains an agenda item during Damae's board meetings with investors.

IP and Portfolio Development

Soon after its foundation, the company's research team set about expanding its IP portfolio by developing improvements to the original technology and creating new inventions directed towards commercial applications. Most notably, they focused on developing a revolutionary system for visualising deep layers of skin at the cellular level in a three-dimensional format, which would provide dermatologists with new, advanced medical imaging systems. Since then, five new patent families have been added to the portfolio, which comprises no fewer than 31 patent applications to date (see Table 1).

Takeaway: IP in High-tech Sectors

Companies operating in high-tech sectors need a robust patent portfolio to ensure technological exclusivity and secure a lasting advantage over competitors.

"Damae's growth and success will depend in part on its ability to protect its products and inventions, in particular by obtaining and maintaining patents in the territories targeted by its business activities, mainly in Europe, the United States and Australia."

David Siret, CTO

As the focus on implementing commercial applications of the medical device intensified, intellectual property protection was also extended to other important aspects of the business. These included design right protection, which has been filed for the company's handheld probe (RCD 007439419-0001) and several trade marks, including DAMAE MEDICAL *(EUTM 1452479)*, deepLive *(EUTM 018239168)* and LC-OCT *(EUTM 018237600)*, used in the branding and marketing campaigns for its imaging systems. Copyright for the company's software, databases and AI solutions is also safeguarded and the domain names it uses in web-based media activities have been registered. (See Figure 4.)

Takeaway: Complementarity of IP Rights

IP rights, such as patents, trade secrets, trade marks, designs, copyright, or domain names are often complementary and should be combined to secure optimal IP protection.

Damae's patent filing strategy is purely focused on protecting inventions relevant to its business strategy, *i.e.,* cover for products in those territories and markets where they will be commercialised. It doesn't intentionally engage in filing blocking patents, but some patents

Figure 4: Medical Probe RCD 007439419-0001

on aspects of the technology that have been superseded by improvements are still maintained, as they serve to prevent the competition from using these solutions.

Damae has devised a system for categorising inventions as high-impact and low-impact patents. High-impact patents contain claims covering a wide scope of embodiments for Damae's core technology to prevent competitors from accessing it by developing around the patent. These patents are filed in most of the international markets where Damae is aware of similar research and medical device development. They typically cover at least 20 countries worldwide, including the main EPO member states.

Low-impact patents emanate from improvements to the core technology that provide additional functional modalities for the final product. Such improvements are not only important for quality and performance, they also make the products more appealing than others in the same market. These patents also deter other companies with non-competing technologies from adapting Damae's inventions for use in their own products. The aim is to file for protection only in those markets targeted by Damae's commercial strategy, which are not as extensive internationally as those for its core patents.

Currently, Damae's patent filing strategy is to gain patent priority with a French national application followed by a PCT application within twelve months. This defers the decision for selection of international states in the National Phase of the PCT application until 30 months after the priority filing (and 31 months for an EPO Regional Application), giving the company time to gather further research data, test prototypes, and delay costs for patent prosecution. The EPO and other international territories of interest are then designated for examination and, after grant, the EPO application is validated in the European countries of strategic importance to the business.

With the introduction of the Unitary Patent system in June 2023, this may provide an alternative and more beneficial route to protection in European countries for Damae. This route simplifies national validation procedures and enables uniform protection in up to 25 EU member states through a single application at a much lower cost. Moreover, in the event of litigation, a single action may be taken before the Unitary Patent Court (UPC) with the potential to gain a ruling that covers all member states of the Unitary Patent system, allowing users to benefit from the associated harmonised and centralised enforcement mechanisms. This may be an attractive alternative for Damae, and a matter of case-by-case decisions, considering the trade-off between the benefit of unified protection in up to 25 EU countries at lower costs and the risk of central revocation at the UPC.

IP Management

Responsibility for IP management at Damae rests with its CTO, David Siret. He is supported by a lead research engineer, Dr Jonas Ogien, who dedicates about 25 percent of his time to IP matters. This involves capturing inventions relevant to Damae's IP strategy by monitoring research results and completing the company's invention disclosure form, discussing new patent opportunities with the CTO, and engaging with patent attorney firms outside in the drafting and prosecution of patent applications.

Internal IP management systems include procedures for maintaining confidentiality, lab notebooks for recording research outputs and invention disclosure forms for capturing and evaluating new inventions. Patent database monitoring is mostly performed on the Espacenet[3] database, which Damae's researchers are very familiar with and which they use regularly for prior art,[4] competitor watch[5] and

3. Espacenet is the EPO's free online patent search tool and is one of the single largest sources of technical information available today with over 140 million patent documents. It provides access to worldwide patent applications, granted patents, complete patent families, the current legal status of applications and a register of all prosecution documents, see *https://worldwide.espacenet.com/*.

4. Prior art refers to all citations including literature, patent specifications, as well as public disclosures of any kind that are relevant to the specific invention under consideration.

5. Competitor watch is the process of performing searches to identify, review and analyse patent applications and other publications released into the public domain by competitors.

freedom-to-operate[6] searches. Technology and competitor watch also extends to vigilant monitoring of literature, conference and exhibition activities. Researchers maintain a list of competitors in the field of optical technologies for non-invasive skin imaging, closely following their patent activities and monitoring competing products for potential infringement of their patents. Damae's IP policy advocates policing and defending its patents, guided by the advice of its patent attorneys as to appropriate action against infringers.

Damae works closely with two patent attorney firms in France: one was selected for its expertise in the field of optics and the other specialises in the medical sector. Although these firms are not involved directly in formulating the company's IP strategy, they are nonetheless advised of the strategic importance of new inventions to its business strategy during discussions on invention disclosures. Their role is to assess the relevance of prior art and draft applications with a set of patent claims that ensures broad protection for the scope of the invention and product applications strategic to the business. They take into account the company's technology roadmap and its publication objectives to advise on the optimal timing of a priority application and to ensure that no disclosures are made prematurely. Regular discussions on inventions and patent prosecution enables the patent attorneys to identify IP opportunities relevant to Damae's business and translate them into relevant IP strategies, which Damae takes on board.

Patents, along with associated research results and clinical studies, hold important media and marketing significance for Damae and constitute a valuable asset in terms of engaging with customers and the dermatology community. Damae derives much benefit from its ambitious scientific communication plan. The goal of this plan is to publish its research outputs in prestigious scientific and medical journals. This not only aims to increase the visibility and credibility of its technology and products in the medical community, but also to persuade clients of the clinical advantages of its products and support clinical dossiers in applications for regulatory approval. Over 80 scientific and medical papers have been published to date.[7]

Takeaway: Avoiding Unintentional Disclosures

Patents and scientific publications can significantly enhance a company's reputation, but should be accompanied by a strategy to avoid unintentional disclosures.

Damae's policy of open publication means that capturing secret know-how in the medical research field does not feature highly in the company's IP portfolio. Damae derives trade secrets primarily from its engineering and manufacturing processes, which are all naturally captured in its process designs, specifications and methods of manufacture. These are recorded both electronically and in production documents and are guarded as important trade secrets for the business.

IP Strategy

Control of the company's core IP is paramount for Damae. As a result, its IP policy is geared towards maintaining complete ownership of its patents and building an IP portfolio independent of third-party access rights. So transitioning from an exclusive licence to acquisition of its first patent was a key transaction, as it brought ownership under Damae's full control. This was a strategically important business decision, particularly with respect to raising finance, as many investors prefer to see major IP assets registered to the company.

Like most business opportunities arising from a disruptive technology, the early phase of the start-up tends to be in a "technology push" mode, so building Damae's patent portfolio has mostly been determined by its R&D outputs. However, its IP strategy is now focused on exploiting a patent portfolio that supports the right products for the right markets and is heavily influenced by user-needs and market intelligence. As a result, customer and clinical feedback is now beginning to influence a "market pull" and determine the direction of R&D, improvements to the technology and the design of Damae's next-generation products.

> *"We have listened to customer needs during R&D phases to achieve the best product/market fit and are still listening to their feedback and input to improve the current product or develop new products. This has inspired recent work on a second generation deepLive probe."*
>
> **David Siret, CTO**

The company is single-minded in its approach to innovation and allocated a substantial budget in the early phase of R&D to capturing inventions and extending its patent portfolio. Damae's corporate values encourage teamwork, open communication and transparency. Researchers working in multidisciplinary teams exchange ideas freely on all aspects of innovation, including IP and related discussions on potential patents, competitor monitoring and prior art. An annual off-site "strategy thinking week" for all staff is an important forum in the company calendar. It involves collective brainstorming and planning strategic objectives and roadmaps for the following year, which form the basis for strategic IP decisions.

Researchers are recognised for their contributions to the IP portfolio and rewarded by a staff incentive scheme. A three-step remuneration bonus is awarded

6. Freedom-to-operate is the process of analysing the claims of a third party's patent to ensure that no aspect of a company's own product falls within the scope of such patent claims.

7. The LC-OCT publication-library is available under this link: *https://www.zotero.org/groups/2551566/damae_medical/library.*

on the basis of achieving the following milestones: patent filing, grant and commercialisation. This is an important incentive mechanism for inventors, but is also governed by a legal requirement for inventor remuneration in France.

The company attaches great importance to collaborating with clinical partners in the testing and validation of dermatological applications for its products and associated software services, such as AI-based clinical decision support software and cloud-based patient data management services. To this end, Damae has established a clinical committee comprising six dermatology centers in Europe, and collaborates with key opinion leaders in the field of non-invasive imaging of the skin at the world's leading academic hospitals to gain support for its technical developments and clinical validation studies.

