Academic/Industry Liaisons

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It has been 37 years since Watson and Crick unraveled the genetic mysteries and catapulted molecular biology into the forefront of laboratory sciences. Events in the academic laboratories since then have been nothing short of revolutionary. We have progressed in our fundamental understanding of the life sciences and have acquired the technical skills to accompany our understanding, with revolutionary implications for products and methods in the treatment of disease. To bring these products and methods into use – into the marketplace – requires as never before that industry and academia work together in strong, effective alliances.

On the surface it seems an ideal time for idea-hungry businesses and down-at-the-heels academic laboratories to get together to serve their mutual interests. Yet that is not happening in a way that is satisfactory to either party. Our own experience working on both sides of this great divide has provided rich evidence of the growing frustration – in industry, at being unable to realize commercial value for financial investments made in university research; and in academia, at failing to realize financial value for intellectual capital.

Industry needs the university. It needs the science that is the product of the academic laboratory to form the basis of product development efforts, keep pipelines full, and enable individual firms to compete successfully in world markets. The future of the pharmaceutical and biomedical industry as we know it lies in developing the products of modern science. The extraordinary difficulty and cost of conducting modern biomedical research preclude the probability of one firm or even the industry as a whole doing it successfully in-house. This is one area in which industry cannot afford to make; it must acquire. And science must be acquired from the university.

And just as industry needs the university, academia needs industry as never before. Modern scientific research is extraordinarily expensive. It is both labor-and instrument-intensive in ways that would have seemed incredible a generation ago. Federal monies, which have supported virtually all the breakthroughs that have led us to the point where real therapies and real cures are being achieved, are no longer able to sustain the momentum they have created. The training of a sufficient number of young scientists, the acquisition of sophisticated instrumentation, and the maintenance of a first-rate scientific establishment are all now beyond the means of even the richest universities. Seed money for the development of promising scientific ideas is virtually impossible to find, and even established scientists find themselves spending a dis proportionate amount of their time scrounging for support.

The lack of satisfactory, sufficiently productive collaboration has an impact broader than any one firm or institution. In the United States, the failure of industry and universities to form strong and productive alliances translates into lost opportunities in the global marketplace as well as lost opportunities for the public good. Japan introduces three times as many biomedical products each year as the United States, and the United States is now in sixth place among countries in terms of scientific patents obtained. Although the United States generates vastly more scientific research than any other country, fewer commercial products are emerging from U.S. companies.

The 1990s are supposed to be the decade of the biotechnological payoff. Ideas generated 10 and 20 years ago from research supported by generous (if still insufficient) government monies, new research, and new production methodologies all are poised for industrial development and application. We are told that the biomedical industry may be to the economy of the 1990s what the computer industry was to the 1970s and 1980s. It would seem that everything is in place for this to occur. Yet it is not happening to the extent once envisioned, and there are those who fear that foreign (i.e., Japanese) preeminence will do to the U.S. biomedical industry what it did to the semiconductor industry of the earlier decades.

The Scope of the Problem

Business and academia have been at odds for centuries. Writing in 1959 in *The Two Cultures and the Scientific Revolution*, C. P. Snow described the distance between the two as "a gulf of mutual incomprehension. . .sometimes hostility and dislike, but most of all lack of understanding." The lack of understanding stems in part from different objectives: the business of business is to make money, while the business of the university is to generate new knowledge. And the hostility and dislike reflect a basic reality: these two groups have never had much respect for each other. "Those who can, do; those who can't, teach" has been a cliche of American business, while academics generally reserve their most profound scorn for businessmen, who are at worst perceived as anti-intellectual and at best merely as a source of philanthropic support. Rarely, if ever, have businessmen and professors been solidly allied in pursuit of the same goal.

Granted that, in some areas of research, respectable and productive collaborations have developed. In the physical sciences, many models exist of research centers formed with industrial partnerships to develop work in areas of common interest. And the use of academic resources to address company-specific problems is a common approach in engineering disciplines.

