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Position Paper of the TransferAllianz

Faster and Smoother Spin-offs with Standardised Key Parameters

Recommendations from the TransferAllianz for the Medical Life Sciences Sector

Fast and simple spin-off processes are crucial to successful technology transfer from research into application. Scientific institutions therefore support spin-off founders in accordance with national funding legislation. They offer various services, from individual advice and tailored coaching to their own funding programmes for development projects and much more.

Negotiating spin-off terms individually with regard to licensing and possible participation – the current status quo at almost all German scientific institutions – involves high expenditure of time, money and personal effort for all stakeholders involved. This is mainly due to vague and divergent ideas about the appropriate participation of publicly financed scientific institutions in the possible economic success of spin-offs, as well as to often different levels of experience between technology transfer and founders.

There is no doubt that more favourable start-up conditions are required that preserve liquidity for spin-offs and their investors. TransferAllianz recommends taking a lead from internationally proven and recognized models that have been developed jointly by leading scientific institutions and investors. This guarantees international compatibility and safeguards the interests not only of the founders and investors but also of the scientific institutions, as well as ensuring that all stakeholders participate fairly and appropriately in the success of a spin-off. Particular emphasis should be placed on the recommendations of AUTM[1] and the industry-specific USIT guides[2] of TenU[3]. In Europe, Dutch and Austrian universities have already published standards that share a similar approach.

The USIT Guides describe best practice and methods for evaluating intellectual property (IP) and promoting technology transfer at universities and research institutes. They enable uniform standards and transparency when drafting investment conditions, are based on broad quantitative and qualitative data analyses, and provide an excellent basis from which universities, investors and founders can make technology transfer, and, in particular, the commercial exploitation of research results more efficient and successful.

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[1] Recommendations of the US technology transfer association AUTM for term sheets for the creation of university spin-offs: https://autm.net/surveys-and-tools/tools/term-sheet

[2] Two different USIT (University Spinout Investment Terms) guides for life science and software: https://ten-u.org/news/the-usit-guide

[3] TenU is an international consortium comprising the technology transfer offices of the University of Cambridge, Columbia University, the University of Edinburgh, Imperial College London, KU Leuven, the University of Manchester, MIT, the University of Oxford, Stanford University and UCL. TenU is funded by Research England and hosted by Cambridge Enterprise.

The main objectives of the USIT Guides for all stakeholders are:

• Standardisation of conditions: Defined terms and clear, consistent framework conditions for spin-offs, investors and scientific institutions avoid misunderstandings and facilitate and accelerate negotiations.

• Transparency and fairness: The use of uniform conditions creates transparency, ensures equal treatment of all spin-offs, and strengthens fairness in negotiations between universities, investors and founders.

• Fair participation of all stakeholders in the value chain.

• Support: Spin-off founders receive guidance and support in order to make informed decisions during negotiations (including with investors).

• Access to best practices: The USIT Guides contain best practices and recommendations based on experiences of successful technology transfer offices.

Key parameters of standard conditions for spin-offs in the medical life-sciences sector

Key parameters for spin-off conditions are always industry-specific – there is no 'one-size-fits-all' solution. TransferAllianz therefore recommends industry-specific approaches based on the USIT Guides. For this position paper, it has developed specific key parameters for conditions in the medical life-science sector. The focus is on IP-based spin-offs. In some cases, other components, such as access to infrastructure, also play a key role and must be included in the negotiation.

These key parameters define a binding framework for spin-off conditions that represents the best possible compromise between an inflexible, fixed standard and the need to consider product- or service-specific features that cannot be adequately addressed by predefined values.

The starting point is always a (usually exclusive) licence agreement for the use of the required intellectual property in a spin-off. The customary international practice is to combine a licence agreement with a minority equity position. Licence agreement and equity are to be regarded as corresponding components that form part of a package. The low licence conditions proposed here are to be seen in the context of the simultaneously proposed equity participation.

The research organisation implements the equity position either directly or indirectly (via a third party). If taking equity directly or indirectly is not possible for legal or structural reasons, virtual shares are an alternative. While an equity position causes co-ownership with extensive corresponding rights (e.g. to participation, speech and information), for which there are clear legal regulations, virtual shares (e.g. exit fee, phantom shares) represent a debt position that must be individually defined in separate contracts. Both, phantom stock and equity require professional investment management, particularly with regard to further financing rounds or an exit.

Key parameters for licensing IP to spin-offs

When using intellectual property, a standard and usually exclusive licence agreement with licence fees, e.g. in the form of milestone payments and royalties, is concluded. The amount of royalties is based, among other things, on the scope of the IP package (e.g. patents, scope of protection, unique position, geographical coverage, etc.), the investment required to reach the market, the degree of maturity of the technology (TRL), benchmarks, and regulatory requirements. In any case, all inventors benefit from the income from a licence agreement, including those without equity in the spin-off.