The deepLive system has been installed in more than 40 centres around the world to date, and mainly by university hospitals, which use it in their own clinical investigations. As early-adopters of the technology, Damae receives valuable updates and feedback from these "referral centres," who also contribute to raising deepLive's profile through their clinical work and publications.

Future Technology Developments

Damae is looking for potential applications of its technology in "microscopic imagery-guided" dermatology procedures in the future. Clinical applications may enable dermatologists to map entire lesions in a tissue with LC-OCT that will automatically define the margins of a skin tumour with precision. This, in turn, will enable the surgeon to minimise scarring and reduce the risk of recurrence and necessity for revision surgery.

Damae has already developed several AI solutions and tools that are integrated into its deepLive platform to aid dermatologists with image interpretation through data analysis and diagnostic prediction of skin pathologies. It will continue to develop further AI tools and services based on web applications that users of the deepLive system can access to store and manage patient data and will extend its patent portfolio to include applications that support these new solutions.

"We will collaborate with more and more centres to position our artificial intelligence (AI) tools as routine companions for dermatologists to facilitate and accelerate diagnosis."

Anaïs Barut

Anaïs Barut
Chief Executive Officer at Damae Medical

Damae has scope to broaden aspects of its future IP strategy to include protection for its new software and AI technologies by filing applications for "computer-implemented inventions," where both software algorithms and technical functions are combined in patent claims. With a continued commitment to pursuing its research and innovation goals, Damae will create a vast amount of knowledge and know-how that is critical to many technical, manufacturing and business functions in the company, but may not be either strategic or appropriate to patent.

This core knowledge will not only add considerable value to the company's IP portfolio, but also to its balance sheet in terms of intangible assets. Such knowledge needs to be documented securely, so that it is accessible for due diligence during investment rounds and in preparing for company valuations. As Damae expands its manufacturing operations, both its patent and know-how portfolios will strengthen its proprietary technology position in sub-supply agreements and provide options to enhance its supplier base.

Takeaway: Patents and Software

Inventions involving software and AI are considered "computer-implemented inventions" (CII) and can be patented at the EPO as long as they have a technical character.[8]

Main Players Involved

Source of IP

- Arnaud Dubois, Main Inventor, Researcher at Charles Fabry Laboratory

The Institut d'Optique Graduate School, Paris-Saclay University and CNRS

- Partner institutions involved in research, innovation and education
- Owners of the first patent application

Tech Transfer Catalysts

CNRS Innovation

- Negotiated patent licence and purchase agreement with Damae

Consortium of VC firms (including Kurma Partners, Eurazeo and BNP Paribas Développement) and Horizon 2020 research and innovation programme

- Provided funding through investments and grants

IP Commercialisation

Damae Medical, *www.damae-medical.com*

- Company established in 2014 with headquarters in Paris, France

8. For further information, see Guidelines for Examination in the EPO: *https://www.epo.org/law-practice/legal-texts/html/guidelines/e/j.htm.*

- Staff: 30 employees
- Management: Anaïs Barut CEO, David Siret CTO, Arnaud Dubois CSO
- Products/services: medical device and research and analysis services in the field of dermatology using a non-invasive optical imaging probe.
- Market and technical area: medical devices, medical imaging, onco-dermatology, dermo-cosmetics and pharmaceutics, research
- Customers: hospitals, universities, dermatology clinics, cosmetic and pharmaceutical industry
- Selected awards: 2022 Winner of the Ivy Award for Young Tech Leader; 2021 Eurostars collaborative Totem European project; 2020 Winner of a contest organised by Health Data Hub; 2019 Winner of Horizon 2020 SME Instrument programme European Commission; 2018 Winner of the World Competition of Innovation organised by Bpifrance; 2017 Anaïs Barut awarded Youngest French Innovative CEO under 30 by MIT Technology Review; 2016 Winner of the Digital Innovation Competition organized by Bpifrance.

Further SME case studies at *epo.org/case-studies.* ■

EPO innovation case studies | ISBN 978-3-89605-343-5 | EPO 2023, Munich, Germany | Editors: Thomas Bereuter, Yann Ménière, Ilja Rudyk | Photos: Damae Medical | 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.

Table 1: Damae Medical's Intellectual Property Portfolio

Patent Families			
No.	**Title**	**Priority**	**Patent number**
1	Optical tomography apparatus and method	20.12.2013	*EP3084345B1*
2	Dynamic focusing system for an optical device	12.01.2018	*EP3714309B1*
3	Devices and methods for line-scanning microscopy	03.12.2019	*EP4070144A1*
4	Systems and methods for performing microscopic analysis of a sample	22.07.2020	*WO2022017784A1*
5	Devices for ex vivo microscopic analysis of samples and in vivo microscopic analysis of the skin	29.01.2021	*WO2022161816A1*

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. Legal events are published in the European Patent Register and can be accessed via *www.espacenet.com.*

Trade Marks				
No.	**Title**	**Application**	**Granted**	**European Union Trade Mark (EUTM) number**
1	Damae Medical	16.08.2018	EU, Australia, US	*1452479*
2	LC-OCT	12.05.2020	EU (AUS, US pending)	*018237600*
3	deepLive	13.05.2020	EU, Australia, US	*018239168*
4	deepMap	26.10.2021	pending	*1664667*
5	deepCloud	26.10.2021	pending	*1666270*
Design Rights				
No.	**Title**	**Application**	**Granted**	**Registered Community Design (RCD) number**
1	Medical Probes—design for handheld deepLive imaging probe.	20.12.2019	EU, AUS, CN, US	*RCD 007439419-0001*

Table 2: Damae Medical's Timeline		
Year	**Business Events**	**IP Actions**
2013	First patent filed protecting LC-OCT technology.	**1st** French priority patent application. Protects apparatus and method of manufacture and use.
2014	Damae Medical founded. Proof of concept for LC-OCT vertical imaging.	
2015	Validation on skin biopsies of the potential of LC-OCT vertical imaging.	
2016	First clinical demonstrator installed. Winner of the Digital Innovation Competition organized by Bpifrance.	Execution of exclusive licence agreement with partner institutions for LC-OCT patent family.
2017	Closing of a €2 million investment round. Proof of concept for LC-OCT 3D stacking.	
2018	Winner of the World Competition of Innovation organized by Bpifrance. CE-marking LC-OCT 2D.	**2nd** patent application protecting: dynamic focusing for an optical device in an immersion medium & a portable LC-OCT apparatus (the hand-held probe)
2019	CE-marking LC-OCT 3D. Launch of clinical validation of LC-OCT 3D.	**3rd** patent application protecting: LC-OCT device and method for producing 3D images. Design right protection for hand-held deepLive imaging probe.
2020	CE mark for deepLive and commercial launch in Europe.	TM applications for: LC-OCT and deepLive. **4th** patent application for: performing microscopic analysis of a sample.
2021	Present in nine countries in Europe, Japan and the United States. Implementation of a scalable production strategy with industrial partners.	TM applications for deepMap and deepCloud. **5th** patent application for: ex vivo microscopic analysis of samples & in vivo microscopic analysis of the skin.
2022	Participation in the first specialised congresses (EADO, EADV). Publication of the 80th scientific paper on LC-OCT and its applications.	Several PCT extensions of patent application and national phase entering of patent families. 30 granted patents in the portfolio to date.

Boosting The Immune Response To Fight Cancer

By Adéla Dvořáková and Bowman Heiden

Abstract

Two entrepreneurial scientists with business experience have created a technology platform for immunology vaccines that make cancer and allergy treatment possible. For product development and technology commercialisation, they founded two startups, S-TARget therapeutics and OncoQR. Thanks to a robust patent portfolio and an IP strategy supporting their business case, they followed several commercialisation pathways, including investments in own research and development, collaborative development and technology out-licensing. IP was essential for gaining revenues early on through licensing as well as for attracting funding. This was crucial given the long time-to-market periods that are typical in biotechnology.

Active Checkpoint Control Immunotherapy

Cancer is the second most frequent cause of premature death due to its ability to circumvent the immune system's defences. Aside from surgery to remove the tumour mass, cancer therapy has traditionally focused on chemo- and radiotherapy. Both types of therapy target rapidly proliferating cells in order to kill them or slow their propagation. However, there are limitations to these approaches, since not all types of cancer respond to these therapies, healthy cells may get damaged and sleeping cancer cells might not be destroyed, which may lead to relapse after the treatment. This makes treatments that activate a person's immune system a particularly suitable strategy to fight cancer. Immunotherapies are promising as a means of targeted treatments that are capable of eliciting, amplifying or suppressing the immune reaction.

Geert Mudde, co-founder of OncoQR, spent much of his scientific career in cancer research aimed at the development of vaccines that build upon the current immunotherapeutic approaches but overcome their drawbacks. In 2009, he and his team developed the so-called

Active Checkpoint Control Immunotherapy (ACCI), which, according to pre-clinical studies, has the potential to selectively and specifically trigger tumour-killing mechanisms naturally available in the immune system, combining a high efficacy with no observed immune system overreactions or other side effects.[1] This research resulted in the creation of the Specific Total Immune Remodulation (S-TIR) platform as a new basis for vaccine development for cancer treatment, which is also suitable for the treatment of allergies and has yet to be tested regarding other diseases. See Box 1.

