From the Board Room

A business perspective on IP: Open innovation vs. open source in commercializing biomedical opportunities

Received: January 1, 2013; Revised February 25, 2013

Arthur A. Boni, Ph. D.
is John R. Thorne Distinguished Career Professor of Entrepreneurship, Tepper School of Business, Carnegie Mellon University.

ABSTRACT

In this article, we address the issues that are involved when developing a strategy for commercializing a discovery that is novel, useful, and non-obvious to someone skilled in the art. Patent(s) may be used as one means of providing a competitive advantage, and in addition this method is quite common as a means to monetize the intellectual asset. Alternatively, a more "open-source" method may be employed as is more typical in dealing with software products or services — thereby opening up the field to collaboration and widespread use. However, other means must then be developed to monetize the asset whether it involves a "hardware" component, software, or both. We argue that to answer these questions, one needs to be very strategic in framing the business model that would be most successful in commercializing the particular discovery keeping in mind that wide dissemination of the innovation is the objective. We focus on issues prevalent for innovation in biopharma, medtech, and medical IT, where high risk, long life cycle, capital-intensive investments are required for commercial introduction.

Journal of Commercial Biotechnology (2013) 19(2), 55–59. doi: 10.5912/jcb.599
Keywords: IP; open innovation; open source; business model

INTRODUCTION

It is not uncommon in academia for researchers to take the position that patenting of inventions would preclude wide dissemination of a technology embodied in a drug, medical device or diagnostic. Why not use an open source approach as is common in the software industry to ensure the widest, and free access to the technology?[1–3] Some argue that open source is the ethical approach since everyone may benefit equally from free access to a breakthrough technology (even though open source may be insufficiently documented and developed to serve as a validated basis for investment as a commercial product). It is often asserted that this approach yields greater societal benefit, since anyone in need of a drug or medical device would somehow have access at a lower cost anywhere in the world. The counterargument is that the use of an open source approach, while altruistic, would result in just the opposite in the field of biotechnology (or medtech). This is a direct result of the structure, and strategy of the industry and the tremendous uncertainty with developing drugs, and also to a certain extent medical devices and diagnostics. Therefore these industries require a certain level of validation of potential products prior to entering the commercialization pathway in any significant way. Even with open source software, it is cited that products such as MySQL did not reach its commercial potential as an open source approach as a stand-alone entity. The financial viability (and extent of market penetration) was questionable at best prior to acquisition by Oracle.[4]

The biotechnology industry, and other technology intensive industries are characterized by a very long, high risk, and extremely capital-intensive development cycle. Therefore, the organization that develops the technology will be required to invest a considerable sum of money to move the technology down the commercialization life cycle spanning discovery, preclinical and

Correspondence: Arthur A. Boni, Tepper School of Business, Carnegie Mellon University, US. Email: boni@andrew.cmu.edu

clinical testing before it is even clear that the potential invention will demonstrate efficacy and suitability for the market. Drug development requires hundreds of millions of dollars (taking into account failures, this amount is estimated to exceed $1B).[5] Medical devices require less, but still significant amounts of investment ranging from tens of millions to fifty million or more. Who would make a multimillion-dollar, high-risk investment without some ability to generate a fair return on that investment? While government funding is helpful in this regard, private sector investment is necessary for commercial introduction. Private sector funding may come from the pharma or medical device industry, from venture capital or both. So shareholders or limited partners who put up the risk capital need to be satisfied. Without risk capital, innovation cannot proceed, hence no one benefits from a discovery or breakthrough.

Another complicating factor is the business model employed in these industries, which we discuss in more detail below. Value creation most often results from the contributions of multiple partners along the value chain, in addition to the value added by the pharma or medical device organization that actually brings the product to market and deals with the distribution of the end product to the patient and provider.

One of the underpinning factors for the success of any business model is that the product be differentiated, and a sustained competitive advantage developed. Patenting is one method for achieving this objective (at least in part). Note in particular the requirement for novelty and utility in exchange for a 20-year period of exclusivity granted to the patent holder. In the biomedical field patents are necessary, but often not sufficient in this regard, and most venture investors in biotech or medtech will not invest in any potential drug or device where a patent (and most probably freedom to operate) is not available.

Below, we discuss the pros and cons of patenting in the biomedical field. We also consider some of the business ramifications in this field, since as noted it is common (and increasingly more common given the move towards collaborative innovation typified by open innovation business models – not to be confused with open source), that multiple parties may be involved to ultimately bring a drug to market.