However, in the biomedical area the fundamental cultural differences between these two groups are often heightened by the promise of great profit to those who can most quickly make it to the marketplace with therapies and cures for modern scourges such as cancer, heart disease, and AIDS. At present, there is an enormous amount of money to be made from advances in biomedical understanding; yet the tension between academia and industry in this field is getting worse, not better.

A recent event at the distinguished Massachusetts Eye and Ear Infirmary (MEEI), a teaching hospital affiliated with the Harvard Medical School, is an example of one of the many things that can go wrong in the commercialization of academic technology. Two academic scientists reported misleading test results at a time when each held significant equity in a company formed to market the product. The episode generated considerable anxiety at universities, which perhaps for the first time fully realized the possibility for conflict of interest among their faculty members. Now most nonprofit federally funded academic institutions are attempting to develop regulations that will preclude the possibility of another episode like the one at the MEEI. The National Institutes of Health (NIH) itself, under pressure from Congress, is attempting to provide guidelines for the research it supports.

From the other perspective, industry has made significant investments in academic research in recent years, often with disappointing results. A pioneer \$10 million, 12-year project between Monsanto and Harvard, begun in the early 1970s, yielded some ,good science" but little of major commercial value. A \$60 million agreement between Hoechst and the Massachusetts General Hospital seems to have had similarly disappointing commercial returns.

As a result of widespread publicity about some of these events, we have all had our consciousnesses raised about biomedical science and the problems, both real and perceived, of tapping its potential.

We believe that at least some of the problems in this troubled relationship stem from the age-old differences between the perspectives and cultures of the two sectors. The university fears corruption of the purity of its pursuits, the prostitution of science to profit. It fears the blunting of the effort to generate new knowledge and the seduction of its scientists into more lucrative commercial laboratories. The university mistrusts the businessmen who, it believes, intend to buy the products of its laboratories at rock-bottom prices in order to sell them at inordinate profits.

Industry doesn't mistrust the university so much as it is frustrated by what it sees as the unfocused activity – and overpriced results – of academic science. But business fails to cope with the exploratory nature of scientific discovery in a way that harnesses it positively.

Achieving Mutual Understanding

What then can be done? We suggest four avenues that may lead to more effective collaborations.

Recognition of Differences. Before anything else can happen, the two entities must recognize their differences – and their interdependence. Recognition of differences will, to paraphrase Samuel Johnson, clear the mind wonderfully. It will also permit the building of trust as both understand that their skills and strengths complement each other, and that their complementary natures can interlock to serve their mutual need. Rather than an adversarial relationship generated by misunderstanding, they can build a relationship in which enlightened self-interest predominates. Two such disparate enterprises cannot develop such a relationship without some changes. But viewed in the light of the potential gain, these changes need not be seen as threatening.

Understanding Product Development. Both sides must recognize that the root of many of their conflicts lies in the fundamental characteristics of the product development cycle, in issues of uncertainty, timing, risks, goals, and costs associated with the process of bringing science to the marketplace. Many of the profound differences between the two partners reflect a poor match as well as a lack of understanding between people who are in fact operating at opposite ends of a long and complicated spectrum.

Pharmaceutical development typically requires at least 10 years for completion as it progresses through a number of complex steps. Academia's role is primarily at the earlier stages of the process, providing ideas, tools, basic scientific understanding, and many of the initial leads that flow into the research pipeline. Industry's contribution is in the later stages: defining and developing specific products and securing the regulatory approvals leading to the market. The risks and costs – and, as a result, the rewards – associated with the various stages of the process differ tremendously. Both sides need to enter the relationship with realistic expectations of the returns due their level of participation.

