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Intellectual property: The driving force for growth and funding

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Abstract For most 'bio-entrepreneurs' the science is the easy part – leveraging that science to create a viable business becomes the real challenge. This paper provides an overview for utilising intellectual property to strengthen a business' attributes, thereby increasing the firm's likelihood of attracting funding and attaining its objectives.

Keywords: business plan, venture capital, strategy, intellectual property, start-up

Introduction

Over the past few years, there has been an increased interest in the formation and financing of biotechnology companies. The vast majority of these companies have their foundation in recent industry innovations – genomics, proteomics, genetic engineering and high-throughput compound screening, among others. Companies have been formed to take advantage of the economic promise of these innovations, with financial investors and big drug companies funding the activities of biotechnology ventures in the expectation of participating in their eventual market value. Most of these ventures have competitors – other firms targeting the same market using a different scientific approach or even the same approach. Those ventures that emerge as the leaders in their market segments not only have some scientific advantage, they also have business advantages, such as strong management, strategic partners, high regard in the scientific community, viable strategic plan and adequate financing. For many of these leaders, their business attributes resulted from the strength of their

intellectual property and ability to take advantage of this know-how in non-research applications.

Intellectual property is defined as the patents, trade marks, copyrights and trade secrets owned by a corporation or an individual. It is an asset legally protected on a national basis. As a protected asset, intellectual property has an economic value, similar to real and personal property. It can be sold, licensed, exchanged or gifted. Its owners can prevent its unauthorised use or sale.

The fundamental value of a biotechnology company's intellectual property is that it grants exclusivity to that company to that technology and the resulting products. The company can further research and develop products without the worry that its technology will be 'stolen' or infringed upon by another firm, including those with greater resources. This protection increases the value of the technology and the biotechnology company. It also compels a larger firm – such as a major pharmaceutical company – to partner with or invest in the biotechnology company to legally gain access to the technology and resulting products.

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Intellectual property alone is insufficient to attract investors or build a viable company. The company with the greatest prospects for funding and growth is one that has strong business attributes, as well as technology strengths. Inasmuch as most biotechnology companies are initially formed around their technology, building the business foundation usually follows the formation of the technology foundation. Companies can take advantage of their intellectual property to strengthen those business facets critical to success. Figure 1 illustrates the way in which intellectual property can have an impact on virtually all aspects of the business.

An overview of the benefits to be garnered by leveraging intellectual property within each of these components is now given.

Revenues

Advancing science to the point of commercialisation, especially the development of a new drug, can cost hundreds of millions of dollars and take upwards of 15 years. While the cost of this research and development is financed largely through outside sources, a portion of these costs, as well as costs of operating the business, need to be defrayed by generating revenues. Demonstrating the ability to use the technology, even in a greatly reduced

format, to produce revenues adds to the validity of the science and its longer-term commercial potential. This increases the appeal of the venture to potential investors in addition to endorsing the viability of the venture.

Biotechnology companies have found various ways to use their intellectual property for near-term revenue generating, including fee-for-service research, licensing of all or parts of the technology, sales of products subject to no or minimal regulatory approval and distribution of the key drug in overseas markets that have less extensive regulatory requirements than the USA and Europe. Examples of actual ventures that have benefited from each of these approaches follow:

- **Fee-for-service research:** a company that devised a proprietary high-throughput screening methodology, which it uses to identify promising compounds for central nervous system diseases, offers access to its methodology to other firms for testing their own compound libraries. This company's long-term 'hit' is the drugs developed for its own account. In the meantime, the company is generating fees for its screening services. It also has agreements to share in the revenues of some of its clients from drug sales resulting from compounds screened using the company's services.