In the language of strategists and economists, each of the parties involved along the value chain will "seek rents" for their contribution to creating and sustaining value in the market. How will value be measured and shared to best ensure balance of risk and reward? One may think of licensing of patents to partners as simply "renting or hiring" the business model of the partner to create and deliver value for the technology, c.f. Chesbrough in his book entitled Open Innovation.[6] Therefore the fundamental breakthrough is often valued lower by the partner who "owns" the business model since that organization has already invested quite heavily in development of other key parts of the business model, e.g., key activities and resources, customer channels and customer relations. To optimize the "rent" it is beneficial for the technologist (university or early stage company) to raise money from the government and private sector to decrease the development and/or market risk and thereby increase the value prior to partnering. Patents are a vehicle by which monetization of an intellectual asset can be conveyed to a partner via a license whether the license is exclusive, non-exclusive or otherwise restricted by the owner.

THE OPEN INNOVATION BUSINESS MODEL AND MONETIZATION OF INTELLECTUAL PROPERTY

There are many sources of extensive information on development of winning business models, c.f. Osterwalder & Pigneur[3] Chesbrough[7], Christensen[8], for example. Basically, the business model is defined as the components that must be assembled by an organization to create, capture and deliver value to customers (those who pay for the product or service). Of course in the biomedical field it is well understood that customers and users may be different entities since there are the 3Ps (patients, providers and payers). The chapter in the excellent book edited by Burns[9] (c.g. Chapter 4, Biotechnology business and revenue models) illustrates the common models in the healthcare industry. These include FIPCO (fully integrated pharmaceutical company), RIPCO (research intensive pharmaceutical company), and FIDDO (fully integrated drug discovery/development organization). These characterizations are useful for categorizing the companies in the biomedical field, however it is more illustrative to take a more fundamental look at the various components of the business model itself. For this purpose one can adopt the very straightforward (and graphical) framework described by Osterwalder. This approach is applicable to any industry. Over the last decade the business models employed in the healthcare sector have been questioned since the industry had difficulty with driving and sustaining innovation; c.f. Pisano.[10]

Osterwalder[3] framed the business model as consisting of 9 separate and necessary parts. On the "*customer side*" there is the (1) customer, (2) the value proposition, (3) the channel to reach the customer, and, (4) the customer relations necessary to sustain and nurture the customer for awareness, consideration, choice and repeat business. Also on that side of the model is (5) the revenue

model, which describes how revenue is actually generated (thru one or more of the 3Ps in this case). For example revenue can be generated by selling a product to the consumer, or by licensing that product to another company who has the ability to interact directly with the customer. For software products, the Software as a Service (SAAS) model could be employed. Download the software and pay a fee — the owner controls the software. Alternately, the so-called Freemium model could be employed whereby the software is provided free (open source) and revenue generated by other means, such as providing a service to the customer or alternately selling a premium version to paying customers, with a free version to others. Osterwalder and Burns cover many different business models (which is beyond the scope of this short article).

The "*company*" side of the business model deals with costs, and the resources, processes and values needed to carry out the business, i.e. (6) key activities, (7) key partners, (8) key resources, and (9) the costs incurred to acquire, build and deploy those assets. Generating and developing intellectual property would be a key activity, as would be the resources involved (people and partners).

The historical business model in biopharma is a "vertically integrated" FIPCO where all of the 9 components were "owned" by the pharma company, with some licensing or partnering providing the company with new drugs for commercialization (along with those discovered and developed in house). With medical devices and medical IT a similar approach was employed. Most medtech/medical IT companies employ a combination of in house development along with partnering and acquisition of new technologies/companies. Over the last decade, however, a more open innovation model has been employed with the pharma or medtech companies partnering extensively across the value chain to acquire, and bring new products to market. In effect an extensive, emerging biotechnology/medtech industry (consisting of RIPCOs, FIDDOs and other startups) has developed to eventually partner with (and be acquired by) the larger organizations that have become much less vertically integrated (still called FIPCOs).

The open innovation business model involves partnering globally, whereby academia, emerging companies and larger organizations that "face the customer" have collaborated to bring innovation to the marketplace. In this paradigm, the existence of intellectual property (particularly in the form of a patent) is considered as necessary conditions for these smaller, emerging organizations to monetize their assets and convey rights to the larger organizations via a license or actually selling part of the ultimate product to the larger partner. Indeed a recent *Journal of Commercial Biotechnology* article by Boni[11] titled "Project, Product or Company", discusses the multiple options or paths to the market that must be considered when developing the commercialization strategy to be employed for translation of a technology or invention into an innovation.