Technology and Mode of Action

S-TIR is a platform technology suitable for cancer treatment and comprises two modules: the generic "warhead" and a disease-specific "immunogen" with which it is connected through a specific connector. The immunogen is the protein produced by the cancer against which an immune response is desired and has the function of a vaccine. The warhead consists of a targeting moiety and a stimulating moiety. The targeting moiety brings the vaccine to special cells (plasmocytic dendritic cells, or pDCs) which will elaborate the vaccine. These elaborating pDCs then send out activating signals to B cells, to produce antibodies against the vaccine and therefore against the cancer, as well as to T cells, to send killer cells specific to the cancer, and even to other regulatory cells, which engage in processes that support the anti-tumoral activity (such as downregulation of factors on which the cancer cells rely for growth). The specific targeting of the vaccine to the pDCs makes a response more likely, and the presence of the stimulating moiety helps activate the support which the body can otherwise not provide.

This modular composition allows the warhead to be combined with different immunogens. Depending on the immunogen's composition, the technology can be used for different cancer targets but also for other purposes, such as the treatment of allergies. According to OncoQR, this special vaccine is expected to be safer, be more specific and offer a wider therapeutic window than other forms of immunotherapy. Moreover, the modular nature of the compound makes the preclinical tests easier and quicker, and the product is cheaper to produce. Right now, two lead candidates have been developed on the basis of S-TIR for the oncology field and have provided *in vivo* proof of concept in non-human primates: OQR200, targeting breast cancer, and TYG100, targeting gastro-enterological cancers such as pancreatic, stomach, colon and gastro-esophageal cancer. See Figure 1.

BOX 1: Immunotherapy Against Cancer

Over the last decade, several approaches that harness the properties of the immune system have been developed and successfully applied in cancer therapy, including therapies with antibodies:

- **When cancer forms in isolated parts of the body, it sends out signals calling on the body to form new blood capillaries (a process called neo-angiogenesis) to get nutrients to grow. This process can be inhibited with antibodies that block the angiogenesis signals, thereby suffocating and starving the cancer.**
- **Cancer cells may start producing proteins not produced by normal cells, or they may produce them in much higher amounts. When that happens, it is possible to immunologically distinguish the cancer from normal cells and engineer antibodies that can directly attack those cells that express the protein. This approach allows for specific treatments that do not blast the whole body with systemic chemo- or radiotherapy. On the other hand, since it is rare that only the cancer cells produce this protein, a certain portion of healthy cells may be damaged, too.**
- **A further approach, using so-called "checkpoint antibodies," aims to disrupt the ability of cancer cells to inhibit the activity of patrolling cells (regulatory T cells, or Tregs). This approach enables them to stay alert and recruit the effector cells charged with killing the malignant cells. However, checkpoint therapy is typically systemic, which can lead to side effects.**

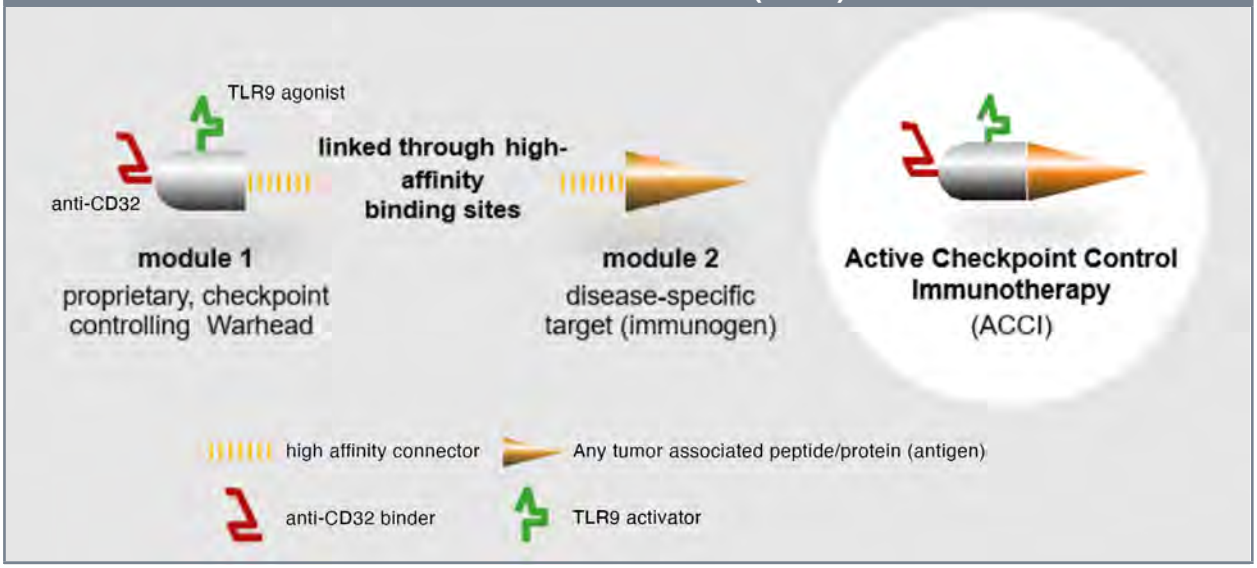
Immunotherapy with antibodies has the generic downside that it often causes unpleasant side effects such as non-specific immune overreactions ("cytokine storms"). The problem of overreactions is less of a concern in a complementary approach: "cancer vaccination," which consists in delivering antigens to the cells of the immune system. If the body does not effectively mount an immune system reaction against one of the proteins that distinguish cancer cells from healthy ones, this approach may help support the body in that endeavour. The difficulty lies in the fact that the cancer antigens can be variant forms of normal proteins, so the immune system may have difficulties in recognising them as fully foreign and need special stimulation. This is where the work of the lead scientist Geert Mudde and his colleagues provided a valuable contribution. They developed the so-called "warhead," which delivers the immunogen to specialised immune cells and stimulates them, whereupon these cells stimulate other branches of the immune system to launch an attack against the cancer.

1. In pre-clinical trials in non-human primates, products developed on the basis of S-TIR have proven to activate several naturally available tumour-killing mechanisms without any observed side effects. See *Therapeutic Principle* | *OncoQR ML*

From Big Pharma to Biotech Venture

As an immunology researcher, Geert Mudde started research on a new technology while working at the pharmaceutical company Novartis. At the time, however, the technology still needed major improvements, and when Mr Mudde left Novartis, the initial patent of Novartis was discontinued. Mr Mudde created his own biotech venture, f-star Biotechnology,[2] in 2006. He

Figure 1: Composition Of A Product Based On The Specific Total Immune Remodulation (S-TIR)



Source: *https://oncoqr.com/technology/mode-of-action/*

BOX 2: Stages of Drug Development

Before obtaining regulatory approval for a drug or a vaccine, the efficacy and safety profile of candidate compounds must be thoroughly examined. The process includes pre-clinical tests in cells and animals, as well as several phases of clinical tests in humans, which require significant investment and can take several years to complete:

Phase	Tested subject	Primary objective
Pre-clinical	Cells (*in vitro)* and animals (*in vivo*)	Determining preliminary efficacy and toxicity and gaining pharmacokinetic and safety information. Studies are mostly done *in vitro* (on biological molecules) or *in vivo* (on whole living organisms) and include testing on animal models, *i.e.,* animals affected by the same disease, often genetically modified.
Clinical phase 1	Less than a hundred patients	Dose-ranging (determining the lowest dose that causes effect and the highest dose without causing harm) to test for safety.
Clinical phase 2	Several hundred patients	Testing potential efficacy while gathering further data on safety and side effects.
Clinical phase 3	Several hundred to several thousand patients	Gathering robust data on efficacy, safety and the overall risk-benefit relationship of the drug. At this stage, the compound is usually compared to a placebo.
Clinical phase 4	Thousands of patients globally	Post-marketing surveillance: gathering detailed information on efficacy and safety, including long-term side effects.

Source: Clinical Trials *(efpia.eu)*

2. The current name of the company is F-Star Therapeutics Inc.

continued research in this area and was able to identify the missing elements, filing the company's first patent for S-TIR in the same year. Mr Mudde eventually left f-star but negotiated an exit deal, including the assignment of all rights to the patent and a commitment from f-star to contribute financially in case he started a new business in the biotech field.

Takeaway: Options Created by IP

The end of a project or business venture need not mean the end for the technology, if the researcher remains committed and maintains access to the IP.

It was around that time when a common friend brought him together with Christof Langer, a biotech engineer with prior business experience. Together, they founded S-TARget therapeutics in 2010 as equal shareholders, with the aim of bringing the S-TIR technology to the market. Geert Mudde and Christof Langer faced a specific challenge in proving their technology: for the pre-clinical *in vivo* study, after having successfully tested in mice for the ability to raise an immune response, they needed to test their technology in a clinically relevant animal model. While mice are useful as model animals in a number of immunological tests, they are not the most appropriate models when it comes to testing a new vaccine, especially if the underlying technology was intentionally built to be human-specific. The immune response of mice differs from that of humans in important ways. For this reason, if one sees a result in mice, it does not mean that the same will be true in humans or in other higher primates. In particular, when it comes to a sophisticated regulatory mechanism like S-TIR, a test in mice would not necessarily yield useful data due to the species-specific interaction between the warhead and cells from human or primate immune systems. A proof of concept of S-TARget's products in primates was needed.

The S-TIR platform was actually developed for allergies as well as for oncology. The anti-allergy vaccine derived from it is supposed to induce tolerance against the antigen it carries, in this case an allergen; anti-cancer vaccines are supposed to induce immunity against a cancer-specific immunogen. While the purpose is different, the basic idea of using the "warhead" to carry the antigen (immunogen) is the same. Therefore, the co-founders decided to test the anti-allergy vaccine in an existing, highly clinically relevant non-human primate model for house dust mite-induced chronic allergic asthma. In 2013, they approached Professor Van Scott at East Carolina University in the U.S., whose disease models had been used by several big players in the allergy field, and tested a vaccine based on S-TIR specifically on captive-bred monkeys suffering from this disease. S-TARget's anti-allergy vaccine was designed to contain the ten most important allergens. The contractual terms with the university included provisions on costs, which in this case were borne solely by S-TARget, and a provision that would give the university a share of the profit in the event that a specific product would reach the market.

