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The Need for Intellectual Property Rights Strategies at Academic Institutions

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This ALLEA statement has been prepared by ALLEA's Permanent Working Group Intellectual Property Rights (PWGIPR). Through its Working Groups, ALLEA provides input on behalf of European academies into pressing societal, scientific and science-policy debates and their underlying legislations. With its work, ALLEA seeks to ensure that science and research in Europe can excel and serve the interests of society.

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Preamble

Today's global economy is significantly characterised by the increasing relevance of intangible assets – as opposed to tangible assets. This is best demonstrated by the following facts. In 1990 the three top car producers in Detroit generated revenues of US $250 billion, had a market capitalisation of US $36 billion and 1.2 million employees. In 2014, the three leading Silicon Valley digital companies had revenues of US $247 billion, a market capitalisation of more than US $1 trillion, but only 137,000 employees.[1] It is anticipated that this shift in relevance from tangible to intangible assets will continue at an accelerated pace.

Countries with high labour costs, but poor natural resources – like most European countries – can only survive in the face of ever tougher global competition with knowledge, technology and innovation leadership. Therefore, a global and comprehensive legal protection of differentiating characteristics of products, software and services from competitors becomes increasingly important. Intellectual Property Rights (IPRs), especially patents, do not only facilitate its owner to exclusively run a business or prohibit others from gaining significant market shares, but also provide security for the high-risk investment in Research and Development (R&D). However, the patent system provides for the mandatory publication of patent applications eighteen months after the filing/priority date and for the requirement that the invention must be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a skilled person. Thus, patents act decisively against secrecy in favour of early publication of research results and their dissemination. Moreover, by exempting from the effects of a patent, inter alia acts done for experimental purposes relating to the subject matter of the patented invention and the use of biological material for the purpose of breeding or discovering and developing other plant varieties,[2] in Europe patent protection does not constitute an obstacle for further scientific and technological developments.[3]

The key to an adequate patent portfolio – for a company as well as for an academic institution – is a cultural change in dealing with intangible assets, which include intellectual property. For Europe's largest applied research organisation, the Fraunhofer-Gesellschaft, but also for leading organisations pursuing fundamental research, e.g. the Max Planck Society or Oxford University, despite their primary mission in society as generator and disseminator of knowledge,[4] a high priority is/has to be to deal with Intellectual Property (IP) in a professional way. All academic institutions need to adapt to this development in order to successfully fulfil the role they are entrusted to play in a national or regional innovation ecosystem.[5]

1 According to figures published in the Special Report-Companies, The Rise of Superstars, The Economist of September 17, 2016, p. 5.

2 Article 27 (b) and (c) of the Agreement on a Unified Patent Court, OJ EU 2013/C 175/01 of 20.6.2013. Although this Agreement due to the Brexit problems has not yet entered into force, national patent laws of EU Member States provide already such limitations of the effects of a patent.

3 The German Federal Supreme Court (BGH) and the German Constitutional Court have clarified that any experiment related to the subject matter of the patented invention, which pursues the enrichment of knowledge, i.e. to obtain further research results, also such as finding further medical uses of a patented drug, even if eventually undertaken for commercial aims, does not infringe a patent (cf. BGH Decisions of July 11, 1995, (1997) IIC 01, 103 – Clinical Tests, and of April 17, 1997, [1998] R.P.C. 423 – Clinical Trials II, and Federal Constitutional Court of May 10, 2000, (2001) GRUR 43 – Klinische Versuche).

4 Which, however, never existed in pure form (see Polanyi M. (1969), The Republic of Science: Its Political and Economic Theory, in Criteria for Scientific Developments, Public Policy and National Goals (Shils, E., ed.), pp. 1-20, MIT Press, Cambridge, MA).

5 Cf. Wessner, C.W. (2007), The Global Tour of Innovation Policy – Innovation does not take place in a laboratory, Issues in Science and Technology, 24: 43-44; also Straus, J. (2008), Intellectual Property vs. Academic Freedom? A Complex Relationship within the Innovation Ecosystem, in The University in the Market (Engwall, L. and Weaire, D., eds.), Portland Press London, pp. 53-65.

Although this Statement addresses specifically only the strategy of academic institutions with regard to patents, the message implied therein equally applies to other categories of intellectual property rights, i.e. copyrights, trademarks, industrial design and plant variety protection certificates. Finally, it goes without saying that all activities related to any IP strategy have to respect the principles laid down in *The European Code of Conduct for Research Integrity,* published by ALLEA in 2017.

Early Developments in the United States of America

Scientific and technological developments since the late 1960s have blurred the traditional dividing line between basic and applied research and have enabled universities and other publicly funded institutions to generate research results eligible for patent protection. The US legislator eventually understood that the US legal regime of the 1970s was in urgent need of an overhaul. Back then, patents originating from federally funded research could only be licensed on a non-exclusive basis, which resulted in less than 5% of the 25,000 to 30,000 government-owned patents being licensed. Consequently, the Bayh-Dole Act (Public Law 96-517) introduced the possibility for private parties to retain patent rights via a 'title in contractor' policy. Small businesses and non-profit organisations, including universities, could retain IPRs resulting from federally funded research. Additionally, in 1980, the Stevenson-Wydler Act (Public Law 96-480) required federal agencies performing research to establish an Office of Research and Technology Application (ORTA) at all government-operated or contractor-operated laboratories with an annual budget of more than US $20 million. Finally, in 1986, the Federal Technology Transfer Act (FTTA; Public Law 99-502) amended the Stevenson-Wydler Act by shifting the emphasis in federal policy from permitting technology transfer to requiring agencies to act vigorously in working with industry in order to commercialise federally funded research.[6]