A REAL ILLUSTRATION

The points argued above are illustrated below in a "mini case" on Stentor, Inc. This case is based on a real commercialization opportunity that arose when the author was director of technology management at the University of Pittsburgh. A company, Stentor, Inc. was formed around a patent; a novel medical technology was brought to market successfully; and, Royal Philips Electronics eventually acquired the company after it demonstrated market traction (the Stentor product was adopted in the Phillips product portfolio and is continuing in use today) — a successful outcome for all parties.

So as not to divulge any private data, this mini case uses only publically available information that appeared in the press just before and after the acquisition, or in the public stock-offering prospectus (S-1) filed by the company with the U. S. Securities and Exchange Commission (SEC). As discussed more fully below, a breakthrough technology was developed in a university laboratory. The inventor/technology developer argued that the technology should be "open sourced" to promote wide dissemination, since he was most familiar with the software industry. The "secret sauce" that enabled this invention was based on a software algorithm, and it is common to try to apply a typical software (or digits) approach to monetization instead of what is more common with hardware (widgets) or chemical/biological entities where patents are almost always employed. In fact the situation described in the Stentor case involves both "digits and widgets", therefore both methods of monetization can be applied. The revenue model employed by Stentor was Software as a Service (SAAS), but the business model itself would necessitate patenting of the algorithm, and thereby enabling the customer to apply the technology to "commoditized" computers — in this case low-cost PCs and not more-expensive workstations. Those of us charged with managing the IP of the university argued that the technology should be patented to promote successful commercialization — as discussed in this article.

Stentor mini case

In the mid part of the 1990's companies such as GE and others utilized specialized computer workstations to transmit and view medical images. These Picture Archiving and Retrieval Systems (PACS) cost well over

$100,000. Dr. Paul Chang, a radiologist at the University of Pittsburgh and UPMC Health System developed a software solution that made it possible to achieve the same objective (managing high quality medical images and information across multiple facilities) at a significantly lower cost, and with an easier to use system that could be deployed in a doctor's office via an ordinary network of desktop PCs. This is a classic disruptive innovation opportunity, c.f. Christensen.[8] Pamela Gaynor, Staff Writer for the Pittsburgh Post-Gazette reported the following in an article published in 2000.[12]

"The high cost of the PACS systems made them prohibitive for all but the nation's largest medical centers, and even then only in the radiology departments. (Christensen would eventually characterize this as a disruptive innovation–provider and point of care). PCs did not have the capacity to handle the volume of data in medical images, and the workstation manufacturers, but only with severe degradation of the image quality. The Chang breakthrough employed a "just in time approach" whereby only those parts of the image needed at the time were handled by a software solution (in effect a compression/decompression algorithm). This was inspired by his visit to a factory that had done away with its parts warehouse by adopting "just in time" delivery of its supplies. Chang argued that this technology would give all physicians at a health system, not just the radiologists' access to top-quality electronic images (and at an affordable price). Chang's initial approach was to develop the software and give it away to the PACS manufacturers with whom he had a working relationship".

So, Chang approached the office of technology management at the University of Pittsburgh, and also officials at the UPMC Health System since he was also part of their radiology department. We all quickly came to the conclusion that while working with the PACS manufacturers was a possible route, there were some downsides to taking that approach so early in the development cycle. Since there were multiple manufactures, there was little incentive for any of them to commercialize the technology for several reasons. First, why disrupt "themselves" and their current product offering, c.f. Christensen?[8] Their business models were not consistent with selling a lower-cost, easy to use solution inherent in the PC/algorithm solution. Secondly, they would be competing with each other with an undifferentiated solution, and without barriers to entry by their competitors (aside from their existing business channels and arrangements). An alternative would be to form a startup company, develop the technology, begin implementing it at UPMC and other hospitals, and then license or partner with selective PACS organizations. With either alternative, a patent would be required to protect the algorithm.

As reported by Ms. Gaynor, Dr. Chang did not want to form a startup company since his principal interest was to develop the technology. As reported, he also wanted to give the technology away for free (essentially the open source approach). Eventually we all agreed that the best approach here was to form a startup company and license the technology to the company that would carry it forward into the marketplace. Coincidentally, UPMC had invested in Lancet Capital, an early stage venture capital group, who agreed to provide the seed funding for Stentor, Inc. Both Pitt and UPMC received equity as a result of the investment and also co-invested in subsequent financings. The partners of Lancet Capital formed a management team with the expertise needed to commercialize the technology.