"When choosing a partner for commercial collaboration, it is crucial to assess all the pros and cons and take measures to mitigate possible risks."

Christof Langer

Christof Langer
Co-founder of S-TARget Therapeutics GmbH and OncoQR ML GmbH

The results were very promising. The anti-allergy vaccine was able to cure the vast majority of the monkeys from the disease they had been suffering from their entire lives. Encouraged by the success, Prof. Van Scott offered to test S-TARget's first experimental oncology vaccine in his non-allergic monkeys. The oncology vaccine TYG100 induced amounts of antibodies against the cancer antigen that were above expectations. It induced antibody titres in all treated animals, exceeding the clinically relevant titres by a factor of 200 to 1000 in the absence of any observed side effects. This success proved the efficacy of the mechanism as such, and as a result, the co-founders decided to separate the allergy from the oncology business with the aim to build two separate companies and two brands for the different areas of application. In 2013, they created the spin-off OncoQR, granting it a worldwide, exclusive licence to the S-TIR platform for use in all areas of oncology.

Protecting the Platform with a Patent Portfolio

The business model around the S-TIR technology is based on creating a platform protected by a robust patent portfolio, which can be used for different specific applications. The basis of the technology platform is the warhead and the connector, *i.e.,* it is the generic module of the technology, which is transformed into a complete product after being connected to a very specific immunogen developed for targeting a concrete disease. This approach allows the company to develop several products in parallel through a combination of its own R&D efforts and exclusive out-licensing to other com-

panies on a target-specific basis, *i.e.,* for a specific immunogen and independent of the indication or disease area. This has the advantage of diversifying the product portfolio while at the same time financing further R&D through licensing revenues (see Figure 2).

Creating a platform is a particularly good strategy in biotech, where product development requires a considerable amount of time and investment. The use of the same basic technology significantly reduces the costs associated with each new product and its time to market. It can also save costs for IP protection, since it is cheaper to patent the platform technology itself rather than different elements of each product separately. This approach enables a fast scale-up once the regulatory approval is there for the first product.

Takeaway: Commercialising Platform Technologies

Prioritising business development around a basic biotechnology platform helps provide efficiency gains in R&D and helps reduce the costs for IP protection.

To support their business strategy consisting of the platform-based commercialisation model, the IP strategy of the co-founders was to protect the key inventions related to the generic module while keeping the costs of IP under control. The technology platform is primarily covered by three basic patents, two providing broad protection of the platform (EP1996230B1 and *EP2872169B1*) and one (*EP3344647A1*) capturing improved elements of the warhead connector (module 1 in Figure 1). Additional patents are focused on the various products for use in oncology, based on specific immunogens for different lead candidates (module 2 in Figure 1). So far, there are two product patents derived from the S-TIR platform for oncological applications: TYG100 for the treatment of pancreatic cancer (*EP2999485B1*) and OQR200 targeting breast cancer (*EP3297658A1*). Further product patents may be filed in the future for other cancer types.

The patent portfolio is complemented by trade secrets, which cover aspects for the most efficient production of the final vaccine that are not covered by the claims of the patents. This know-how, together with practical support for manufacturing for (pre-)clinical trials, is provided under a non-disclosure agreement to the licensees of the platform. The main advantage of this strategy is two-fold: protecting only the most important elements of the technology allows for savings on patenting costs; at the same time, the patents as such do not disclose sufficient information to potential infringers to allow them to manufacture the product on their own in the most efficient way.

Takeaway: Complementarity of IP Rights

Broader protection of the platform through a combination of patent portfolio and trade secrets can provide better protection against infringement and also extends the protection period.

Takeaway: IP and Technology Licensing

Patents are important instruments for technology transfer. However, licensing agreements are generally of a higher value for both sides when they include not only patent rights but also secret know-how and further support for upscaling production.

Over the years, S-TARget and OncoQR have both benefitted from their scientific advisory board, which consists of scientific and business experts, as well as investors. This board not only supports both companies during the scientific developments but also provides guidance and advice on financial aspects.

Takeaway: Advisory Boards

Biotech startups may benefit from setting up an advisory board composed of renowned scientists in the field as well as investors and business experts.

IP Management

IP related to the S-TIR platform is, in principle, managed by the two co-founders who jointly decide on IP-related issues. However, the help of a specialised patent attorney right from the start was important to be able to assess the pros and cons of different options. The patent attorney's expertise has been helpful to the co-founders not only for questions of patent prosecution but also for taking decisions on their patent and business strategy, as well as for setting up licensing agreements. The patent attorney was involved in every important IP-related decision and covered all relevant aspects by herself. Only for patent applications in certain jurisdictions did she rely on support from local patent attorneys.

"The robust patent portfolio allowed us to attract funding and create opportunities for collaboration."

Geert C. Mudde

Geert C. Mudde
Inventor, Co-founder of S-TARget Therapeutics GmbH and OncoQR ML GmbH

The route chosen for the filings is typically an international (PCT) application filed with the European Patent Office. The decisions on the three basic patents were driven by cost-optimisation as well as the aim of broadening the protection of the platform technology in the most flexible way. The second patent was of strategic importance in this respect, as it covers a broader geographical territory than the first one and also includes China. The third platform patent, which protects the improved warhead connector, was filed almost ten years later than the first patent and made it possible to extend the duration of patent protection for the technology as a whole. Finally, different product patents enable a further extension of patent protection for a specific product, regardless of the lifetime of the patents protecting the basic technology.

Applying Both an Open and an Exclusive Licensing Strategy

Early on, the co-founders had already thought of different possible future scenarios and introduced a smart licensing strategy with license-back provisions that enabled them to keep control over the technology and benefit from improvements made by its licensees. Licences for S-TIR are usually granted as exclusive licences for further product development on a target-by-target basis, for any indication the licensee chooses. In addition, the licensor and all licensees of the S-TIR platform automatically obtain the right of free, non-exclusive and worldwide use in a non-competing field for any technology improvements made by other users. This system of license-back provisions effectively creates an open-innovation type of platform, where all licensees benefit from each other's contributions to improve the basic technology, as long as they are not competitors to each other. For S-TARget and OncoQR, this strategy turned out to be extremely helpful in negotiations, which could be focused on the specific field of use, while the improvements by others were automatically included in the deal. To date, it has also resulted in several technological improvements of the warhead. See Table 1.

Takeaway: License-back Provisions

A system in which licensing agreements include the right to use improvements made by other users is a great way to continuously increase the value of a platform technology as well as simplify negotiation.

When setting up the licensing agreements aiming at product development, Mr Mudde and Mr Langer learnt an important lesson: patenting costs relevant for licensees should also be borne by the licensees. Otherwise, the co-founders might end up bearing all the costs while taking on an undue risk: that they will not be able to recover these costs in the event the licensee does not enter and succeed in the market. See Figure 2 on Page 179.

Takeaway: Patent Costs and Licensing

When setting up licensing agreements in the biotech field, it is good practice to ensure that a fair portion of the patenting costs is borne by the licensee, to mitigate the risk of losses.

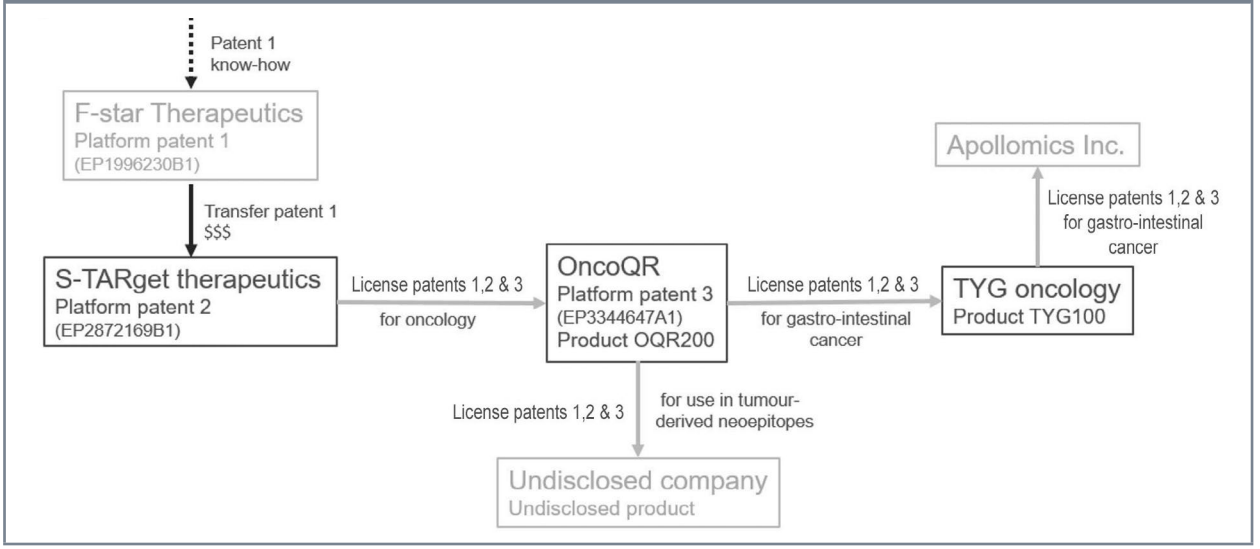
Financing

The main options for financing the R&D efforts of biotechnology startups are public grants, private funding from venture capitalists or business angels, and collaboration with a big pharmaceutical company. S-TARget was initially financed by private investment and a pre-seed grant from an Austrian funding agency. The IP developed so far, which protected its basic technology, in combination with the expertise of the two co-founders, especially their scientific and business competences, was crucial for obtaining this first pre-seed grant. Over the following years, the R&D in S-TARget and OncoQR was financed mostly by national funding programmes (approx. 25 percent) and revenues from out-licensing (approx. 75 percent). For several years (2014–2017), income was secured by revenue from an exclusive licence for use in the allergy field granted to the German company Allergopharma. The allergy business thus turned out to be an important pillar that financed further development in the oncology field. Demonstrating great foresight, the co-founders negotiated a three-fold payment structure: upfront pay-