6 Straus J (2017) Intellectual Property Rights and Bioeconomy, JIPLP 12:576-590. Cf. page 581 with further references.

The tangible outcome of this US legislation and the increasing cooperation between research institutions and industry is impressively reflected in the aggregated data for the contribution of inventions from Public Sector Research Institutions (PSRIs). PSRIs *"have participated in the applied phase of research that led to discovery of a drug, if it, solely or jointly, created intellectual property specific to the drug that was subsequently transferred to a company through a commercial license"*.[7] These data reveal that, between 1991 and 2006, 153 drugs were developed (and FDA approved) from PSRIs research results. For example, the National Institute of Health (NIH) Intramural Research Program resulted in 22 new drugs with which respective patents were granted between 1991 and 2007.[8] It is remarkable that drugs and biologics still under licence from NIH generated sales of US $4.7 billion in 2010. In addition, sales for drugs and biologics for which patents had already expired, were about US $2.2 billion in 2010. Thus, the total worldwide sales in 2010 for inventions of the NIH Intramural Research Programme alone amounted to at least US $6.9 billion.[9] The instrumental role that NIH patents have played in achieving such impressive and beneficial 'tangible' results should be obvious.[10]

7 Stevens AJ et al. (2011) The Role of Public-Sector Research in the Discovery of Drugs and Vaccines. New England Journal of Medicine 364:535-541. Cf. page 537. These authors emphasise that in most cases the intellectual property was a patent or patent application, but that a few products have used proprietary biologic materials developed and licensed by the academic institution.

8 Chatterjee SK, Rohrbaugh ML (2014) NIH Inventions Translate into Drugs and Biologics with High Public Health Impact. Nature Biotechnology 32:52-58. Cf. Table 3 at page 54.

9 Ibid., page 56-7.

10 It is worth to be mentioned that almost one third of US patented inventions (in 2017, 45,220) – and the more important part as measured by future citations, renewals and novelty – relies on federal research investment (Fleming, J. (2019), Government-Funded Research Increasingly Fuels Innovation – Nearly a third of U.S. Patents directly rely on federal research, Science 364: 1139). This situation is best reflected in the most recent report on patents in Proteomics related to methods of proteomic screening, identification and analysis, showing that out of eight patents seven are owned by academic institutions (The Regents of the University of Michigan, University of Kansas, The Board of Trustees of Stanford University, University of Pittsburgh of the Commonwealth System of Higher Education, Massachusetts Institute of Technology and partners, Nationwide

Knowledge and Technology Transfer in Europe

Some countries lack the financial resources and infrastructure necessary to implement IP strategies at universities, or they are only available to major universities. In this case, the major universities should offer IP assistance[11] to all other universities in the country through their so-called Technology Transfer Office (TTO) network and, in return, share the profits[12] of the patents created through the TTO network with the major universities. As Italy does not have a TTO network, this was likely the reason why the Italian legislator, contrary to the international trend, has recently changed the law, so that university professors and assistants, rather than universities, own their inventions. With the introduction of the University Organisation Act (UG 2002),[13] Austria repealed a comparable legal provision, as the economic success has failed and additional problems have arisen.

While securing the IP in academic institutions is important and challenging enough, it is only one side of the coin. The other side is to utilise the secured IP. Companies may exploit their IP themselves by maintaining their market positions and increase the likelihood of returns from their R&D investments. However, academic institutions are unlikely to commercialise innovative products themselves. Besides the traditional ways of dissemination, academic institutions should apply their IP to benefit the national and global economy more directly via collaborating with industry: establishing licence agreements and supporting spin-offs, while strengthening the academic environment in parallel.

In 2008 the European Commission (EC) adopted Recommendation of 10 April 2008 on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations.[14]

The EC recognised in its Knowledge Transfer Study 2010-2012 that European public-sector research institutions (PSRIs) were not yet as effective as American PRSIs when it came to commercialising research results and producing invention disclosures, patent applications or licence income. Compared to the USA, Europe spent on average 3.3 times more research expenditures to earn €1 million in licence fees.[15] Moreover, most institutions across Europe that are responsible for the commercialisation of academic research results lost money, despite the vast pool of IP available.[16] Hence, the EC sought for mechanisms to strengthen TTOs in PSRIs and launched the call 'Capacity-Building in Technology Transfer (CBTT)'.[17] Its aim was to transfer IP and technology into industry through R&D contracts, licensing and spin-outs more effectively.

The CBTT call resulted in the three-year project PROGRESS-TT – 'Public Research Organisation Growing Europe through Best Practice Solutions for

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Children's Hospital, The Ohio State University) and only one by a company (Amber Gen), ((2019) Nature Biotechnology 37: 1126).

11 Such as patentability assessment, patent application drafting or patent marketing

12 See the examples "Performance-based (quota litis) consultant services" from the chapter "Benefits for the academic institutions" and "Cost- and surplus-sharing model" from the chapter "Benefits for the scientists".

13 https://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf, §106 (Last accessed 4 April 2019).