Stentor was formed in 1998 and set up operations in Silicon Valley and R&D operations in Pittsburgh. Just two years later, in 2000, they made a "big splash" at the Radiological Society of North America meeting and appeared to be "pushing the industry" according to a clinical radiologist and professor at the University of Pennsylvania, as reported by Ms. Gaynor. After additional investment by Lancet and others, a public offering was planned as the company was gaining market traction. Prior to the IPO, Philips acquired the company for $280 million in cash in 2005, providing a good exit for the investors and originators of the technology ($45.1 million for UPMC — $36 million over their investment of $9.1 million — and $10.8 million for the University of Pittsburgh, c.f. (http://upmc.com/media/NewsReleases/2005/Pages/stentor-release-05.aspx).

From a commercialization perspective the startup, Stentor, brought a truly revolutionary technology to the market via a disruptive innovation (both technological, and point of care), and its products are widely available to the medical community. The public thereby benefitted since cost was reduced and the method of deploying radiological images and data was made more efficient and widespread. It could be argued that human health was improved substantially as well. Could this all have been achieved with an "open source approach"? Not likely. If an open source approach had been taken, it is likely that the "state of software development" would not have been accepted or sufficient for the key commercial players in the market at the time to proceed with commercialization (aside from differentiation and competitive advantage provided by IP). Indeed, even the Google Android open source software approach was insufficient to incentivize key partners to proceed with commercialization (much of this work had to be done in house, and in the case of Stentor, universities/medical centers are not set up to support products. Patents are an essential part of the biomedical business model and provide part of the competitive advantage required to acquire

resources and deploy breakthrough technologies — and improve human health. In this case moving forward with a startup company provided the means and resources to demonstrate the value of the technology and a suitable partner for on open innovation business model. Thus, in the spirit of open innovation, a promising technology was acquired by a larger partner and the product was made available to benefit the public.

ACKNOWLEDGMENT

I wish to acknowledge that while serving as director of technology management at the University of Pittsburgh and leading up the Stentor transaction, I worked very closely with two other individuals who assisted significantly in what became a noteworthy success. I am very grateful for the insights and assistance provided by Scott Lammie of the UPMC Health System and David Kalson, an attorney with Cohen & Grigsby, PC. It took a collaborative team approach to work through the complexity of the process (especially to convince the inventor that the "fork in the road taken", i.e. the startup pathway and the patent filing was the best choice).

REFERENCES

1. Landry, John and Rajiv Gupta (2000), "Profiting from Open Source", Harvard Business Review, (HBS Product F005030pdf.eng).
2. Robert A. Bergelman and Philip Meza (2001), Harvard Business School Product SM85-pdf.eng, "Open Source Software Challenge in 2001".
3. Osterwalder, Alexander and Pigneur, Yves, *Business Model Generation*, Wiley.
4. Vance, Ashley (2009), "The Open Source Business Model for Business is Elusive", New York Times, Published November 29, 2009.
5. DiMasi, J. and Grobowski, H. (2007), "The Cost of Biopharmaceutical R&D: Is Biotech Different?," Managerial and Decision Economics, No. 28, 469-479. Also see Tufts Center for the Study of Drug Development, Tufts CSDD Impact Report 10, No. 1 (2008).
6. Chesbrough, Henry (2006), *Open Innovation*, the New Imperative for Creating and Profiting from Technology, Harvard Business School Press.
7. Chesbrough, Henry (2006), *Open Innovation Business Models, How to Thrive in the New Innovation Landscape*, Harvard Business School Press.
8. Christensen, Clayton M. and Raynor, Michael, E. (2003), *The Innovators Solution, Creating and Sustaining Successful Growth*, Harvard Business School Press. Also see Christensen, Clayton M., Anthony, Scott D., and Roth, Erika, "Seeing What's Next", HBS Press (2004).
9. Burns, Lawton Robert, Editor (2012), *The Business of Healthcare Innovation*, 2nd Edition, Cambridge University Press.
10. Pisano, Gary P. (2006), Science Business, *The Promise, The Reality, and the Future of Biotech*, Harvard Business School Press.
11. Boni, Arthur A. (2012), J. Commercial Biotechnology, Vol. 18, No. 2.
12. Gaynor, Pamela, Pittsburgh Post-Gazette (July 9, 2000), Also see http://old.post-gazette.com/business news/20000709spot4asp.