Table 1: Types Of Licences Foreseen By OncoQR And S-TARget

Types of licences for S-TIR	
Target-by-target platform licensing (commercial)	Licensing the three basic patents protecting the platform on a worldwide exclusive basis for use in combination with a specific immunogen, independent of the indication.
Product licensing (commercial)	Licensing of the complete product (warhead connected with an immunogen) for further development or commercialisation.
Research licences (non-commercial)	Licensing of the platform in combination with one or more specific targets for non-clinical use, which may show the clinical relevance of new targets and potentially lead to obtaining a commercial licence. This type of licence may result in additional evidence and data or improvement of the warhead.

Figure 2: Current Main Business And Licensing Structure



ment, milestone payments and an anti-shelving fee.[3] This secured enough income for the company for the potential scenario in which Allergopharma would not develop the technology for market entry, which actually materialised. In addition, the rights to develop animal-specific vaccines for use in veterinary medicine have been licensed to the company Angothera.

Takeaway: Payment Structure in Licensing Contracts

Setting up licence agreements with multiple types of payments may help secure income in case of different scenarios. This creates a "portfolio of commercial possibilities" and maximises the value of the technology.

National funding programmes in different countries helped S-TARget and OncoQR to raise enough capital for the first trials. For example, in 2013, S-TARget was able to get approximately one million euros from an Austrian seed funding programme, which it used for developing the warhead, preparing the first two S-TIR vaccines and the non-human primate studies that showed the proof of concept. After the first pre-seed and seed funding, the disadvantage of further grants for the development of S-TIR was the usual requirement of granting authorities, according to which the company has to contribute a significant percentage of the grant from its own resources (co-funding). Getting next-stage funding in Europe proved to be difficult, also because the co-founders were avoiding any form of financing that would mean a dilution of their shares in the company and loss of control. Involving VCs or business angels when the technology had not reached a certain technology readiness level involved the risk of putting the co-founders in a weak negotiation position. On the other hand, in the pharma industry, where product development lasts until regulatory approval is given, R&D requires substantial monetary investment. Therefore, for a small company, it might be beneficial to involve a VC at a certain stage or engage in a strategic partnership with a larger company.

Takeaway: Involving Venture Capitalists

There is a window of opportunity for involving VCs for startups. It should not be too early (ideally after obtaining the proof of concept), but still before other funds are used up, for the startup to strike a win-win deal.

Not being willing to lose control over their companies and following the successful licensing deal in the allergy field, the co-founders focused on negotiations with several big pharma players in the field of oncology. These companies were attracted by the promising results from pre-clinical trials. However, all negotiations with big pharma have so far remained on hold pending a proof of concept from phase 1 clinical trials. It is not unusual in this field for potential industry partners to want to see a proof from trials in humans prior to in-

3. Including an anti-shelving fee in the licence agreement usually takes the form of a minimum-royalty guarantee to the licensor, obliging the licensee to pay a minimum royalty or a default amount set out in the agreement after a specified period of time. Inclusion of such a provision protects the licensor from having their technology "shelved," *i.e.,* not further developed or commercialised. Anti-shelving provisions can also include the possibility of the licensor retreating from the deal in case of non-development of the technology within a certain period.

vesting. The resulting challenge is thus to find the path to getting clinical phase 1 data.

The Path to Product Commercialisation in Oncology

Since the conception of the technology, the co-founders could make use of the patent system to maintain enough control to be able to transfer and out-license the intellectual assets in their business interest and create different options for bringing the technology to the market. Currently, the co-founders are pursuing three main paths towards the clinical phase 1 trials in oncology: a collaborative model partially based on out-licensing S-TIR for the product TYG100, own R&D through OncoQR for the product OQR200 and a third path based on out-licensing to an undisclosed company.

TYG100 is the first pilot product derived from S-TIR in oncology targeting gastro-enterological cancer. OncoQR established a collaborative development model with a UK-based company, which was at that time developing a similar product, although with far inferior results. While the partner could contribute with experience from clinical trials that Mr Mudde and Mr Langer did not have, in 2013, OncoQR provided the licence to S-TIR in exchange for a 50 percent share in the newly established company, TYG oncology Ltd. Currently, TYG is in-licensing the platform from OncoQR for use in this group of targets and further out-licensing the TYG100-related patents (product licence) to a US-based company, Apollomics Inc., which is working towards bringing the product to clinical trials. This deal represents one of the possible paths towards getting initial clinical data and subsequent regulatory approval for the technology. It also secures the manufacturing and delivery of the warhead to OncoQR for possible clinical phase 1 trials.

BOX 3: Successful R&D Collaborations

When engaging in R&D collaborations, companies should aim for a win-win agreement. In some instances, it might be unavoidable to provide access to IP to the other party for free. However, in such cases, there should be a clear written and binding statement defining which assets are provided by which party, for how long, on what basis and for what purpose. At the same time, clear and unambiguous exit regulations should always apply in case the collaboration needs to be dissolved.

For the second product, OQR200, which is developed in-house by OncoQR itself, the co-founders have intentionally selected the immunogen HER2/neu, a protein involved in the proliferation of breast cancer cells, since it is probably the best-studied cancer target to date. The pre-clinical *in vivo* studies in (healthy) non-human primates were carried out by OncoQR to study the immunological reaction in the body. These tests have, for the first time, proven that, apart from polyclonal HER2/neu-specific antibody expression, large numbers of clinically relevant cytotoxic T cells could also be induced. Based on the results, all cancer-killing mechanisms of the immune system have been activated by the product in monkeys, the animal whose genome is most similar to that of humans.

In 2022, OncoQR out-licensed the platform for use in patient-specific, tumour-derived neoepitopes, which represents another pathway to commercialisation for the products derived from the S-TIR platform.

OncoQR and S-TARget still have a way to go before their disruptive immunotherapy based on the S-TIR technology platform reaches cancer patients. However, a smart IP strategy aligned with an agile business strategy has so far enabled them to create several different options paving the way for future technology commercialisation.

Main Players Involved

Source of IP

Geert Mudde

- Lead researcher and main inventor of the S-TIR technology
- Co-founder of the companies f-star Biotechnology, S-TARget therapeutics and OncoQR
- Actively involved in the business strategy and IP portfolio development

Christoph Langer

- Co-founder of the companies S-TARget therapeutics and OncoQR
- Actively involved in the business strategy and IP portfolio development

Professor Van Scott at East Carolina University

- Professor of physiology
- Involved in testing on non-human primates for allergy and oncology

Tech Transfer Catalysts

National funding agencies

- Providing pre-seed and seed financing and several follow-up grants to finance pre-clinical development

IP Commercialisation

S-TARget Therapeutics GmbH

- Founded in 2010
- Out-licensing two main patents for different use cases to finance R&D in oncology

OncoQR ML GmbH

- Founded in 2013
- In-house development of the product OQR200
- Out-licensing the third main patent for different use cases to finance R&D in oncology
- 50 percent participation in TYG oncology and collaborative research for the product TYG100

TYG oncology Ltd
- Founded in 2013
- Collaborative research with OncoQR for the product TYG100

f-star Therapeutics Inc.
- Filing the first platform patent in 2006

Allergopharma GmbH & Co. KG

Angothera GmbH

Apollomics Inc.
- Licensees of S-TIR technology for uses in allergy, veterinary medicine and specific fields of oncology

Timeline of Main Events

IP Actions:

Filing of patent 1 (platform)—2006
Filing of patent 2 (platform)—2012
Filing of patent 3 (platform)—2015
Patent filing (product TYG100)—2013
Patent filing (product OQR200)—2015

Business Events:

Founding of S-TARget therapeutics—2010
Founding of OncoQR ML—2013
Founding of TYG oncology—2013
Pre-clinical trials on NHP in the field of allergy—2013
Pre-clinical trials on NHP for TYG100—2013
First licensing agreement for S-TIR—2014
Pre-clinical trials on NHP for OQR200—2014, 2017
Out-licensing for tumour-derived neoepitopes—2022

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Table 2: S-TIR intellectual Property Portfolio

Patent Families

Platform Patents

No.	Title	Priority	Patent number	Comment
1	Bispecific molecule binding TLR9 and CD32 and comprising a T cell epitope for treatment of allergies	3 March 2006	*EP1996230B1* *WO2007098934A1*	S-TARget therapeutics GmbH Use in oncology exclusively licensed to OncoQR ML GmbH
2	Immunoregulatory vaccine	13 July 2012	*EP2872169B1* *WO2014009209A2* *WO2014009209A3*	S-TARget therapeutics GmbH Use in oncology exclusively licensed to OncoQR ML GmbH
3	Coiled-coil connector	1 September 2015	*EP3344647A1* *WO2017037158A1*	OncoQR ML GmbH
Product Patents				
4	Gastrin peptide immunogenic composition	21 May 2013	*EP2999485B1* *WO2014187743A1*	TYG oncology Ltd
5	HER2/neu immunogenic composition	18 May 2015	*EP3297658A1* *WO2016184862A1*	OncoQR ML GmbH

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. Legal events are published in the European Patent Register and can be accessed via *www.espacenet.com* under legal status.