14 http://ec.europa.eu/invest-in-research/pdf/ip_recommendation_en.pdf (Last accessed 4 April 2019).

15 https://ec.europa.eu/research/innovation-union/pdf/knowledge_transfer_2010-2012_report.pdf page 128-129. (Last accessed 4 April 2019).

16 http://www.progresstt.eu/download/progress-tt-brief/?wpdmdl=498 page 2. (Last accessed 4 April 2019).

17 https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/cbtt-1-2014 (Last accessed 12 February 2019).

Technology Transfer'.[18] Europe's most experienced TTOs were encouraged to share their expertise and best practices with their less experienced counterparts to help boost Europe's ability to turn knowledge into commercialised products and services. More than a hundred European TTOs participated in the PROGRESS-TT activities resulting in improvements in their overall performance. More than one thousand European TTOs were catalogued creating a publicly available database.[19] Best practices and case studies were identified to serve as a main resource for ongoing training of professionals and as guidance for TTOs.[20]

With origins reaching back to the 1970s, the Association of University Technology Managers (AUTM)[21] and the Association of European Science and Technology Transfer Professionals (ASTP),[22] founded in 2000, have evolved as the leading knowledge transfer associations in the US and Europe, respectively. Their missions include promoting technology transfer, commercialisation, and innovation on the interface between PRSIs and industry. They establish and exchange best practices; train professionals; support technology licensing, commercialisation, open innovation, creation of spin-outs; and offer the networking opportunities needed for a prosperous knowledge and technology transfer. For example, the Technologie Allianz,[23] PraxisAuril[24] and Transfera.cz[25] became the leading national knowledge and technology transfer associations in Germany, the UK and the Czech Republic, respectively.

18 http://www.progresstt.eu (Last accessed 12 February 2019).

19 https://ipib.ci.moez.fraunhofer.de (Last accessed 10 February 2019)

20 https://www.astp-proton.eu/resource-center/best-practice-library/ (Last accessed 12 February 2019).

21 https://autm.net (Last accessed 12 February 2019).

22 https://www.astp-proton.eu (Last accessed 16 February 2019)

23 https://www.astp-proton.eu (Last accessed 16 February 2019)

24 https://www.praxisauril.org.uk (Last accessed 19 February 2019)

25 http://www.transfera.cz/en/ (Last accessed 12 February 2019)

In a recent study, Maicher et al.[26] have identified five fundamental pillars for the prosperity of a technology transfer office. *First*, the IP policy and its official support by high-level management. *Second*, the university and its environment, including its prestige as well as its entrepreneurial spirit. *Third*, the TTO internal organisation, necessitating well-trained professionals that are both integrated within the institution as well as networked with other institutions and industry. *Fourth,* the involvement of researchers, since their ideas are the first stage of innovations and since only they know how an idea may become reality in the first place. *Fifth*, industry and their financing, providing on the one hand the resources for covering costs at the early stages of product development and on the other hand the power for a successful commercialisation. For new or less experienced TTOs, it is important to know that their success depends on all of these aspects and it may take more than a decade until the TTOs have utilised the full potential of the academic institution.

It is worth mentioning that also under the auspices of the World Intellectual Property Organisation (WIPO) important activities in developing IPR policy for universities and research institutions are taking place.[27] In particular, WIPO is running a number of country projects to support the development of such a policy. WIPO also maintains a dedicated website with IPR policy documents from European, US, and universities from other countries, as well as from research institutions.

26 Maicher L, Mjos KD, Tonisson L (2019) Intervention Opportunities for Capacity Building in Technology Transfer. In: Granieri M, Basso A (eds), Capacity Building in Technology Transfer. The European Experience. Springer, Cham, pages 29-46.

27 https://www.wipo.int/about-ip/en/universities_research/ip_policies/ (Last accessed 4 April 2019)

Europe’s Technology Transfer Offices and their Achievements

In the statistics of patent applications under the Patent Cooperation Treaty (PCT) published in 2017, the French Commission for Alternative Energies and Atomic Energy (CEA) and the Fraunhofer-Gesellschaft are world leaders in the field of public research institutions.[28] This top position is put into perspective, because in a general ranking of all patent submitting institutions, universities and companies, CEA and Frauenhofer-Gesellschaft are "only" ranked #63 and #75 respectively as well as one place below the best university, the University of California System (#30), followed by MIT (#76), Harvard (#121), the University of Oxford (#320), the Technical University of Denmark (#424), the Imperial College London (#427) and the École polytechnique fédérale de Lausanne (#444).[29]

With more than 30 years of history, Oxford University Innovation (OUI) has become a showcase of UK's technology transfer.[30] OUI manages the commercialisation of IP developed in Oxford through licensing, spin-out creation and material sales. It provides researchers with commercial advice, funds patent applications and legal costs, and identifies and manages consultancy opportunities for academics. OUI also administers a seed fund, whose goal is to assist university researchers to successfully transform good research into good business by providing access to managerial skills, securing or enhancing IP, supporting additional R&D and funding the design and construction of prototypes.[31]

Since 2010, a separate team manages the equity stake acquired by the university subsequent to the creation of a spin-out.[32] In 2015, Oxford Science Innovations (OSI) was established as the university’s preferred partner for the provision of capital for spin-out companies. Since then it raised GBP £600 million from a diverse group of investors and is now able to provide investment capital for Oxford University’s businesses based on research from Oxford's Mathematical, Physical, Life Sciences and Medical Sciences departments.

