Business Partnerships in Agriculture and Biotechnology that Advance Early-State Technology

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ABSTRACT

Given the expertise of large agricultural companies with respect to product development from cutting-edge research, these companies often choose to in-license technologies from small biotechnology companies and universities rather than relying solely on in-house efforts. This chapter provides an overview of the interest of large industry players in sourcing early-stage technologies from companies, how best to communicate those opportunities to companies, and what to expect in terms of valuing the technology and structuring a licensing deal. Large companies are generally interested in creating new products or new technologies that are commercially viable and that help establish sustainable agricultural economies. But, in addition, they generally support providing products and technologies that bolster subsistence farming and humanitarian efforts, while recognizing the need to protect the company's intellectual property against unauthorized uses for commercial or other unintended purposes.

1. WHY LARGE COMPANIES LICENSE TECHNOLOGY

Not unlike most other industries, large companies in agriculture excel in the product development portion of research and development (R&D). Nevertheless, they have come to recognize that a large share of the innovative, early-stage, cuttingedge research in agriculture takes place at universities and smaller companies. Large companies have invested heavily in the infrastructure needed to develop, register, and bring products to market. While product development requires significant resources and funds, such investment is economically feasible because it has inherently less risk than investment in early-stage research. Partnerships and collaborations with other entities allow large organizations to diversify away the higher risk associated with earlystage research by creating the opportunity to access a much larger portfolio of technologies developed by thousands of different entities, as opposed to relying solely on the large organization's own internal research programs. Smaller companies and universities can focus on cutting-edge research and discovering new solutions, without carrying the burden of investing resources, and instead can realize value from their discoveries through licensing and/ or partnering with larger companies for subsequent product development and commercialization. This model has been adopted by the pharmaceutical industry: in its quest to discover blockbuster drugs, most large pharmaceutical companies have chosen to in-license technologies from small biotechnology companies and universities rather than relying on in-house research alone.

2. THE AGRICULTURAL INDUSTRY

Although the agricultural and pharmaceutical industries have come to share the model of inlicensing new early-stage technologies as opposed to investing internally in higher-risk research, a number of fundamental differences with regard

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to the model exist between the two industries. These differences are reflected in how the pharmaceutical and agricultural companies tend to structure the relationships and agreements with their technology partners.

The length of time required to develop seed products is considerable. When using classical breeding approaches, developing a conventional seed product takes a minimum of five years, on average. When transgenic traits are involved, the time needed to develop and commercialize a new seed product, including the time needed to obtain regulatory approvals in multiple countries for the import, export and cultivation of the crop, can be seven to ten years.

There are additional reasons for the lengthy development time lines, including limited planting times, long growing cycles, and rigorous multilocational testing for efficacy and environmental impacts. From an investment perspective, an early-stage–genetic-trait technology may not begin to return a profit until ten years from the initial discovery, if it ever does.

The cost of bringing an agricultural product to market can be less than a pharmaceutical product, and the per-unit value of an agricultural product is also far less. Additionally, in the agricultural arena there are only a few major crops of interest, and within those crops a relatively small number of higher-value agronomic traits-for example, drought, insect, disease, and herbicide tolerance as well as a number of quality traits-that can justify the investments needed to develop a transgenic crop solution. This is different from the situation in the pharmaceutical industry where there are many different therapeutic areas companies can target. It should be no surprise that the few large agricultural companies investing in the development of early-stage technologies have significantly overlapping interests, making the industry extremely competitive, with a strong focus on protecting IP (intellectual property) rights. As evidence, over the last decade there has been significant consolidation, and today there remains only a handful of major competitors investing in new technologies for the agricultural industry.

Similar to companies in the pharmaceutical industry, agricultural companies vigorously protect against competitors and do so through various means including patent protection, plant variety protection, trade secrets, and trademarks. Also, unlike most small companies, which have only a regional focus, large companies look to market their products worldwide, including in developing and emerging markets.

