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Introduction

Due in part to the Bayh-Dole Act of 1980, which incentivized universities to commercialize their technology, the number of academic spinouts has grown in recent years. [1] This is particularly true in the life sciences space, where a number of spinouts from academic institutions are now notable industry players. [2] Spinout entities, sometimes called academic spinoffs or startups, originate from within a university or other academic institution, with the institution often taking a minority stake in the company. The "spun-out" entity's founders are typically employees (including faculty), postdocs, students, or alumni of the institution, and the company's most critical assets often include intellectual property (IP) owned by the institution and licensed via the institution's technology transfer office (TTO).

Partnering, acquiring, or otherwise contracting with a spinout presents unique considerations and risks given the spinout's ties to an institution. This article focuses on academic spinouts and the diligence and other issues to be mindful of when negotiating opposite such companies.

Common Issues and Considerations

Ownership of IP

A key consideration with academic spinouts is that the academic institution's IP policies may make the ownership of a spinout company's IP uncertain, as both the academic institution and the company may have ownership claims to the same IP. In particular, academic institutions may own IP related to the spinout's business if the institution's time, money, or resources were used in its development. This can occur, for example, if a graduate student conducts his or her own research—unrelated to any academic project—but uses specialized institution lab equipment to do so. Such scenarios may result in the academic institution owning the IP in a research project, creating issues of title for the startup. Left unresolved, title issues may undermine the startup's ability to practice, attract financing, or partner its technology. Even if resolved, title issues can disrupt diligence processes, adversely impacting relationships with key stakeholders and increasing costs.

It is thus important to understand who developed the company's IP, under what circumstances, and how this affects ownership vis-à-vis the academic institution's IP policies. Under their policies, academic institutions typically own IP created by employees, faculty, postdoctoral fellows, and students (i) in the scope and course of their employment—if an employee; (ii) with significant use of institution research facilities or resources; (iii) using financial resources received by or through the institution (e.g., gifts, grants, funds, or contracts); or (iv) participating in research projects or certain educational programs at the institution. The types of IP covered under the policies typically include potentially patentable inventions, discoveries, developments, and methods,



as well as unpatented research materials (e.g., cell lines, organisms, proteins, or DNA/RNA). Copyrights, particularly for computer software, are also included, and may be covered under a separate, copyright-specific policy.

Some IP policies state that the institution has discretion to enter into agreements with third parties that include exceptions to the policies. If an exemption does not apply, it may be worth asking for a release of rights or assignment of ownership of the IP back to the inventor. For example, under their IP policies, Harvard may elect to release its rights in sponsored computer software to the applicable creators under certain circumstances, and Stanford may agree to release all interests in an invention if it decides not to file a patent application for a disclosed invention. Policies also include many exemptions for copyrights in scholarly and artistic works (e.g., student theses, faculty course materials, journal articles, or paintings) to the extent they are not sponsored or commissioned by the institution.

Licensing Agreement

If, based on diligence, it appears a company's IP may be partially or fully owned by an academic institution, then potential collaborators should confirm that the company has a license in place to use the IP. While in some cases the institution may assign its IP rights to the startup, more commonly the institution-owned IP is licensed to the company, either with or without exclusivity. Therefore, the license agreement is a critical document from a diligence perspective. It is important to review a copy of the agreement to confirm that it is sufficient for the startup's needs and to identify any material restrictions or obligations on the startup. In particular: [5]

- Licensed Technology: Confirm that the license grant includes all technology (e.g., inventions covered by patents or patent applications) and related materials or technical information (i.e., know-how) needed for the startup's business.
- License Scopel Exclusivity: Understand whether the license grant to the startup is exclusive or non-exclusive. Academic license agreements may include both an exclusive license under licensed patents and a nonexclusive license under licensed know-how. If tangible research materials are licensed, universities will sometimes grant an exclusive license, though exclusive know-how licenses are less common. The license may also be limited to a particular field or territory, and the extent to which this appropriately matches the startup's operations should be considered.
- Sublicensability: Confirm whether any sublicense granted by the spinout under the IP would be permitted or would require the institution's prior consent. Also look out for mandatory sublicensing requirements, which are not uncommon in academic licensing and may interfere with a startup's ability to solely determine commercialization of the IP. Mandatory sublicensing serves the institution's nonprofit mission to make its technology more widely available for public benefit, for example, by requiring the licensee to sublicense an invention to a third party to fill an unmet market need (e.g., an underserved population or indication).
- Sublicensing Revenue Share: Review any sublicensing revenue terms, which require the licensee to share with the institution a portion of revenue that it receives from sublicensing the IP. Such provisions can hamper the startup's ability to defray IP development costs through strategic sublicensing arrangements. Moreover, depending on the breadth of the definition of "sublicense revenue," the institution may effectively be receiving a share of revenue generated from the sublicensing of the startup's own (i.e., non-institution-owned) IP.
- Termination: Review termination provisions for any atypical termination rights the institution may have. Also check the terms that apply to any sublicenses in existence at the time of termination, for example to confirm that in the event the agreement is terminated, any sublicenses granted to a third party remain in effect as a direct license from the academic institution.
- Diligence: Confirm that the startup is meeting its diligence and related reporting requirements; failure
 to comply with diligence requirements can potentially result in the institution terminating the license or
 converting an exclusive license to a non-exclusive one. Compared to commercial licensors, academic



licensors often set firm diligence milestones on the licensee company because of their interest in expanding public access to their technologies and protecting against the risk of "shelving" institution technology.