In OUI's fiscal year 2017/2018, it received a university grant of GBP £3.5 million, which it primarily invested in the external costs of patenting inventions.[33] During that year it received 457 invention disclosures, created 21 spin-outs, managed 3881 patents, closed 694 deals, distributed GBP £8.9 million to researchers, and created GBP £17.6 million of revenue, while Oxford University's income from research grants and contracts was GBP £579.1 million.[34] As a comparison, in 2011, the Office of Technology Licensing at Stanford University brought in US $ 66.8 million from royalties, while Stanford’s total budget was US $4.1 billion, whereof US $1.2 billion were for sponsored research.[35] The latter figures show that the process of technology transfer is not a self-sustaining cycle and thus the monetary aspect of technology transfer should not be overstated.

28 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2018.pdf, table A18 on page 32. (Last accessed 12 February 2019)

29 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2018.pdf, table A17 on page 31. (Last accessed 12 February 2019)

30 https://innovation.ox.ac.uk (Last accessed 12 February 2019)

31 https://innovation.ox.ac.uk/award-details/university-challenge-seed-fund-ucsf/ (Last accessed 12 February 2019)

32 Oxford Spin-out Equity Management: https://innovation.ox.ac.uk/news/oxford-spin-out-equity-management/, Feb. 8th, 2019. Brochure: https://innovation.ox.ac.uk/wp-content/uploads/2017/07/OSEM-brochure-August-2016.pdf (Last accessed 12 February 2019)

33 http://annualreview.innovation.ox.ac.uk/accounts/ (Last accessed 14 February 2019)

34 https://www.ox.ac.uk/about/organisation/finance-and-funding?wssl=1 (Last accessed 12 February 2019)

35 Leute KL (2013) Fostering Innovation for the Benefit of Society: Technology Licensing’s Role at Stanford. In: Hishida K (eds.), Fulfilling the Promise of Technology Transfer. Fostering Innovation for the Benefit of Society. Springer, Heidelberg, pages 71-81.

Oxford Nanopore Technologies founded in 2005 as a spin-out from Oxford University develops and sells DNA sequencing products. As of February 2019 it raised a total of GBP £451 million in investment.[36] In 1998, Cambridge Enterprise provided initial seed funding for founding the Cambridge University spin-out Solexa, which develops and commercialises genome-sequencing technology.[37] In early 2007, Solexa and its technology were acquired by Illumina for US $650 million.

Celebrating its 25 years of existence, University College London Business holds 237 patent families and 74 equity holdings.[38] The UCL spin-out Endomagnetics, created in 2007, allows radiologists to accurately mark the site of breast tumours and enables the precise removal and treatment of breast cancer; it raised a total funding of over US $22 million and the company's products have already been used in over 35,000 procedures across 300 hospitals in more than 30 countries.[39]

In 2002, Ablynx was established as a spin-out of the Vlaams Instituut voor Biotechnologie (VIB) and the Free University of Brussels (VUB) and received seed financing of €2 million.[40] It focuses on the discovery and development of a novel class of antibody-derived therapeutic proteins, for a range of serious life-threatening disease areas, including inflammation, thrombosis, oncology and Alzheimer's disease. In 2018, Ablynx was acquired by Sanofi for US $4.8 billion.

Founded in 1970, Max Planck Innovation (MPI) advises and supports scientists in evaluating inventions and filing patent applications.[41] It markets technologies to industry and coaches founders of spin-outs. MPI oversees about 1,200 inventions and has shareholdings in 16 companies.[42] Since 1979 MPI has managed about 3,900 inventions, has closed more than 2,400 licence agreements and, since 1990, coached around 130 spin-outs.[43] The total revenues for inventors, the Max Planck Institutes and the Max Planck Society currently amount to more than €400 million. FLASH, MPI's technology for magnetic resonance imaging (MRI) has helped MRI to achieve a breakthrough in medical diagnostics.[44] Leading manufacturers of MRI devices took over FLASH within a few months and, eventually, i.e. some only after protracted legal disputes, contributed to around €155 million in licence revenues.[45]

CERN, the Mecca of high-energy physics research exploring the very constituents of matter, established a Knowledge Transfer Group in 1997. It promotes and transfers the technological and human capital developed while permanently improving accelerators, detectors and computing at CERN. In 2017, the group received 73 invention disclosures and signed 41 knowledge transfer deals, while 23 start-ups and spin-outs use CERN technology.[46] One of CERN's most successful technologies is Medipix, which initially addressed the needs of particle tracking at the large hadron collider. Currently, it is under licence by eight companies in various fields ranging from medical imaging to material analysis.[47]

36 https://nanoporetech.com/about-us (Last accessed 12 February 2019)

37 https://www.enterprise.cam.ac.uk/case-studies/solexa-second-generation-genetic-sequencing/ (Last accessed 12 February 2019)

38 https://www.uclb.com/about/ (Last accessed 12 February 2019)

39 http://www.endomagnetics.com (Last accessed 12 February 2019)

40 https://en.wikipedia.org/wiki/Ablynx https://www.ablynx.com/investors/sanofi-acquires-ablynx (Last accessed 20 February 2019)

41 https://www.mpg.de/knowledge-transfer/technology-transfer/ (Last accessed 12 February 2019)