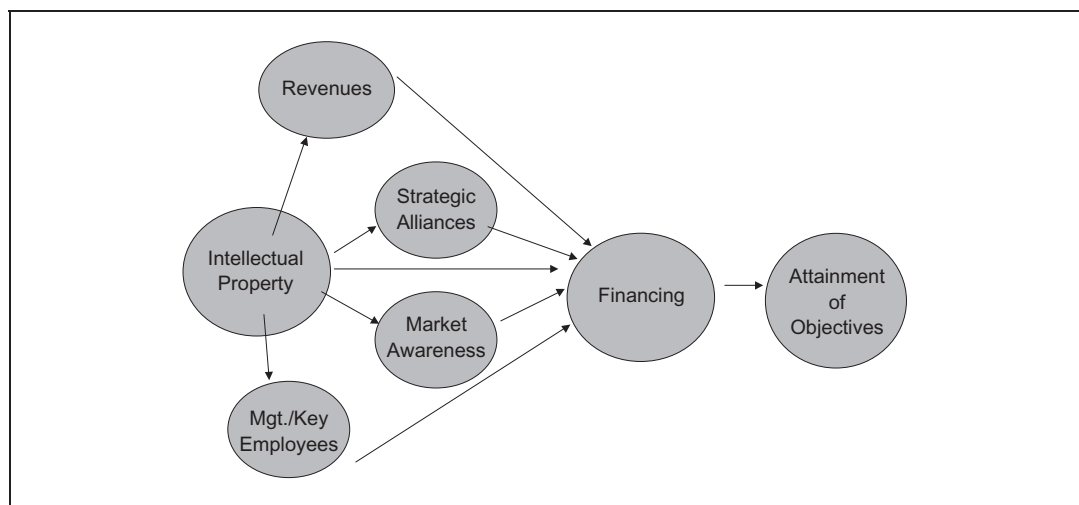


Fig. 1 The impact of intellectual property on business

- **Licensing of technology:** a venture has developed its own strain of knockout mice, which it is using in its own targeted research endeavours. Demand by other biotechnology firms for mice with this specific gene knocked out is strong and the company licenses its mice for a fee. In the meantime, it continues its own activities to develop one or more drugs.
- **Sales of less regulated products:** a company is working on the development of a drug for the treatment of a gastrointestinal disorder. It utilises its science to create a line of diagnostic products for identification of the same and related disorders. Being non-invasive, these products are able to reach market more quickly and at a substantially lower cost than the treatments, which are subject to the extensive regulatory process in the USA and Europe. The company enters into an agreement with a major pharmaceutical firm to have that firm market the diagnostic. This generates revenues, creates awareness and provides the company with a partner for the longer-range treatment product, when it receives pre-marketing regulatory approval.
- **Product sales in overseas markets:** a company has developed a drug, which is entering Phase III clinical trials in the USA. It enters into an agreement with a distributor in India to sell the drug in that market, which has less stringent regulatory requirements. This generates revenues, as well as providing outcome information on the drug.

The optimal near-term revenue model depends on the venture, its intellectual property and the extent to which the science has been developed. A successful firm, however, will balance near-term and long-term revenue objectives and use its intellectual property to achieve both.

Strategic alliances

Another source of revenues for biotechnology ventures is development contracts with established pharmaceutical

or biotechnology firms. These contracts are based on the perceived long-term economic value of the venture's intellectual property to the strategic partner. This is determined by the potential partner assessing the size of the market for which the drug is intended, the probable price it can charge for the drug, the cost of producing and delivering the drug to a representative share of that market, among other considerations. The resulting forecast profits need to be consistent with the drug company's return on investment criteria for an alliance to be formed. If an alliance is formed, the drug company typically provides the venture with a stream of payments in accordance with predetermined milestones or other benchmarks. These payments can be a significant contributor to revenue and cash flow. In addition to being a major source of funding, strategic alliances offer the following benefits:

- **Validates the science:** big pharmaceutical companies typically spend considerable time and expense validating a venture's intellectual property. Therefore, an agreement with one or more of these firms corroborates the science and its potential economic value. This serves to increase the appeal of the venture to the investment and scientific communities.
- **Facilitates funding:** venture capitalists, investment bankers and individual investors value strategic partnerships greatly. This facilitates raising capital to fund the financial shortfall, as well as increases the valuation at which the capital is obtained.
- **Covers the high cost of the regulatory process:** strategic alliances commonly provide for the partner to finance the development of the venture's technology until it leads to a marketable drug, device or other 'blockbuster' product. This typically includes funding all or most of the cost of clinical trials related to securing pre-marketing regulatory approval. Such arrangements ease the venture's financial burden, as well as enable management to focus its time on progressing research and development

and growing the company rather than on capital raising.

