

ultimate agreement, such as a royalty rate range for a license agreement. Although there is usually no penalty if the planned relationship never happens, MOUs may increase the likelihood a binding agreement will eventually be successfully negotiated and executed.

**Option agreements.** Some potential licensees may want to closely evaluate the technology or business opportunity before committing to a full license, while others may want to seek investment while the license agreement is being negotiated. In these cases, the potential licensee may find executing an option agreement advantageous. Option agreements are essentially contractual promises under which the IP's owner promises the company an exclusive, time-limited opportunity to negotiate a license to its IP (the option). During the term of the option, which can range from as short as a month or two to a year or more, the potential licensee no longer has to worry that the technology will unexpectedly be licensed to someone else. An option's terms can vary widely, from little more than a promise to negotiate to a detailed set of financial and non-financial terms and conditions, with the former taking much less time and effort to put into place.

**License agreements.** Putting a license agreement in place between a company (the licensee) and your research institution (the licensor) involves negotiating terms and conditions under which the company will be permitted to commercialize the licensed IP. Under a license, the licensee typically obtains the rights necessary to commercialize the IP in return for financial consideration and performance commitments to your institution. While the exact terms will vary according to the specific technology involved and the license's scope, license agreements tend to share a number of core elements: (i) an exclusive or nonexclusive grant of rights to practice specific IP in specific sectors (e.g., territory, field of use) for a specific amount of time (the term); (ii) appropriate financial considerations for such rights (upfront license fee, royalty on sales, milestone

achievement payments); (iii) legalese, including clearly expressed representations and warranties (what each party attests to or guarantees which, for the research institution, is typically very little), a division of liabilities between the parties (non-profit institutions tend to absolve themselves of any liability to the licensee and require the licensee to indemnify the institution against any third party lawsuits stemming from the license by paying all legal costs); (iv) restrictions on use of names; (v) performance obligations and milestones that must be met if the licensee is to keep the license (diligence obligations); (vi) for patentable inventions, terms specifying who manages and pays for the patents; and (vii) for US-government-funded inventions, an explicit statement of the obligations of the licensee to the government under the Bayh–Dole Act.

TTOs often try to license platform technologies and research tools (such as antibodies, animal models and cell lines) non-exclusively to ensure broad public benefit. Technologies with narrower applications, such as, therapeutic compounds, those requiring significant investment to translate into products and those with startup potential, are generally licensed exclusively. To allow for maximum commercial exploitation, exclusive licenses may be restricted to specific market segments or territories, allowing multiple companies to obtain exclusive licenses to commercialize the same technology in different niches. Licenses for certain tangible IP may involve the transfer of materials (biological materials such as antibodies and cell lines, tissue samples from specific

patient groups and detailed databases). In these cases, the license agreement may double as an MTA.

License agreements are complicated<sup>1</sup>. It is the TTO's responsibility to ensure not only that the final agreement shields you and the institution from liability and protects your interests, but also that there are no loopholes in the agreement the licensee can exploit to avoid making the payments due under the license, especially if the company's efforts are very successful, and large amounts of money are at stake.

### Firm foundations

The people negotiating agreements on your behalf and for your institution are skilled at creating a firm legal foundation for successful research and/or subsequent commercial relationships. But your assistance can help make sure each agreement achieves the desired goal, such as, for example, setting up a smoothly operating research relationship, quickly obtaining a desired material or enabling a startup company to more easily raise money, without creating any unnecessary impediments to your success. And by understanding the agreements needed in various situations, as outlined in this article and **Figure 1**, you will be better able to help your institutional representatives craft the best agreement possible.

### COMPETING FINANCIAL INTERESTS

The authors declare no competing financial interests.

1. Chitale, S., Lawler, C. & Macfarlane, S. *Nat. Biotechnol.* **34**, 1222–1225 (2016).

## PODCAST

### First rounders: Jeffrey Leiden

Jeff Leiden is chairman, president and CEO of Vertex Pharmaceuticals. His conversation with *Nature Biotechnology* covers rebuilding Vertex toward cystic fibrosis, competing for talent in the innovation economy and dropping out of high school to enter college early. <http://www.nature.com/nbt/podcast/index.html>.