42 http://www.max-planck-innovation.de/en/technology_transfer/successful_track_record/index.php (Last accessed 12 February 2019)

43 http://www.max-planck-innovation.de/de/technologietransfer/erfolgsbilanz/ (Last accessed 12 February 2019)

44 https://www.mpibpc.mpg.de/16020256/pr_1811 (Last accessed 12 February 2019)

45 http://www.max-planck-innovation.de/en/news/press_releases/news.php?European%20Inventor%20Award%20for%20fast%20MRI%20in%20medical%20diagnostics&id=5013 (Last accessed 12 February 2019)

46 https://kt.cern/sites/knowledgetransfer.web.cern.ch/files/file-uploads/annual-report/knowledge-transfer-report-2017.pdf, pages 6-7, (Last accessed 12 February 2019)

47 https://medipix.web.cern.ch/buy-medipix-and-timepix-based-products (Last accessed 12 February 2019)

Given the vast amount of activities and initiatives in the field of technology transfer, it seems advisable that all remaining European academic institutions follow suit. Some academic institutions do not have the critical mass to justify the establishment of a full-fledged knowledge transfer office (KTO) capable of managing all tasks related to patenting, licensing and founding. As an initial guidance, such academic institutions may cooperate with e.g. a nearby university already experienced in the field of technology transfer to obtain the necessary knowledge of all processes involved. An academic KTO needs to serve as a central contact point of first choice for researchers and industry. It should keep the process of commercialisation lean in order not to interfere with the institution's main mission and it should master the art of decision preparation. While the proximity to researchers has proven to be an essential ingredient during various stages of a commercialisation approach, a KTO may outsource certain tasks to external agencies, such as e.g. the evaluation of inventions, the market analysis, the drafting of patent application, patent prosecution and the monitoring, and the exploitation of technologies via licence agreements or transfers of ownership.

Wherever there is research, scientists contribute to the improvements of methodologies and develop new technologies and instruments. Such contributions for research purposes deserve also the attention of industry. Releasing an IPR strategy, which fits the institution's mission and promoting technology transfer activities ensures an academic institution to keep up with global developments.[48] Firstly, it allows bridging the gap between publicly-funded research and privately run businesses, which is highly desirable from a socio-economical viewpoint. Secondly, it allows dealing with IP in a professional way, which became increasingly important to political stakeholders and industry leaders. Thirdly, it allows agglomerating the widest public support necessary for high-risk/high-gain research.

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48 Sangberg PR et al. (2014) Changing the academic culture: Valuing patents and commercialisation toward tenure and career advancement. PNAS 111:6542-6547.

Benefits of Implementing an IPR Strategy

Although the introduction of IPR strategies at academic institutions has positive consequences and manifold benefits for stakeholders,[49] the most important, overarching benefit of these IPR strategies should be seen in their contribution in improving national/regional, even global innovation performance, i.e. eventually leading to badly needed marketable products and processes.

Benefits for Academic Institutions

Secured IP attracts partners

The implementation of innovative ideas from basic research into marketable products is a risky, cumbersome and expensive process. At the same time, there are great market opportunities and profits for the industrial partner if the implementation is successful. However, the high implementation costs only pay off if the new product cannot be copied by competitors, i.e. the core know-how contributed by the academic institution is protected by IP rights. Otherwise a competitor would be able to copy the product, offer it cheaper than the 'inventor' on the market, since it had no implementation costs for product development and thus will dominate the market. The 'true' product inventor is the loser. The example shows that a potential cooperation partner who has become aware of the unique expertise of an academic institution through scientific publications will only enter into a long-term cooperation to implement brilliant ideas from basic research if the know-how of the academic institution is protected by patents.

49 https://www.wipo.int/about-ip/en/universities_research/ip_policies (Last accessed 4 April 2019)

Background and foreground IP

Beside the unique expertise and infrastructure, dealing professionally with IP attracts companies and ensures long-term project cooperation with academic institutions. Already secured IP that originates from fundamental research, allows companies to exclusively access critical technologies and know-how. While the so-called background IP is important to initiate collaboration, the protection of foreground IP is at least equally important. From the company's point of view, the academic institution should transfer as much knowledge as possible to the company's portfolio. For the academic institution, this will be acceptable as long as this happens at normal market conditions, the freedom to pursue research remains, and cooperation with others is still possible. Thereafter, licensing fees can contribute to the financing of basic research at the academic institution.

By securing and transferring IPRs, the cooperating company obtains a limited guarantee to pursue its product development, while avoiding undesired copying by market competitors. Since the academic institution is in permanent need to publish, securing the IP beforehand is the only way to protect a cooperating company from replicas by its competitors.

To prevent any potential conflicts of interest arising from questions regarding ownership and rights associated with IP, it is common to identify the background IP of all parties prior to entering into a research agreement and to clarify beforehand access rights to foreground and background IP, as well as the sharing of revenues.[50]

50 Such a practice is mandatory e.g. in Horizon 2020 projects and recommended by the World Intellectual Property Organisation. Cf. Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)' Article 41 – Article 49. https://op.europa.eu/en/publication-detail/-/publication/3c645e51-6bff-11e3-9afb-01aa75ed71a1/language-en (5.10.2018), European Parliament and of the Council of the European Union (2013) Regulation (EC) No 1906/2006 of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013) Article 39 – Article 51. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1906 (5.10.2018),

In such a case when each contractor brings in its own project relevant background IP, a solution to the conflict of interest would be a prior agreement, which grants the jointly developed foreground IP to the financing company.