- **Provides distribution and marketing of the drug:** the typical partnership gives the pharmaceutical company partner the marketing rights to the drug whose development it funded and the venture a participation in the resulting revenues (through royalties or revenue/profit sharing). This arrangement provides broad distribution, branding and advertising for the drug, which the venture would not have the budget or sales force to otherwise undertake.

Securing strategic partners is a time-consuming and cumbersome task and the competition for such alliances is strong given the benefits they yield. To be most effective, management should approach those firms that are already committed to or are aggressively pursuing the market that the venture is targeting. These firms are likely to have the best grasp of the venture's intellectual property and its commercial potential. They also have the sales force, marketing savvy and network of relationships that can ensure rapid and cost-effective penetration of the market. With the mechanisms in place, they are likely to be the most receptive to new products that solidify or strengthen their market share.

Business management

Competent business management is critical to the future of any biotechnology venture. Experienced business people bring an important dimension to a venture, especially one whose founders are primarily scientists and technologists. While the scientists pursue the development of the intellectual property, the business people focus on turning that intellectual property into revenues, profits and market value. This ability to convert the intellectual property into tangible economic value is, in the final analysis, the objective of investors, founders, key employees and strategic partners.

Experienced, talented business executives will typically decide to accept a position

based, in large part, on the strength of the venture's intellectual property and the economic upside of this intellectual property. Therefore, to persuade business management prospects to join the company, the scientists-founders need to detail the commercial potential of the science and the competitive advantage of the products that the venture will bring to market vis-à-vis existing products and other products in development.

The venture should target professionals who have experience and knowledge of the market segments that the company is targeting. These executives are likely to have a greater understanding of the value of the intellectual property and, more importantly, will have established relationships with appropriate decision makers in major pharmaceutical firms, facilitating the formation of strategic alliances.

The value of the intellectual property is also a major component in motivating others to assume advisory roles. Typically, a scientific or medical advisory board comprises outside scientists working in the company's field. The greater the merits of the science, the more renowned the scientists attracted to the advisory board. A strong advisory board can provide several benefits, including 'opening doors' to decision makers at potential partners; generating awareness of the company in the scientific community; providing validation of the science to the financial community; and helping to attract other noteworthy researchers to the company. Given the importance of these advisors, the venture should pursue those prospective advisors they believe can provide the most value to the company from both a scientific and business perspective.

Market awareness

The fastest way to create excitement for the venture is to promote its intellectual property and its potential to treat or prevent diseases directly or to provide tools to other biotechnology firms in their disease prevention/treatment goals. Initially, this is

best done through science-related events, ie presentation at conferences, articles in professional journals and publicity in trade journals. As the 'buzz' increases, the likelihood of crossing over to more mainstream business and general publications increases. One major benefit of increased awareness is increased interest by potential financing sources.

Financing

Virtually all biotechnology companies need to obtain capital from outside sources to realise their objectives. The cost of developing blockbuster drugs or technology is too great and the near-term revenue potential too limited to enable a biotechnology venture to fund itself completely through operations.

The financial community recognises the weight of the intellectual property on an investor's decision and, today, most venture firms and investment banks employ doctors, scientists and other professionals with direct

expertise to review investment candidates. They also subject a venture's patents – pending and issued – to extensive review by legal advisors.

Extending beyond the 'science', these investors also assess the ability to use that science to bring products to market. At this point, the business factors become critical in their decision – the management team, advisory board, revenue potential, strategic partners, etc. As demonstrated in this paper, these can be built into strong attributes by utilising the venture's intellectual property effectively.

Conclusion

A biotechnology company has its foundation in its intellectual property. To that end, a venture that creates and implements as a strategy that capitalises on this foundation to build other strengths within the business, significantly increases its ability to attract financing and build a viable business.

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