- Government Rights: If the licensed inventions resulted from federal funding, the licensor is required by statute to reserve rights for the U.S. government. Any exclusive licensee must also comply with certain requirements for substantial manufacture in the U.S.
- Institution Investment Rights: Confirm whether the institution has any right to further invest in the startup
 company. For example, academic licenses may include a right for the institution to participate in future
 investment rounds. Universities may also have an equity stake in the company and include anti-dilution
 provisions in the agreement to protect their ownership percentage as the startup raises funds.

Compliance Obligations

Lastly, it is important to confirm that the spinout and institution-affiliated individuals at the spinout are in compliance with relevant institution policies.

Formation

Depending on the circumstances, it may be worth confirming that the company was properly established, since formation of a startup may require approval of the institution's TTO. MIT, for example, states that the choice to establish a startup is a joint decision made by the Technology Licensing Office and the academic inventors, ^[6] and Stanford requires its personnel to obtain approval before forming new entities that license Stanford IP or that relate to the personnel's institution responsibilities. ^[7] It can thus be useful to inquire about what discussions the academic entrepreneurs have had with their TTO regarding formation of the company, including discussions around ownership and protection of the company's technology.

Conflicts of Interest

While forming a spinout entity creates a degree of separation from the academic institution, issues can still arise due to various conflicts of interest stemming from a faculty member or student's involvement with the company. It is thus important to understand how any institution employees, faculty, or students at the company keep their activities separate from the institution and its resources, in compliance with institution policy. Universities are concerned that any overlap between the academic's involvement with the startup and their work at the institution may compromise the direction, conduct, or reporting of their academic research—such as by withholding research results from the institution or only providing results on a preferential basis. Academic institutions are also concerned that institutional resources may be used for personal gain or for the benefit of the startup.

Because of this, academic institutions' conflict of interest policies can have strict requirements. For example, Stanford requires inventors to disclose any financial interest (e.g., equity, options to obtain equity, or consulting fees) in a startup to the Dean's office, ^[8] and MIT requires that faculty annually disclose their outside professional activities to their department head. ^[9] Additionally, Stanford limits faculty to consulting for a startup to a maximum of 13 days per quarter, and prevents them from serving in managerial roles (e.g., CEO or Chief Scientific Officer). ^[10] Moreover, Stanford personnel (i.e., faculty, staff, and postdocs) must obtain approval before becoming affiliated with outside entities where they undertake activities that are similar to their responsibilities at Stanford. ^[11] It is thus important to review the institution's conflict of interest policies, identify any potential conflicts that apply, and confirm whether they are appropriately disclosed or managed.

Conclusion

Many successful companies began as academic spinouts. By undertaking diligence that includes areas that may disproportionately occur in academic spinouts, a potential collaborator or acquirer can maximize the



opportunities the business relationship offers, while identifying and mitigating certain risks. While this article raises common issues to be aware of, each transaction with a spinout will have different concerns depending on the nature of the parties and the relationship at hand.

Footnotes

- https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today; https://blog.victech.com/university-technology-licensing-part-2-assessing-the-opportunities-and-negotiating-licenses ("[T]he number of startups created based on university-licensed technologies has more than tripled in the last 20 years").
- https://blog.innovation.pitt.edu/university-startup-investment-is-booming; https://www.linkedin.com/pulse/future-business-university-startups-rise-tradetower-infizic/
- 3 <u>https://otd.harvard.edu/uploads/Files/IP_Policy_6-11-2019_%28FINAL%29.pdf</u>, page 7.
- 4 <u>https://doresearch.stanford.edu/policies/research-policy-handbook/intellectual-property/inventions-patents-and-licensing</u>, Section 2(D). See also <u>https://otd.harvard.edu/uploads/Files/IP_Policy_6-11-2019_%28FINAL_%29.pdf</u>, Section I. G.
- 5 <u>https://www.ropesgray.com/-/media/files/articles/2023/01/20230112_practical_law/20230112_practical_law.pdf</u>.
- 6 https://web.mit.edu/tlo/documents/MIT-TLO-inventors-guide.pdf, page 22.
- 7 <u>https://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/faculty-policy-conflict-commitment-and-interest</u>, Section VI (A).
- https://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/faculty-policy-conflict-commitment-and-interest/, Section VI (B); https://adminguide.stanford.edu/chapters/guiding-policies-and-principles/conflict-interest/staff-policy-conflict-commitment-and, Section 2(C).
- 9 <u>https://policies.mit.edu/policies-procedures/40-faculty-rights-and-responsibilities/45-outside-professional-activities</u>, Section 4.5.
- 10 https://otl.stanford.edu/researchers/startups/best-practices-startups-stanford, see "Inventor Responsibilities."
- 11 <u>https://doresearch.stanford.edu/policies/research-policy-handbook/conflicts-commitment-and-interest/faculty-policy-conflict-commitment-and-interest</u>, Section VI (A).