In a case when the project generates foreground IP directly based on background IP of one of the two project partners, this foreground IP may fall to the partner who holds the respective background IP. The industrial partner receives free and non-sublicensable rights of use and exploitation in the field of the joint project.

The need to control the transfer of foreground IP to companies demonstrates the importance of an IPR strategy for an academic institution. IPR provisions laid down in cooperation contracts allow handling long-term projects including projects with several partners and without limiting the scope of the academic institution to cooperate with third parties.

University handling of IP and spin-outs

The creation of spin-out companies from universities has become widespread and occasionally very profitable. The essential start is the university owning the background IP. Then a source of outside funding is required to finance the fledgling company.

There is however a huge variation in the percentage of the company which a particular university demands in return for licensing the IP. Sybil C K Wong et al.[51] show this percentage ranges from zero or a couple of percent to as much as 60%. UK and European Universities tend to be at the high end. Obviously the lower the percentage take, the more attractive and easier it should be to raise external funding.

European Commission (2008) Commission Recommendation of 10 April 2008 on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations Annex I §15-§18. https://publications.europa.eu/en/publication-detail/-/publication/743a513c-e1ab-455e-a2f2-20ef43c3060e (5.10.2018), European IPR Helpdesk (2018) How to define and manage background in Horizon 2020. https://www.iprhelpdesk.eu/news/how-define-and-manage-background-horizon-2020 (5.10.2018), WIPO (2012) Model Intellectual Property Policy for Universities and Research Institutions §5.1 – §5.8

51 Sybil C K Wong et al., Keys to the kingdom, Nature Biotechnology 33, 232-236, Table1 & 2, Feb.26th, 2015. https://www.nature.com/articles/nbt.3159 (Last accessed 17 June 2019)

When a newly created company fails and becomes valueless, the original percentage ownership is of no consequence. On the contrary, it is only likely that a company grows and becomes very valuable after several further external funding rounds. However, as universities generally do not have the resources to participate in such further funding rounds, their share in ownership is consequently heavily diluted. This is certainly true of the spin-out companies which have achieved valuations in excess of a billion euros.

An alternative which could be attractive both from the point of view of the academic institution and from the investors would be for the academic institution to receive only 5% of the company for its IP, in the form of a '**golden share**', which means that this percentage holding is not diluted for the next two or three funding rounds. This follows the logic that a small percentage of a large number is preferable to a big percentage of a small or zero value. Furthermore, it would be desirable for all European academic institutions to adopt a comparable percentage and formulation. This would greatly assist in the growing instances where a company is being created from the IP of more than one institution.

Innovation-friendly image and indirect return

An IPR strategy should not primarily focus on generating returns or gaining research funds. It may also contribute to an innovation-friendly image of the academic institution, which then allows differentiating itself from other research institutions and universities. At first, the establishment of knowledge transfer offices, the implementation of an IPR strategy and the creation of initial IPR will very likely create additional costs, which may not be recovered by direct returns. However, after several years, returns from licensing or selling of technologies might cover patenting expenditures.

Most importantly, IPR activities at academic institutions open up great indirect return potential for the national economy.[52]

52 Therefore, the academic institution has to ask the lender or the state for a compensation of the additional costs especially during the initial build-up phase. Cf. European Commission (2008) Commission Recommendation of 10 April 2008 on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations Annex I §8-§11 and Annex II §6-§7.

Inspiration from collaboration

Questions arising from the implementation of fundamental research findings in applications tackling pressing technological, environmental or socio-economic challenges give new impulses to fundamental research at the academic institution. Thus, the practical aspects of research and development will inspire the more theoretical questions and vice versa.[53] This is even more likely for technologies originally developed as solutions in one particular field, which then find applications in a distinctly different field, thereby allowing tackling hitherto unaddressed questions. Very often, general technological advancements, the maturity of instruments and their widespread availability build the very basis for ground-breaking research.

Performance-based (quota litis) consultant services

On the way from the invention disclosure to the patent application, the academic institution requires external consulting services to assess the novelty and market potential of the invention and to prepare the patent application. The remuneration of these consulting services could be performance-based, so that the consultants are encouraged to perform at their best, while saving costs for the academic institution. Performance-based (quota litis) means that the fees for consulting services are set significantly lower than market prices and that additional payments are made for patent granting and successful marketing. The total payments to the consultants will be significantly higher than the market value of the services provided, resulting in a win-win situation: For the academic institution, the cost is reduced if the patent is rejected and the consultants benefit if the patent is granted and the marketing is successful. However, this type of consultancy contract requires the involvement of very specialised lawyers on the side of academic contractors in order to avoid being overreached by financially stronger partners.

53 Franzoni C (2009) Do scientists get fundamental research ideas by solving practical problems? Industrial and Cooperate Change 18:671-699.