Companies are also partnering in new ways, with foundations and public sector institutions, to support basic research, local markets, and subsistence farming in developing countries. In addition to the more immediate humanitarian and capacity-building benefits, the ultimate objective of these partnerships is to develop new, profitable and sustainable agricultural markets for local farmers and growers, ensuring a reliable and safe food supply in those countries. Companies, including Syngenta, have provided strong support and donated proprietary technologies through a number of foundations, including the Syngenta Foundation for Sustainable Agriculture. Companies are generally willing to offer their proprietary products and technologies in support of subsistence farming and humanitarian efforts, while recognizing the need to protect their intellectual property against unauthorized uses, such as for commercial or unintended purposes. This good will is often simpler to extend to places where commercial opportunities are limited.

3. MARKETING NEW TECHNOLOGIES TO LARGE COMPANIES

In contacting a company, there are generally two approaches: (1) contact a licensing or business-development individual or (2) contact a company's research organization. With respect to the first approach, it is possible to develop relationships with licensing and business-development professionals by being active in organizations, such as the Association of University Technology Managers (AUTM), Biotechnology Industry Organization (BIO), and Licensing Executives Society (LES). This way, relationships can be easily established through networking and through these contacts professionals can gain an understanding of a potential partner's interests and how well matched those interests are to a subject technology that one may be hoping to out-license. Companies have a tendency to be more responsive to people they know and with whom they have shared experiences. Also, companies are able to be more responsive when they are provided information that seeks to target their needs and interests. If no personal contact inside the company has been established, a promoter can at least visit a company's Web site and review the available information on that company's current products and research interests. Targeting specific technologies to specific companies that are likely to take an interest in the technologies usually has a much greater impact than does using mass e-mails to describe multiple technologies to potential partners. A technology that may be of interest to a company can be overlooked in a long list. Also, having an up-to-date, easyto-navigate Web site with technologies displayed allows a company to see, on their own time, what is of interest.

When sending information to a company's licensing department, it is important to note that often such information is reviewed quickly and, only if it has some quality or aspect that fits specifically with the needs and strategic interests of the company, does it gain further review by personnel who may be able to gauge the relevance and value of the technology. Thus, it is important to include clear information on the potential uses and commercial value of the technology. Without this, depending on how quickly the information is read, something of a highly technical nature may end up being overlooked.

The second method for approaching a company is on a scientist-to-scientist basis. This typically provides a more direct route into a company, because scientists (especially those used to operating in a commercial environment) are usually uniquely situated to see the fit of a technology and determine whether it provides a solution to a real business need. Companies rely, among other things, on their researchers to scout technologies, in their respective areas of expertise, that could result in new products that further the company's business objectives.

4. WHAT COMPANIES ARE LOOKING FOR

Agricultural companies look to in-license technologies that have commercial applications, resulting in better products or more efficient methods of producing existing products. Ultimately, a technology will be reviewed in terms of its financial impact. Many technologies are interesting from a scientific point of view but do not have clear commercial applications. Licensors can make their technologies more attractive to agricultural companies by focusing on the potential commercial relevance of the technology. The commercial applications must also be financially feasible from a product development and competitive perspective.

Ultimately, every technology needs a champion within the target company, someone who has identified and believes in the scientific and commercial relevance of the technology. Champions are usually the very scientists who will ultimately develop the technology for market. Champions on both sides of a deal are critical if the deal is to be successful. Too many times, technology is in-licensed and sits on the shelf or is applied inappropriately because champions were absent or were under-resourced. Part of the due diligence for in-licensing any technology should be to ensure that the project is resourced sufficiently and that champions are identified and are able to make the project move in accordance with agreed-upon timelines.