• The royalty rate shall be

- 1% to 4% for therapeutics (small molecules, gene and cell therapies, repurposed drugs, vaccines or similar) depending on the stage of development of the product,
- 0.5% to 1.5% for pure know-how licences,
- 3% to 6% for medical devices in risk Class IIa-III (including software as a medical device) and *in-vitro* diagnostics,
- 5% to 20% for medical devices in risk Class I, software and research tools, depending on the degree of maturity and service character.

• Milestone payments and royalties are agreed at common market rates but adjusted in line with the equity share, and a cash-preserving way forward for spin-offs and investors (‘back-loaded’), i.e. payments are only made when there is sufficient cash available.

• The spin-off bears patent costs from start and reimburses sunk patent costs of institutions, usually within a period of 2 years.

- In the case of universities, reimbursement of sunk patent costs plus employee invention compensation shall be due.4
- Where costs are too high, reimbursement of sunk costs can be adjusted.
- The responsibility for any patent litigation and defence lies with the spin-off.

• The institution receives an exemption for research and teaching.

• Where relevant and appropriate, anti-stacking clauses, combination product provisions, and a suitable option on future IP in the same field of technology or area of application will be included.

• Where relevant and suitable, an annual minimum licence fee (EUR 2,000 to 20,000 creditable against royalties) will be agreed to ensure that the IP will be diligently developed. The sub-licence fee shall range between 5% and 30%, depending on the state of development but can be significantly higher, when market conditions dictate this.

• The institution will not make representations and warranties for the IP beyond ownership.

[4] This is due on reimbursed patent costs, since the term ‘gross revenue’ in Section 42 of the German Employee Inventions Act is to be understood broadly, i.e. it includes all assets that accrue to the employer from the exploitation of the invention. Cf. ‘Genveränderungen’, LG DüDo, judgment of 18 January 2011 - 4b O7/10, para. 27 f.; OLG DüDo, 12 April 2012 - I-2 U 15/11; Federal Court of Justice, 05.02.2013 – X ZR 59/12, paras. 28-39. Pursuant to Section 42 ArbnErfG No. 4, the employee inventor compensation for universities is 30%. The total reimbursement thus amounts to at least 143%.

Key parameters for participation in spin-offs

Founders benefit from the professional support of the investment management team at the scientific institution. The investment management team should have the experience required to protect founders from common mistakes and can support founders' vis-à-vis investors. Further advantages of an equity position of the institution, in addition to harmonising interests, are an increase in the credibility/reputation of the spin-off, access to the network and infrastructure of the institution, and the realization of a back-loaded deal model.

The spin-off terms presented here are based on the internationally established models described above, but in some cases, these conditions went beyond the already spin-off friendly conditions of the current USIT Guides[5]:

• 10% to 15% dilutable equity in spin off (generally 10%, more e.g. in cases with a very strong and broad IP situation or extensive support by the institution),

• or, where suitable (e.g. in spin-offs that locate in the US): 5% non-dilutable stock up to a Round A-Financing or a company value (post-money) of EUR 10 million.

Individual solutions are required if the institution's IP share is weak, or the spin-off is based on know-how/IP prior to the employee joining the institution.

With its recommendations for the medical life-science sector, TransferAllianz has drawn on compatible, internationally established models. The specific recommendations proposed here for the medical life-science sector validate and clarify these models. Further industry-specific recommendations, for example based on the recently published USIT Software Guide, will follow.

[5] Level of participation of 10% to15% instead of 10& to 25% in the USIT Guides.

Glossary:

IP: Intellectual property (patents, copyrights, trademarks, know-how, software, material, data, etc.)

Anti-stacking clause: A provision that ensures that royalties from different licensors within a product do not cumulate excessively

Combination product clause: Regulates royalties for products that include several licensed active substances or are sold with other licensed components

Exit fee: Debt position that becomes due in the event of a company sale

Royalty: Payments made by the licensee to the licensor for the granting of a commercial right to use IP

Indirect equity: Equity in a company held through an external technology transfer partner

Dilution: Describes the reduction of an equity position through financing measures

Pre-money/post-money: Company valuation before a financing round (pre-money) or after (post-money) a financing round

Back-loaded deal model: Start-up-friendly approach in which the majority of the compensation for a licence (from the scientific institution to the spin-off) is deferred to a later point in time, for example after certain financing targets have been reached or an exit has been made, so that the spin-off and investors are not burdened by early cash-out to the licensor(s).

Reps & warranties: Representations and warranties regarding the legal and financial situation of the IP or technology licensed to the spin-off.

TransferAllianz e.V. is the German association for knowledge and technology transfer. It unites universities, universities of applied sciences, non-university research institutions, patent exploitation agencies and other transfer service providers in a growing nationwide network. Through its approximately 110 members, TransferAllianz has access to the experience and research results of over 250,000 scientists in public research. More than 1,000 new spin-offs are created in the member institutions every year, of which around 25% are IP-based spin-offs (2021 survey). The aim of the TA activities is to promote the transfer of knowledge and technology from science to industry and society in a structural and sustainable way, thereby strengthening Germany as a centre of innovation.