Trade Marks

No.	Title	Application	Granted	European Union Trade Mark (EUTM) number
1	S-TIR (owner S-TARget therapeutics GmbH)	15 September 2014	EU, Australia, US	*013256474*

Smarter Prognostic Tests For Early-Stage Breast Cancer

By Ciaran O'Beirne

Abstract

OncoMasTR 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 helps clinicians confidentially determine the best treatment options, thus avoiding overtreatment 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 Gallagher at University College Dublin (UCD) in 2012 and was then exclusively licensed 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 U.S. firm and the creation of a new start-up company.

A Global Problem

According to the World Health Organisation (WHO), there were 2.3 million women diagnosed with breast cancer and 685,000 deaths globally in 2020. Indeed, breast cancer is the most common cancer among adults, and it is the first or second leading cause of female cancer deaths in 95 percent of countries. In February 2023, the WHO released a new Global Breast Cancer Initiative Framework, recommending that countries implement early detection, timely diagnosis and comprehensive management of breast cancer to save 2.5 million lives from breast cancer by 2040.

While patient outcomes are consistently improving, the heterogeneous nature of breast cancer presents significant challenges for clinicians in determining disease progression, especially when the disease is detected in the early stages. Approximately half of all new breast cancer diagnoses are in women with early stage, hormone receptor-positive and HER2-negative breast cancer,[1] and the majority are prescribed endocrine therapy in combination with chemotherapy following surgical removal of the tumour. However, chemotherapy may only benefit around 30 percent of

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

women with early-stage breast cancer, while the remaining 70 percent may experience regression of the cancer without chemotherapy. Despite this, many women are still prescribed chemotherapy as a default treatment, even though it can have significant physical, emotional and psychological side-effects, only because it is currently quite difficult to determine a patient's risk of cancer recurrence.

Founding OncoMark

Professor William Gallagher
Co-founder of OncoMark

Cancer biology, diagnostics and molecular therapeutics have always been central to the research interests of William Gallagher, Professor of Cancer Biology at UCD School of Biomolecular & Biomedical Science. His experience as a Marie Curie Fellow with Rhone-Poulenc Rorer (now Sanofi-Aventis) in the late 1990s sparked his interest in commercialising his research outputs. He started to consider setting up a spin-out company to address critical and unmet needs for cancer patients. Steve Penny, who had previously worked in financial services and had joined Prof. Gallagher's lab as a mature student, shared this vision. Together they established OncoMark in May 2007, following participation in NovaUCD's Venture Launch accelerator programme, which provides academic researchers with the skills they need to set up a business, such as drafting a business plan, raising investment and IP protection strategies.[2]

The company did not initially seek to raise investment via typical channels such as venture capital, but instead focused on grants available to SMEs under the European Commission's FP7 programme. Over the course of the following years, Prof. Gallagher, representing either UCD and/or OncoMark, was able to co-ordinate four Industry-Academia Partnership programmes in breast cancer, melanoma and prostate cancer, and one FP7 Collaborative Project programme focused on discovering new rationalised therapy options for difficult-to-treat subtypes of breast cancer. This use of the FP7 programme was quite innovative at the time: besides providing working capital, it ensured that the funding was not equity-diluting.

The involvement of Prof. Gallagher and OncoMark in these consortia had multiple benefits. The funding allowed the company to recruit researchers from across Europe and, growing to a team of 15 with expertise in oncology, it enabled OncoMark to establish its reputation as an innovative company and, importantly, facilitated the development of connections and networks with a pan-European range of academic institutions and companies in that field. The collaborations also opened up access to biobanks, which are large repositories of biological samples such as blood, tissue, urine and other fluids. These materials are collected from individuals with disease and they enable researchers to study the effects of new drugs and treatments on human biology and disease in a way that is both efficient and cost-effective. This would subsequently become important when validating OncoMark's future product, the OncoMasTR technology.

Takeaway: Research Funding

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

The Development of OncoMasTR

The OncoMasTR technology arose from a research collaboration between Prof. Gallagher representing UCD and Prof. Adrian Bracken, a leading expert in the field of cancer epigenetics,[3] representing TCD.

Prof. Bracken's research interests in understanding fundamental aspects of cancer cell biology complemented Prof. Gallagher's interests in translational cancer research. With Prof. Bracken as the lead Principal Investigator, they successfully applied for a Commercialisation Fund grant to Enterprise Ireland in 2012. Enterprise Ireland is an Irish government agency responsible for the development and growth of Irish enterprises in world markets and also funds academic research projects with commercial potential. The objective of the project was to develop more accurate and reliable prognostic and predictive biomarkers to help both doctors and patients make better informed treatment decisions.

Using gene expression profiling, a technique which

1. ER-positive, HER2-negative early-stage breast cancer is a common subtype of breast cancer. ER-positive means that the cancer cells have receptors for the hormone oestrogen, which can promote their growth. HER2-negative means that the cancer cells do not have an overexpression of the HER2 protein, which can also promote their growth.

2. See *https://www.ucd.ie/innovation/researchers-and-students/venture-launch-accelerator/*.

3. Cancer epigenetics is the study of heritable changes in gene expression that are not caused by changes to the DNA sequence, but rather by alterations to the chemical modifications of DNA and histone proteins that regulate gene expression. Prof. Adrian Bracken was elected a European Molecular Biology Organization (EMBO) Member in 2021, having been nominated by Nobel Prize winner Thomas Cech, in recognition of his significant achievements in the field of life science research.

had been previously used to identify gene expression signatures found to correlate with different aspects of tumour progression, they succeeded in identifying "drivers" of cancer proliferation. When combined with additional biomarkers, these drivers had the potential to become a superior prognostic assay when compared to other pre-existing tests for early-stage cancer. The inventors called this cancer proliferation signature OncoMasTR (derived from Oncology Master Transcription Regulators). The OncoMasTR test measures the expression of a number of prognostic genes, as well as reference genes, and estimates the probability of distant recurrence for breast cancer patients. This helps clinicians determine the best treatment options for their patients, avoiding the costs and severe side-effects of unwarranted chemotherapy.

Takeaway: Collaborate to Innovate

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

Commercialisation Strategy

Recognising the commercial potential of OncoMasTR, Profs. Bracken and Gallagher submitted an invention disclosure to the technology transfer offices (TTOs) in TCD and UCD. Following review and consultation, the TTOs decided to file a joint priority patent application in the names of the two universities and in parallel signed a Joint Ownership Management Agreement (JOMA) to address issues such as the payment of patent fees and future revenue sharing. The joint patent application, for "A method for predicting risk of recurrence of cancer," was filed with the EPO in 2014 (*EP3194621*).

The TTOs knew from experience the significant challenges in licensing diagnostic technologies to established companies at a low Technology Readiness Level (TRL) without supporting clinical validation data. One model to overcome this challenge was to license the technology to a spin-out company that could then secure the necessary investment to "de-risk" the technology by bringing it to a higher TRL and increase the potential for successful commercialisation.

Even before the patent filing, OncoMark had expressed interest in licensing the OncoMasTR technology. The company was a credible licensee from the perspective of the TCD and UCD TTOs as it was co-founded by Prof. Gallagher, who, in addition to being a co-inventor with expert knowledge of the licensed technology, was recognised as someone who had the drive and vision to bring research outputs to market. It was well-funded, had a strong research team, an extensive network of partners that could assist in clinically validating the technology and a strong advisory board comprising key opinion leaders. Importantly, the company had prepared a robust and comprehensive commercial plan that included external investment to sup-

Laboratory of OncoMark

port the development and validation of the technology. The proposed licensing of the OncoMasTR technology to OncoMark also had an additional benefit for UCD as it broadened the company's product pipeline, which could in turn increase the value of the company, thereby benefiting the shareholders, including UCD.

Takeaway: Spin-out to Increase the TRL

For university inventions, licensing the patented technology to a spin-out company can help increase the TRL and the probability of a successful commercial launch, as well as supporting the development of a long-term R&D partner.

Following negotiation and agreement of terms, the parties signed a licence agreement in December 2014, whereby TCD and UCD granted OncoMark a worldwide exclusive royalty-bearing licence, which included the right to sublicense the technology in all fields of use. The licensed technology included the patent application and related non-patentable technical information, which included an algorithm that was kept as a trade secret. The payment structure included a licence fee linked to the first sale of product, but was largely based on royalties of net sales, or net receipts in the case of sublicences. The agreed royalty rates reflected the stage of development of the technology and industry norms, and were based on a sliding scale linked to cumulative sales targets. In addition, the agreement allowed for royalty stacking, whereby the royalty rate could be reduced to a pre-agreed level in case OncoMark would have to license third-party IP to develop a product. The sublicence rates were also based on a sliding scale linked to cash investment in the licensed technology and structured in such a way that the sublicence payments to the licensors were high in situations where the licensee might seek to sell the company along with the licensed technology at an early stage of development, before the true value of the technology could be fully assessed.

Finally, OncoMark had the right to acquire the licensed technology five years following execution of the agreement, subject to reaching pre-agreed sales targets and provided the assignment fee was negotiated in good faith and reflecting fair market rates so as to be consistent with EU State Aid rules. In addition to the payment terms, the licence agreement included standard terms addressing a wide variety of issues, including rights to improvements, confidentiality, reporting, publication, infringement, warranties, liabilities, and termination provisions.