Location, Location. Both groups should recognize that location may play an important if subtle role in the process. Distance may make the heart grow fonder, but proximity tends to stimulate incipient passion. When industry, having made a significant dollar investment in the work of academic laboratories, is willing to invest time as well by sending its own scientists into the labs with the professors, the synergism generated by

proximity will pay off. Mutual goals agreed upon in the executive offices are absolutely critical; shared goals in the lab create an excitement that can generate remarkable productivity. Despite the apparently dis appointing results of its Harvard relationship, Monsanto subsequently committed \$62 million to a program with nearby Washington University. This program includes shared decision-making and the movement of scientists between the two institutions. Both the university and Monsanto say that, with adjustments on both sides, it has worked well: by its eighth year, in 1989, more than 40 patent applications had been filed.

Clear Ground Rules From the Start. In negotiations, each side should state its goals and objectives, as well as the scope of the collaboration, at the outset. Of equal importance are the terms for cashing out. Starting points, ending points, and milestones must be established. Terms of ownership must be clear, as must be the process for resolving ownership questions that may arise once the work is under way.

Implications for Industry

Firms seeking productive partnerships with academia need to establish realistic goals, invest time as well as money, permit decentralized decision-making, and strive for the optimum interface.

Realistic Goals. Success in these relationships cannot ordinarily be equated with the identification of specific products. It stems instead from the ability to recognize the potential commercial applications of research advances. The key objective of industry should be to tap into basic research to ensure that it is fully exploited from the commercial perspective.

Said another way, industry must not expect to find products in labs; it must instead be alert for the possibilities of products. It must also understand the need for further development investment, essential if the possibility of a product is to be realized by the commercial/industrial partner.

In biomedical research, the types of goals that are realistic and achievable from academic collaboration often include:

• Better understanding of a disease mechanism, such as the role of amyloid protein in causing type II diabetes

• New research approaches or tools to tackle specific problems, such as the development of quantitative immunoassays to measure receptor activity on tumor cells

• "Manufacturing" methods, such as techniques for producing perfect electronic and optical crystals for biosensors or mammalian cell expression systems for the production of high-molecular-weight human proteins

Too often, companies are frustrated by the absence of a tangible "product" in their academic collaboration – when the real jewel lies in a process or an insight that could in turn be used to develop a product.

A firm seeking to exploit academic science – either by up-front funding of a university research program or by identifying licensable technology within the academic laboratories – needs to begin with some well-thought-out, realistic "basic science" objectives.

Investing Time as Well as Money. Clearly, many of these goals are difficult to realize through a discrete technology transfer mechanism. To realize a productive return from academic relationships, industry needs to invest not only money but also the time necessary for developing the relationship and understanding the potential of the science. The biomedical industry is based on ideas of extraordinary complexity. Yet too often a company representative, spending a few hours with a scientist in a lab, is expected to understand both the activities of the lab and the implications of that activity. This approach is remarkably unproductive. Persons sent to discover the possibilities of new products must be willing and able to spend time in the labs – time counted in days, not hours. Exchanging scientists between the two organizations is an even better approach for longer-term collaborations.

Decentralized, Responsible Decisions. To compete effectively for the fruits of academia, the hierarchical organization of the typical company must give way to an organization that can make and implement decisions quickly. Such a change would go a long way toward addressing the university's extensive frustration with the prolonged bureaucratic decision-making that now characterizes American business and the resultant preference of many universities for dealing with small entrepreneurs or non-U.S. firms.

Such flexibility could be accomplished by establishing within the company a group that can cut red tape and make and implement decisions. This group must have the blessings and the support of top management and a pot of discretionary money. Organizations of this sort are not unknown in corporate America, but neither are they very common. Often, having been spun off by an imaginative CEO, they are subsequently left to languish in corporate left field.

The Optimum Interface. The representatives of U.S. firms who now turn up in academic laboratories are typically nonscientific and alone. In contrast, many Japanese firms send teams that include scientists – or scientifically trained people – who are better able to understand the implications of what they see. Teams often combine to provide the skills and talents necessary to make the creative leap from observing science to

envisioning a product. A solitary representative making periodic brief visits to academic laboratories simply cannot be expected to achieve the same results.