4.1 *Risks of technology*

Most technologies from universities or small companies are at an early stage and so, by nature, carry significant risk from a product development perspective. Licensors need to recognize the significant time, resources, and money required to move a project through development to a successful launch. Costs include R&D expenditures, IP and patent costs, regulatory-approval costs, and production and marketing costs. All of these need to be taken into account when allocating the value associated with bringing the technology to market. Later-stage technology (such as one that has already been proven in a relevant crop) would of course have a higher value. How data is generated to prove a technology also needs consideration. Studies conducted in a greenhouse or in non-elite germplasm do not always translate well into the field where the product may be exposed to the full range of environmental and other effects. Many times, a company will want to evaluate a technology over the course of two or three years in order to understand how it works, across multiple environments outside of the laboratory or greenhouse environment, before agreeing to negotiate final commercial terms. Because of the risk associated with technology, large companies often prefer to start with a research or evaluation license, with an option for a commercial license, building in key terms to the option that ensure that commercializing the product, if field trials are successful, will be economically feasible.

4.2 *Type of technology*

Different types of technologies have different applications and so have different values associated with them. An agricultural technology can generally be classified in one of two ways: (1) as an enabling technology that helps or enables a product to be created (for example, gene promoters that drive the expression of proteins or tools that enable or enhance the ability to transform a particular crop) or (2) as a technology that is itself a product or that causes a seed product to contain a characteristic or trait that provides a benefit to the grower, the manufacturer, or an end-user of the product and for which the seed company can derive additional value.

Enabling technologies are helpful for bringing products to market, but in many cases such technologies are only alternatives or improvements on other methods or technologies that accomplish similar tasks. Because a number of substitutes may exist for an enabling technology, they are usually of less value than technologies that embody products. Accordingly, large agricultural companies are likely only interested in a nonexclusive license for enabling technologies, allowing freedom to operate with the technology. The companies are likely hesitant to pay running royalties, preferring instead up-front fees, annual fees, or milestone payments. It should be noted that while enabling technologies often are used across a number of projects, the majority of these technologies and projects will not progress to market.

Product technologies, on the other hand, are those that are brought to market. For this category of technologies, agricultural companies are often interested in exclusive rights in order to obtain a strategic advantage in the marketplace. Because such technology directly translates to sales and revenues, it has an inherently higher value.

5. TECHNOLOGY VALUATION

Valuing technologies is a difficult and complex task because of all the uncertainties in getting a technology to market. Often, there is a disparity in the value attributed to a technology by the licensor and by the licensee. This is particularly true in the agricultural industry due to an asymmetry of information: one company having access to more complete information than the other for determining the cost of bringing a product to market and the potential revenue sales of the end-products would bring. In the agricultural industry there are not always comparable deals with which to compare prospective products, especially as companies embark on new market areas that involve traits outside of established traits, such as insect resistance and herbicide tolerance. Additionally, in order to sell certain traits in the market, the traits must be combined with other input or agronomic traits to which the licensor has not contributed. Value will also be influenced by the presence of competitive traits in the market. This adds additional complexity to the valuecapture discussion.

The value of an early-stage technology needs to be discounted based on time to market, the time value of money, technical risk, and the risk associated with obtaining regulatory approvals. Value also must account for the amount of resources invested in commercialization. Many licensors discount or overlook these factors because they are deemed to be out of their control, but the risks remain and should influence the valuesharing discussion. Other factors that effect value sharing include whether additional licenses are needed for commercialization for ensuring that a product can be brought to market with maximum freedom to operate. If other licenses are needed to bring a technology to market, the issue of "royalty stacking" comes into play, whereby multiple royalties on a product can exceed the profit margin on the product, making it impractical to commercialize.

Traditional royalties based on net sales rarely work in agricultural licensing deals because of the issues associated with royalty stacking and the fact that many technologies—from early-stage enabling technologies to trait-related technologies—may be employed in developing the final product. Companies understandably try to avoid paying royalties to licensors on the value contributed by other technologies, whether in-licensed or developed by the company. For the same reasons, large companies also try to avoid paying product-based royalties on enabling technology because the enabling technology by itself may not drive additional revenues.

In most cases, companies can agree to a royalty based upon the value that a particular technology adds in the marketplace. Models such as a percentage of trait-related revenue or fixed-fees per unit are available to licensors.