Strategic Patent Prosecution

The TTOs elected to file the priority patent application with the EPO to take advantage of the comprehensive search report that is provided within the priority year. The EPO was also the preferred filing office, since it was clear from the outset that commercialisation efforts would target the European and U.S. markets. OncoMark had responsibility for the prosecution of the application under the terms of the licence agreement and the application subsequently entered PCT the following year (PCT/EP2015/071524).

At the national/regional stage, OncoMark, in consultation with TCD and UCD, elected to validate the application in the major European markets and also to file in the U.S. In addition, the company took a strategic decision to file in other countries with a large addressable market and for which there existed a well-developed reimbursement system. Hence, the patent was also filed in Canada, Japan, Israel, New Zealand, and Australia.

While the claims in the granted European patent extend to a variety of cancers, the granted U.S. patent is limited to a diagnostic of breast cancer. This difference in allowable claims between the EPO and the USPTO reflects the complexities arising from the 2012 U.S. Supreme Court decision restricting eligible subject matter in the *Mayo v. Prometheus* case.[4] In an effort to overcome this limitation, Cepheid is pursuing two U.S. continuation applications, one with broad claims that extend the patent to other cancers, and the second with additional claims in support of breast cancer.

Takeaway: 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.

Securing Investment and Expertise

In 2014, OncoMark applied for funding under the EU SME Instrument to drive the development of the licensed technology. The SME Instrument formed part of the European Commission's Horizon 2020 suite of programmes with an objective to support high-risk, high-potential small and medium-sized enterprises and to develop and bring to market new products, services and business models that would drive economic growth. OncoMark and the OncoMasTR technology aligned well with the objectives of the SME Instrument, but while the company's application was favourably reviewed and scored well, it was not initially approved for funding. One contributing factor was that the evaluators considered that the OncoMark team at that point lacked commercial experience and a proven track record of bringing products to market.

4. See A. Sasha Hoyt, "The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S.," *Medical Diagnostic Technologies*, 79 *Wash. & Lee L.* Rev. 397 (2022).

At this same time, Des O'Leary, an industry veteran with over 25 years of experience in the diagnostic sector, was seeking to leverage his extensive commercial experience and explore opportunities with start-up companies. He started his career as a clinical biochemist in the 1980s before moving to industry in the early 1990s, where he held different roles in manufacturing, research and development. Most importantly, he spent 12 years with Biotrin, an Irish diagnostic company, where he rose to become its Chief Executive Officer and later General Manager of Diasorin Ireland.[5]

He joined Enterprise Ireland's Business Partner programme. This programme seeks to match individuals with sectoral experience with spin-out companies to help them develop a business plan and then potentially take a senior management role with the company and raise investment. While he met with several companies, none of the opportunities really caught his interest. Fortuitously, he was introduced to OncoMark by his former boss in Biotrin, who was serving as a Board member of NovaUCD, the Centre of New Ventures and Entrepreneurs in UCD, where OncoMark was based. This introduction was timely. Dr Mairin Rafferty, who had been CEO of OncoMark since 2013 and had previously served as COO since 2009, was herself looking at other opportunities. As such, the company needed to recruit a new CEO and so Mr O'Leary and the management of OncoMark entered into discussions. Mr O'Leary was attracted by the commercial potential of the licensed technology. Concomitantly, OncoMark recognised that Mr O'Leary would greatly strengthen the identified gaps in the SME Instrument application given his extensive management and commercial experience in the diagnostics sector.

After Mr O'Leary joined the company as CEO in 2015, OncoMark immediately reapplied for the SME Instrument funding, this time successfully securing €2.7m in June 2015. At this stage, the company employed approximately 15 people, but they were predominantly researchers with little product development experience. Therefore, Mr O'Leary pivoted the company's strategy from research to product development and made a number of key hires to enable this. In addition, knowing the significant costs required for the clinical validation, regulatory approval and launch of a product, he sought to leverage the SME Instrument funding to secure further investment. The proposition was attractive to investors, because not only was Mr O'Leary well known and respected within the investment community, but the potential of the licensed technology was also persuasive, and the SME Instrument funding was in the form of a grant without dilutive impact on the company's equity. In 2017, the company successfully raised an additional €2.1m from a syndicate of Irish investors including Kernel Capital, Irrus Investments, HBAN MedTech and Enterprise Ireland to fund the transition of the test from clinical validation to regulatory approval and full commercialisation.

Takeaway: Experienced Senior Management

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

"The OncoMasTR test is designed to enable a more personalised approach to patient care, helping clinicians to determine which patients should not receive chemotherapy, ultimately improving their quality of life."

Des O'Leary

Des O'Leary
CEO at OncoMark

Moving Closer to the Market

With the €4.8m in resources at its disposal and new hires, the company narrowed down the test from the initial 10-11 candidate OncoMasTR genes in the patent application to 3 prognostic genes and made steady progress in developing and validating the OncoMasTR test for breast cancer in accordance with the Clinical and Laboratory Standards Institute (CLSI) guidelines. In 2016, the company also applied for a word (TM12158EU01) and a figurative (TM12157EU01) trade mark for OncoMasTR.

In 2018, the OncoMasTR test was CE-marked under the CE-In Vitro Diagnostic Directive and three independent external clinical validation studies were initiated using specimens from over 2,000 women with ER-positive, HER2-negative early-stage breast cancer. Key conclusions from these studies indicated that OncoMasTR was prognostic for distant cancer recurrence and provided superior prognostic value when bench-

5. He led the development of the company's infectious disease portfolio, successfully securing CE marking and launching over 15 new patent protected diagnostic tests, two of which achieved FDA Pre-Market Approval including a test for Parvovirus B19 which captured 70 percent of the worldwide market. Following the 2008 acquisition of Biotrin by Diasorin, an Italian diagnostics company, he became General Manager of Diasorin Ireland, a position he held until he decided to pursue new opportunities in 2013.

marked against the "gold standard" Oncotype DX Recurrence Score (RS) which analyses the level of 21 genes that have been linked to tumour progression and response to treatment.

In parallel, the company initiated market due diligence and networking within the diagnostics sector. As part of the company's due diligence efforts, Mr O'Leary and key members of his team attended the American Society of Clinical Oncology (ASCO) conference in Chicago in 2016. At the conference, Mr O'Leary actively sought to engage with potential partners and he initiated discussions with company representatives of Cepheid, a leading molecular diagnostics company headquartered in the U.S. with over 2,000 employees that was established in 1996. While mainly known for its product lines in infectious diseases, sexual health and healthcare-associated infections, Cepheid did have tests for leukaemia, breast and bladder cancers. Wishing to broaden its oncology portfolio, the company had made a strategic decision in 2016 to expand its oncology business unit with a focus on urological and breast cancers. As part of this strategy, Cepheid was scouting for suitable opportunities.

Takeaway: Finding Partners

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

This initial meeting was followed by a further meeting with senior Cepheid representatives later that same year. Coincidentally, Prof. Gallagher struck up a conversation with an Austrian oncologist whom he sat beside on a flight on his return from a major breast cancer conference in the U.S. It transpired that the oncologist acted as a consultant to Cepheid. On learning of Prof. Gallagher's research interests, and in particular the OncoMasTR technology, he indicated that the technology potentially would be of interest to Cepheid.

These interactions put OncoMark and the OncoMasTR technology firmly on Cepheid's radar. While it was important to Cepheid that patent applications had been filed in support of the OncoMasTR technology in key countries, this alone was not sufficient to "close the deal." The company primarily wanted to see clinical validation. Thankfully, OncoMark did have the relevant data, having conducted initial clinical studies, leveraging its network of partners that had been developed during the previously referenced FP7 grants, and the validation data was persuasive enough for the parties to recognise the potential synergy of integrating the OncoMasTR technology with Cepheid's GeneXpert molecular diagnostics platform which aligned with Cepheid's strategy of extending its oncology portfolio.

Takeaway: Clinical Validation

For technologies related to diagnostics, clinical validation is often a prerequisite for partners to really consider the business opportunity. Partnering can be instrumental to achieve that at reasonable costs.

Securing the Deal

Ensuing discussions took place with the Danaher Group, Cepheid's parent company, on the acquisition of OncoMark over the course of 2017 and 2018. Ultimately, Cepheid chose to "de-risk" the deal by first investing in the company to fund a proof-of-concept study to demonstrate that OncoMasTR could be successfully integrated into Cepheid's GeneXpert platform. This led to a substantial investment offer from Cepheid and an option to acquire OncoMark at a future date and at a pre-agreed price as part of the investment terms.

Cepheid's investment offer posed a dilemma for OncoMark. Its own development and validation efforts had progressed very well. A number of key academic papers supported the use of OncoMasTR in predicting the risk of tumour recurrence in patients with early-stage node-negative breast cancer and the results of independent external clinical validation studies were positive. In addition, the company had successfully secured the CE mark for the OncoMasTR test, had agreed terms with a leading manufacturing partner and had developed labelling and packaging material in advance of the product launch. However, Mr O'Leary knew the significant barriers associated with the launch of a new product, and the investment required to recruit a sales force necessary to access new markets and gain market share. Cepheid had an established diagnostics platform and a decentralised model with the U.S. hospital system that would enable the quick adoption of the OncoMasTR test. The Board of OncoMark had to consider the pros and cons as to whether to have "a big slice of a small pie, or a small slice of a big pie." Ultimately, the Board voted to approve Cepheid's offer and OncoMark's own plans for a product launch were cancelled.