Thus, biomedical companies looking for ideas in academia need to send into the field people with realistic goals and objectives, who will be given the authority to be responsive and the time it takes both to develop a relationship with the academic scientists and to understand a new scientific process or discovery.

Firms establishing long-term programs of university collaboration should make certain that the entire academic research team understands the ultimate objective of the firm and that both parties are in agreement regarding the scientific unknowns standing between the current state of knowledge and the desired program. Success will be enhanced by:

• Beginning with clearly stated hypotheses that will be tested during the program

• Educating the academic team in the product development process, including regulatory requirements, and providing marketing perspective to the team

- Holding reasonably frequent, integrated project team review meetings
- Exchanging scientists

Regardless of the situation, companies must not expect a quick or precise payoff. They must be more attuned to the investment of years than to quarterly write-offs, and willing to value advances in understanding as part of the total return.

Implications for Academia

Academic institutions that want to form effective partnerships with businesses must learn to accept some risk, make genuine commitments to these efforts, and establish realistic ground rules.

Thoughtful Investment/Return Trade-Offs. The culture of academia is essentially conservative. Most universities contemplate change with apprehension and implement it very slowly. Few universities take risks. While there is little doubt that such an attitude protects the endowment, academic CEOs looking for rewards from their research must abandon their view that all risk belongs with the industrial sponsor. Academic institutions must begin to consider investing in their own technology. If academia wants royalties of more than a few percentage points, it must offer for licensing potential products that are far enough along the development pipeline to reduce the risk associated with bringing them to the marketplace. The farther along the pipeline, the closer to market; and the more hurdles that have been cleared, the higher the likelihood that the product will be commercialized. Institutions must stop expecting large up-front payments, full research support, significant royalties, and no risks.

Not all institutions should move into the realm of product development. "Stick to your knitting" has an age-old wisdom that still applies. In many cases, universities may be better served by focusing exclusively on the development of new knowledge, leaving product development to the industrial world. However, the anticipated returns must correspond to the degree of participation and associated level of investment.

If You're Going to Do lt, Do lt Well. If academia chooses to engage in entrepreneurial activity, it must recognize that it is entering a fundamentally new business that, at a minimum, requires specific budgets and staffs to accomplish the job. Funds must be made available for the technology transfer process to operate effectively; it cannot be constrained by minimal budgets and an ambiguous relationship to executive management.

Academic CEOs attempting to enhance their research establishments by successful technology transfer must be genuinely committed to the activity. At present, many nonprofit CEOs are embarrassed, apologetic, and even scornful of the profit-making venture. Too often, for-profit activity on the part of biomedical institutions and universities is regarded as only slightly above prostitution and embezzlement, activities which are ceded to be all right in industry but lacking the gentility appropriate to the eleemosynary sector.

Realistic Ground Rules in For-Profit Activities.

There are sensible and feasible ways to oversee for-profit activities within the academic sector, in order to avoid conflict-of-interest problems. Universities and biomedical institutions must develop appropriate procedures to monitor and audit activities in their near-commercial sphere to safeguard against conflict or even the appearance of conflict in these situations. As the United States learned in the 1920s, prohibition is usually not the best way to control desires. Realistically recognizing the strong interest of scientists in the nonprofit sector to participate in some way in the commercial rewards available from their work, and developing sensible ground rules for protecting the process from conflict of interest, is probably a far better solution than prohibition. It is also a far better way to attract and retain staff than forbidding them to participate in the rewards.

Conclusion

The misunderstandings that have plagued the industry/academia relationship can be resolved without major compromise.

Both parties must make an effort to understand each other's processes – processes related both to the evolution of science toward a tangible product and to decision-making within each organization. They must, as used to be said of marriage, each be committed to an involvement on a long-term basis, understanding that the relationship will have its ups and downs. And they must not lose sight of the objective. By working together, each side can provide for effective transfer of value between these two worlds.

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