Benefits for Scientists

Balance between patenting and publication

Publications about new findings play a vital role in the career of a scientist. However, the filing of patents is considered too tedious and time-consuming and therefore leads to reservations.[54] Researchers anticipate a decrease in research productivity and quality by engaging in the commercialisation of research; they are concerned about the extra effort and time, potentially impairing one's individual career. Thus, patenting may appear as not being worthwhile. However, experimental studies proved such preconceptions at least partially wrong. An academic patent has "little if any negative impact on dynamics of the subsequent scope and trajectories of scientific research, while it can still contribute to improving technology transfer from academia to industry and foster academic entrepreneurship".[55] Additionally, patents may contain valuable information well beyond other types of literature, since their descriptive parts do not need to satisfy any formal requirements. Therefore, utilising and extending the patent literature may be advantageous in the daily scientific research.

On the other hand, studies indeed showed that the patenting process delays publications in scientific journals. More severely, "academic patents covering radical technological improvements with an extraordinarily wide range of applications or instruments that are essential for subsequent research can have a strong negative impact on

54 Calderini M, Franzoni C (2004) Is academic patenting detrimental to high quality research? An empirical analysis of the relationship between scientific careers and patent applications. KITeS Working Papers 162, KITeS, Centre for Knowledge, Internationalisation and Technology Studies, Universita' Bocconi, Milano, Italy. Davis L, Larsen MT, Lotz P (2011) Scientists' perspectives concerning the effects of university patenting on the conduct of academic research in the life sciences. J Technol Transf 36:14–37. Jensen PH, Webster E (2011) The Effects of Patents on Scientific Inquiry. The Australian Economic Review 44:88–94. Clark J (2015) Do Patents and Intellectual Property Protection Hinder Biomedical Research? A Practical Perspective. The Australian Economic Review 44:79-87.

55 Franzoni C (2011) Academic Patenting and the Consequences for Scientific Research. The Australian Economic Review 44:95-101.

scientific evolution in the long run".[56] A well-chosen IPR strategy and well-trained technology transfer professionals are key to mitigate such adverse effects.

Published patents support the economy and the researchers' reputation

Registering for IPRs supports the economy. Next to the applicants, published patents also mention their inventors and this generally contributes to the reputation of researchers. Industrial employers may put more emphasis on the number of patents, than on the number of peer-reviewed papers. Receiving a granted patent, which at least in Europe lacks a "grace period", necessitates the filing of a patent application before publishing the invention in any way. However, filing a patent does not impede subsequent publications. At the same time, giving due consideration to the question of patentability during the research work may trigger the cultural change needed. Furthermore, the chance to contribute sustainably to the economy of one's home country by registering for IPRs may additionally motivate researchers.

Cost- and surplus-sharing model

The IP strategy may include a cost- and surplus-sharing model, which provides the researchers of the academic institution - on a voluntary basis - with the opportunity to act as entrepreneurs and to profit intellectually as well as financially from the exploitation of their own scientific research findings. The research group and, if appropriate, each individual contributor to the invention can pay to a certain extent a part of the costs for the patent application, patent maintenance, and patent exploitation up to the international granting process (e.g. PCT).[57] If a granted patent is successful on the market, the parties will additionally profit from their risk assumption by receiving a bigger share from the patent's financial surplus than with the standard cost and surplus sharing model.[58]

Benefits for the International and National Economy

IPRs enable exclusive product marketing

Providing new technologies and innovative products, materials or procedures to national or international companies will lead to new jobs and the creation of additional revenue, ultimately contributing to the social and economic wealth. Especially in case of performing basic research, further R&D spending to build prototypes or to follow up with clinical trials is required for eventually ending up with a marketable product. Holding IPRs, allowing to exclusively produce, and market the product is necessary for a company to justify any future investments. Therefore, companies prefer academic institutions capable of carefully treating and protecting any results of financed research. This is particularly true when they seek long-term partnerships necessitating the continuous protection of cumulated IP. Additionally, companies rather tend to cooperate with academic institutions with a well-managed patent portfolio, allowing them to get access to unique technologies in their field of interest. Thus, it is imperative that an academic institution installs and executes a prosperous IPR strategy.

Foundation of spin-out companies

Another sustainable way of a technology transfer from an academic institution to the economy is via forming a spin-out company. Eventually, researchers who want to implement and exploit their own research can fund and run the company. However, next to the founding idea, the scientist must additionally have an entrepreneurial mindset and/or seek partners with business related skills. For boosting the chances of a

56 Ibid.

57 Increasing the financial contribution of inventors and their research group may have several benefits including a higher commitment on the part of the inventors and the R&D group to the patenting process and thus a higher likeliness that a notification of an invention results in a commercially relevant patent. Giving an individual inventor and the research group the option to pay part of the costs poses a novel approach but needs to be in accordance with national law and other institutional agreements. The prevailing practice remains that the PRO, an industry partner or a government supported patenting program bears the expenses in connection with the protection and commercialisation of Intellectual Property. (Cf. WIPO (2012) Model Intellectual Property Policy for Universities and Research Institutions §8.25.

58 Distribution of income from monetary exploitation of patented technologies varies from institution to institution. One typical model allocates 30 % of revenues to the inventor(s), 30 % for the research group and 40 % to the academic institution.

spin-out's success, "incubators" are emerging in many countries, providing entrepreneurial support. If the spin-out is successful, it brings innovative – eventually disruptive? – products onto the market, transforming basic research into real-world applications. It will generate profits in favour of its owners and licensors, create new jobs and again contribute to the social and economic wealth of a nation.