Using existing funding and bolstered with the new investment provided by Cepheid, OncoMark further validated the OncoMasTR test. The company initiated real-world, decentralised evaluations of the OncoMasTR test at a number of sites in Ireland and the Netherlands, which confirmed that the overall precision of the OncoMasTR test was high. The company also successfully completed the proof-of-concept study demonstrating that OncoMasTR could be successfully integrated into Cepheid's GeneXpert platform. This provided Cepheid with the confidence to exercise its option and it acquired OncoMark in March 2021.

"A GeneXpert version of the OncoMasTR test is a very important part of our portfolio plan for breast cancer diagnostics and it has been a pleasure working with the former OncoMark team on this programme."

Scott Campbell

Scott Campbell
Senior Vice President and General Manager, Oncology, Cepheid

Presently, Cepheid is completing further clinical studies in advance of a submission to the U.S. Food and Drug Administration (FDA) for registration, with plans to launch the OncoMasTR test under the brand name Xpert Breast Cancer Insight. The impact of this product will be a more tailored treatment plan, based on the disease recurrence risk of an individual patient that will hopefully reduce the need for unnecessary chemotherapy with associated adverse effects for thousands of women diagnosed with breast cancer.

Creating Another Business Opportunity

In 2021, the founders and management of OncoMark chose to reinvest the money they realised from the sale of OncoMark and established a new diagnostic start-up company called OncoAssure. Based in NovaUCD, OncoAssure is developing new panels of cancer biomarkers for applications in prostate cancer, melanoma and other cancers. OncoAssure plans to create new employment opportunities and develop new prognostic tests, both through its own internal research efforts and also via collaborations with UCD, other academic institutions and companies. These different collaborations will potentially improve the quality of life of cancer patients and positively impact patient outcomes.

Main Players Involved

Source of IP

William Gallagher

- Co-inventor
- Researcher of Cancer Biology in UCD and a former Director of the UCD Conway Institute of Biomolecular and Biomedical Research (2016-2021)
- Co-founder of OncoMark
- Chief Scientific Officer of OncoAssure
- Selected awards: 2019 Science Foundation Ireland (SFI) Entrepreneurship Award

University College Dublin and Trinity College Dublin

- Collaborative research project resulted in the invention
- Owners of the patented technology

IP Commercialisation

OncoMark

- Company established in 2007 with headquarters in Dublin, Ireland
- Products/services: OncoMasTR, a multi-parameter prognostic test for early-stage breast cancer
- Market and technical area: research in cancer diagnostics
- Acquired by Cepheid in 2021

Cepheid

- Leading molecular diagnostics company, headquartered in the U.S.
- Investment in OncoMark and subsequent acquisition of the company in 2021
- Preparing product launch of OncoMasTR under the brand name Xpert Breast Cancer

OncoAssure

- Diagnostic spin-off company founded in 2021

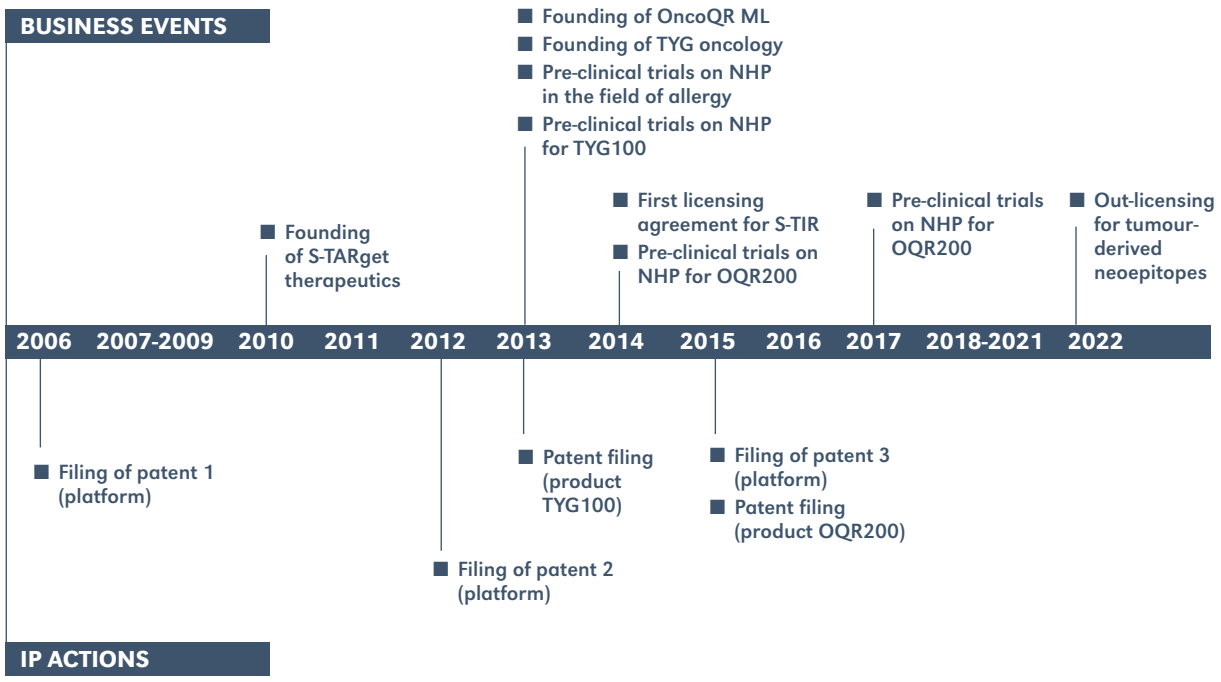
Further technology transfer case studies at *epo.org/case-studies.* ■

Table 1: Relevant Intellectual Property Portfolio

Patent Families			
No.	**Title**	**Priority**	**Patent number**
1	A method for predicting risk of recurrence of cancer	19.09.2014	*EP3194621* *PCT/EP2015/071524*
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. Legal events are published in the European Patent Register and can be accessed via *www.espacenet.com* under legal status.			
Trade Marks			
No.	**Title**	**Application**	**European Union Trade Mark (EUTM) number**
1	OncoMasTR	20.12.2016	*016188278* *016188336*

Key Dates And Milestones Associated With OncoMasTR Technology		
Year	**Business Events**	**IP Actions**
2007	OncoMark founded.	
2012	Collaborative research project between UCD and TCD.	
2014	Licence of technology to OncoMark.	Original invention relating to the OncoMasTR technology was jointly filed by UCD and TCD at the EPO.
2016	Development of OncoMasTR by OncoMark. Training and verification of OncoMasTR assay was completed, with poster presentation of the data at the San Antonio Breast Cancer Symposium. Further development and validation studies were conducted according to Clinical and Laboratory Standards Institute (CLSI) guidelines.	
2018	The OncoMasTR assay was CE-marked under the CE-IVD directive. Three independent external clinical validation studies were initiated, using specimens from over 2,000 women with ER-positive, HER2-negative early-stage breast cancer. Key conclusions: • OncoMasTR was significantly prognostic for distant recurrence (DR) in all three studies. • OncoMasTR provided superior prognostic value to Oncotype DXTM Recurrence Score (RS) in two of the studies. Cepheid and OncoMark begin collaboration discussions to develop a GeneXpert version of the OncoMasTR assay.	European patent granted and validation in several European countries.
2019	OncoMark initiated real-world, decentralised evaluations of the OncoMasTR assay in Ireland and the Netherlands. Key conclusions from the beta-site testing and analytical validation indicated that: • Overall precision of OncoMasTR was high • OncoMasTR scores were consistent across a >100-fold RNA input range • OncoMasTR displays robust analytical performance and is potentially suitable for decentralised use Cepheid and OncoMark enter into a formal collaboration to develop a GeneXpert version of the OncoMasTR assay.	
2020	Cepheid assigns Xpert Breast Cancer Insight trade name to GeneXpert version of OncoMasTR assay. Cepheid demonstrates analytical equivalency of Xpert Breast Cancer Insight assay to OncoMasTR assay. Cepheid demonstrates the fidelity of risk score reporting between Xpert Breast Cancer Insight and OncoMasTR in characterised specimens.	U.S. patent granted. Cepheid filed two U.S. continuation applications.
2021	Cepheid demonstrates clinical equivalency of Xpert Breast Cancer Insight to OncoMasTR. Cepheid initiates real-world evidence and clinical validation studies for the Xpert Breast Cancer Insight prototype test. OncoAssure founded.	
2022	Integration of OncoMasTR onto Cepheid's GeneXpert platform.	

OncoTR Technology—Timeline



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Licensing Course 2024
Rotterdam, Netherlands

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2025 LES International Annual Conference
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LES 2024 USA-Canada Annual Meeting
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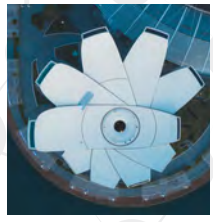


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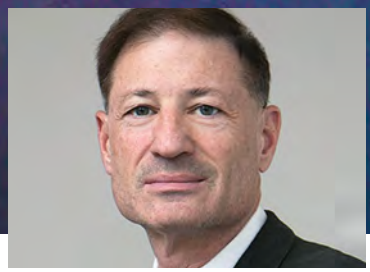

Russell Levine

PARTNER, KIRKLAND & ELLIS LLP

Closing out the conference, we will have Russell Levine presenting his highly anticipated **"Top 10 Court Decisions of the Year Affecting Licensing",** which he has presented at both the LES Annual Meeting and the AUTM Annual Meeting to standing-room-only audiences for many years.

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