6. TERMS OF THE LICENSE

When companies choose to in-license technologies, especially in the agricultural and biotechnology industries, the parties need to consider several issues that must be specified in the license:

• payments: Fees for a deal need to be balanced in accordance with the use and risk profile associated with a technology. In some instances, this balance will be achieved over the life of the license during which payments through license fees, milestones, and royalties can be paid on net sales. In other instances, for example, involving a nonexclusive license to enabling technology, this may be a one-time payment. For product technologies, payments are traditionally spread out over the life of the license, reflective of the risk factors and the development timeline, so that when there is heavy R&D spending, license costs are not excessive, and do not become disincentives, but do

reflect the time frame over which revenue is actually obtained from the product.

It is important for a licensor to maintain flexibility with regard to how payments are structured, in order to meet the needs of agricultural companies, especially as new markets are explored. Many times small start-up companies are seeking to exit within three to five years from the time they are established, usually because of the expectations of the venture-capital-investor community. This can create tension in getting a deal done because of the expectation to be paid out, while there is still significant development and product risk remaining, long before the company begins to see revenue from the investments it has made and is making.

- exclusivity: Every company would relish being able to exclude others from obtaining a strategic advantage in the market, but sometimes obtaining exclusivity may be neither necessary nor cost effective. Many factors will effect the need or desire for exclusivity, including financial implications, the opportunity to block or license competitors, and the opportunity to create a competitive position in the marketplace.
- field of use: For licenses where the licensor intends to carve out exclusivity in a field of use, the licensor will want to ensure that fields don't overlap and that fields are divided in such a way as to not destroy value for other potential licensees. Agricultural companies will many times consider specific fields of use (for example, specified crops, or specific traits of interest) as a way to obtain exclusivity in a particular market.
- diligence: With regard to diligence provisions, the parties need to acknowledge that these provisions and timelines should be reasonable but flexible. This is especially true for certain agricultural technologies, for example, seed products, due to the uncertainty and risks associated with it, including technical, field and environmental risks, and regulatory science-related risks. Agricultural companies recognize the desire

of the licensor in having diligence provisions, but overly restrictive provisions can put a license at risk. Most companies welcome reasonable diligence requirements as they ensure that a technology will be evaluated and developed in a commercially reasonable timeframe. The role of champions to encourage open and ongoing communication between the licensor and the licensee with regard to diligence provisions, making adjustments as necessary so that the technology develops to the benefit of both parties.

- publication: Licensors need to work with the large agricultural companies to ensure that publications made after the license term begins (especially for exclusive licenses) do not interfere with the opportunity to capture intellectual property and, therefore, diminish the value of the technology. Close cooperation should ensure that the right to publish is not compromised while ensuring that appropriate protections are obtained before making the publication. Mechanisms for handling publication are fairly well established between public sector institutions and industry.
- improvements: In order for a technology to reach its full potential, it will be in the interest of both parties to allow agricultural companies to access improvements to the underlying technology.
- timelines: It is important for the licensor and the licensee to be responsive when negotiating a license agreement. In instances where delays are expected, these should be communicated promptly as the business may be relying on a particular timeline to drive product development. Excessive delays can result in a loss of interest and/or a loss of funds.

 after the deal: Transfer of know-how or materials as provided for in the license needs to be carried out in a timely manner. The agreement should define whom the appropriate contacts are to ensure that the potential of the technology can be fully realized, especially in those instances where the company is evaluating the technology and questions may arise. Often times continued access to technology experts is expected and should be welcomed in order to realize the full benefit of the license.

7. CONCLUSION

Large agricultural companies are interested in accessing and utilizing technology that helps them gain competitive advantages in the marketplace. Universities and research institutes can, through licensing agreements, partner with these companies, which have the resources, as well as the product development and marketing capabilities to translate early-stage technologies into products that bring benefit to consumers. Furthermore, such technology partnerships can result in products or new technologies that can provide, not only humanitarian benefits in the developing world, but also can help establish sustainable agricultural economies in all countries.

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