Conclusions and Recommendations

ALLEA

» Aware of the genuine mission of publicly funded research – namely the generation and early and wide dissemination of new research findings;

» Aware of the high priority of open access to such research findings;

» Aware of the importance which publicly funded research plays for the scientific and technological development and innovation in Europe;

» Aware that innovation is a pillar of a sound economy and thus a precondition for healthy science;

» Aware that not only the US legislation of the 1980s referred to above, but also the Chinese, the Japanese, and the Korean (Republic of) legislation, which followed suit, resulted in most remarkable patenting activities which served as a decisive vehicle to translate publicly funded research into innovative products and processes;

» Aware that the Chinese Academy of Sciences (CAS) has more than 2500 patent families in the area of artificial intelligence, among them the largest deep learning portfolio, with 235 patent families;

» Aware that Europe and its publicly funded research organisations which are in competition with their counterparts, e.g. in the US, China, Japan and the Republic of Korea, and elsewhere, despite the undertaken efforts, seemingly still underperform in comparison with their counterparts in translating their research findings into innovative products and processes.

ALLEA Recommends That

Independent of their size, research, human and financial resources, academic institutions in Europe should adopt a holistic approach to their IPR strategies. They should be set forth in clear and transparent rules providing for:

» Measures necessary for acquiring knowledge about IPRs and the awareness of the importance of IPRs for innovation on a macro- as well as micro-economic scale, for all researchers as well as for selected administrative personnel of the institution;

» The adoption, in line with the applicable law(s), of clear rules as regards the obligations of employees to report their research findings (invention disclosure), observe the publication policy of the institution, and co-operate in the prosecution of the resulting applications for patents and other IP rights;

» The adoption, in line with the applicable law(s), of clear rules as regards an adequate remuneration of employees in the case of commercialisation of their research findings, as well as clear rules on the sharing of such proceeds by the respective department(s) or institute(s);

» The adoption of measures for securing financial and human resources for establishing in-house structures, and/or external mechanisms for dealing with invention disclosures, filing and prosecution of IPRs, monitoring of the granted IPRs (necessary to detect possible infringements, etc.), commercialising of such rights either by licensing, assignment or spin-outs;

» The adoption, in line with applicable law(s), of clear rules on ownership in the IPRs resulting from cooperation with other academic and/or industrial partners;

» The adoption of clear rules as regards the handling of IPRs in case of spin-outs and their financing by external investors;

» In order to support such IPR strategies, the European legislator should envisage a legal framework similar to those adopted by, e.g., the US, China, Japan and the Republic of Korea;

» In particular, the European legislator should undertake all the necessary steps to finally introduce into the European patent law a rule on a general "grace period", which will, as it does in Australia, the US, Canada, Japan and in many other countries, enable early publication of research results without automatically giving up proprietary rights in the published findings;

» In order to incentivise translation of publicly funded research results into innovative products and processes protected by IPRs, the European legislator as well as the legislators of the Member States should seriously consider preferential tax treatment of the income generated from commercialisation of publicly funded research results;

» National, regional and local governments should support cooperation between academic institutions in the commercialisation of their research results. They should provide the necessary human and financial resources for optimising the cooperation of the existing TTOs of various institutions in order to achieve synergetic effects. This is of particular importance to enable smaller universities and research institutions with limited human and financial resources to benefit from intellectual property rights strategies implemented by stronger players in the field.

About the ALLEA Permanent Working Group Intellectual Property Rights

Intellectual property rights (IPRs), be it patents or copyrights, play an important role in academic activities and are fundamental for their outreach towards the public and their services to society. Without the appropriate protection of inventions and creations, incentives for researchers to focus on applied research and for scientific institutions to disseminate innovative ideas and practices are diminished. Technology and knowledge transfers from academia to other partners are now central in the eco-system comprising research organisations, public institutions and private actors, such as companies and NGOs.

To ensure that innovation flourishes and is financially supported in a competitive global environment, ALLEA closely follows those research policies, such as open access and open science, relying on an adequate delineation and use of IPRs. ALLEA maintains a continuous dialogue with EU policymakers, national and international authorities and other stakeholders to contribute with its expertise to this legal and policy framework in the interest of scientific progress. The ALLEA Permanent Working Group Intellectual Property Rights has been in existence since the 1990s and has prepared and issued reflections, declarations and recommendations on the most challenging topics of IPRs.

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Read more: https://allea.org/intellectual-property-rights/

About ALLEA

ALLEA is the European Federation of Academies of Sciences and Humanities, representing more than 50 academies from over 40 EU and non-EU countries. Since its foundation in 1994, ALLEA speaks out on behalf of its members on the European and international stages, promotes science as a global public good, and facilitates scientific collaboration across borders and disciplines.

Academies are self-governing bodies of distinguished scientists drawn from all fields of scholarly inquiry. They contain a unique human resource of intellectual excellence, experience and multidisciplinary knowledge dedicated to the advancement of science and scholarship in Europe and the world.

Jointly with its members, ALLEA seeks to improve the conditions for research, to provide the best independent and interdisciplinary science advice available, and to strengthen the role of science in society. In doing so, ALLEA channels the expertise of European academies for the benefit of the research community, decision-makers and the public. Outputs include science-based advice in response to societally relevant topics, as well as activities to encourage scientific cooperation, scientific reasoning and values through public engagement.

ALLEA is constituted as a non-for-profit association and remains fully independent from political, religious, commercial or ideological interests.

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