Interaction between Industry and Universities

FILIP DE CORTE*

COLLABORATIONS BETWEEN UNIVERSITIES AND INDUSTRY: THE CONCEPT

Collaborations between certain departments of university and industry have always existed in modern times. However, something has clearly changed over the last years. Particularly in the area of biotechnology and chemistry, collaboration between universities and the pharmaceutical industry has increased dramatically. Even well into the 1980s, the R&D organizations within European industry only had but a few formal research collaboration agreements with universities. Nowadays, negotiating and managing contracts, be it research collaborations, agreements for research fellows, agreements for contract work, Material Transfer Agreements, secrecy agreements, is becoming a key process within an industrial R&D organization. So what has happened? Pharmaceutical companies started to realize that they did not have the monopoly on good ideas and that any one company could not expect to generate more than a fraction of the totality of valuable intellectual property. It dawned upon the industry that no company could expect to survive solely on what it can generate internally. Moreover, the investment community started sharing these thoughts. Indeed the stock market rewards those companies that announce one research collaboration deal after another. On the other hand, universities started to realize that their research actually generated important intellectual property and that they could become crucial partners for the industry. Said partnership could then generate income for university laboratories where money is always a scarce resource. This trend of increased collaboration between industry and universities started in the United States and, particularly, the enactment of the Bayh-Dole act of 1980 changed a lot in the United States: it allowed the universities to reap the actual benefits of the intellectual property they themselves had created.

EXPECTATIONS OF UNIVERSITIES VERSUS EXPECTATIONS OF PHARMACEUTICAL INDUSTRY

The relationship between universities and industry is not a marriage made in heaven. There clearly is a clash of two different worlds. And this clash is the basis of some of the difficulties that are encountered with research collaborations between industry and universities.

Universities

Researchers at universities are trained in the scholarly tradition that holds academic freedom as a valuable good. It is generally held that academic freedom can be hampered or frustrated if research were to be restricted by religious, political or economic pressures. Hence, universities feel very strongly about full freedom in research and especially full freedom in the publication of the results. Based upon that same idea of academic freedom that research should not be hampered by—amongst others—economic influences, the university inherently is embedded in a "not-for-profit" environment or atmosphere. The topics of research are more determined by human curiosity and the field of interest of a researcher. It is not uncommon that the focus of the research that is performed in a laboratory shifts over time. New, more interesting avenues are explored and create the basis for other and further research. University laboratories have a limited project portfolio due to increasing specialization. Concerning compensation, a university laboratory is probably seeking two things: a short term income independent upon results but rather dependent upon the amount of effort that has been invested and (hopefully) a royalty stream related to a product that would hit the market.

Industry

How different is industry! There, knowledge is perceived as a property that has been acquired by investing money in research. This intellectual property should be protected and industry expects this knowledge to give a certain return on investment. Hence, publishing—although not contrary to the objective—is not always a priority. Clearly industry is for-profit. The main objective of the pharmaceuti-

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cal industry is to discover and develop new marketable drugs. Therefore, the research effort is more focussed. However within the research organization, many projects have to compete for the same resources (be it money or people). At a senior management level in industry, portfolio management is performed using not only scientific criteria. Often it is not understood or fully appreciated by the academic collaborator that the project related to the research collaboration will be one of many. Priority will be determined on the basis of given criteria and the strategic value may change over time. So however interesting from a scientific point of view a project can be, the decision can be taken to stop or at least lower the priority of that project because of portfolio reasons. Another difference is that the pharmaceutical industry wants to make payments dependent upon results linked to concrete milestones. Moreover (depending upon the situation), the pharmaceutical industry will often not readily be inclined to grant royalties linked to sales of end products.

THE PROCESS OF REACHING AN AGREEMENT ON RESEARCH COLLABORATION

Theory

Theoretically the process to setup research collaboration is quite simple. The process starts with the non-confidential phase where the university's general, non-confidential information and possible assets in the light of a potential collaboration are investigated. Following the evaluation of the non-confidential information of the external party and the decision to proceed, a secrecy agreement is signed. Subsequently, the confidential phase starts during which a more in-depth analysis of the proprietary information is performed. Then the final agreement is discussed wherein topics like inventorship, ownership of intellectual property, publication, payments, indemnification et cetera are discussed.

Practice

The non-confidential phase. The actual process often looks quite different. Collaborations can start because a researcher from the industry has met his colleague from academia at a conference, for example. The relationship at that point in time is often a friendly one and the thing that unites them is the scientific interest in a certain topic. They encounter a mind alike and in an atmosphere of academic freedom they start talking about their research.... and—very important detail—there are no lawyers around to sour their relationship. Hence, collaborations often start off completely contrary to the prescribed process. Confidential information is already exchanged without the necessary precautions in place. It is important to mention that there are at least two dangers involved. The first risk is the disclosure of novelty destroying information and the second is contamination. It is important to note that both parties are exposed to those risks.

• *Novelty Destroying Disclosure.* Novelty is an important criterion for patentability. Novelty means that the invention does not form part of state of the art. And according to Article 54(2) of the European Patent Convention: "The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." Case law has made it quite clear that disclosure to a single person not bound by a confidentiality agreement even in an oral form is making the information "available to the public." Hence, disclosing confidential information over a drink during the closing dinner of a conference is sufficient to endanger the patentability of the invention related to that information.

• *Contamination.* The second problem with exchanging information before a secrecy agreement is in place is the problem of contamination. What is contamination? Contamination occurs when unwanted confidential information is received. Basically the problem with receiving such information is, that if the receiving party would exploit his own but similar information (say by filing patent applications on it) the receiver will have to prove that he already had his own information before receiving the external information. Providing proof in court proceedings of when someone knew something is very hard to do. It should be noted again that contamination for the Academic World almost seems counter intuitive. In the spirit of academic freedom, it is very much appreciated that information is exchanged. How can knowing more be bad?

The confidential phase. The confidential phase starts after the secrecy agreement is signed. Notwithstanding the fact that a secrecy agreement is in place, it is generally perceived that confidentiality in a university laboratory is difficult to maintain. In view of the concept of academic freedom, often students (even students that are not related to that particular laboratory) can walk freely in the laboratories and scientific problems are discussed with every interested person.

A further problem is what could

be coined as the problem of "non-unity of the university."When a research collaboration with an industrial partner is negotiated, the requirement that the partner does not have a collaboration with another party in the same field is likely to be entered into the agreement. For universities, this seems to be difficult to maintain. The university department can offer exclusivity. However, it seems almost impossible to ensure that nobody else within the university would be doing related work in a similar agreement with another party.

In addition, also the discipline to mark all the information "confidential" during the confidential phase is lacking as well as the usage of putting orally discussed items on paper. It should be noted that many problems would never have arisen if during the initial discussions one had made proper note of who had the initial idea for a certain invention.

The final agreement. The main topics discussed during the negotiations leading up to the final agreement are inventorship, ownership of intellectual property, publication, and payments.

• *Inventorship.* Not too many problems are encountered with inventorship. However it is important to mention that inventorship is a legally defined concept. Yet there are still people who consider a patent or a patent application simply as another publication, so they are inclined to name everyone who was involved in the project as an inventor. This is not in accordance with the concept of inventorship in patent law. On the other hand, there is still the odd research leader who thinks that he or she and preferably he or she alone is the inventor just because he or she runs the laboratory. This seldom is the case. It is also hard to explain that in the case where the invention is already clearly suggested in the scientific program, the inventorship resides with the person who designed the scientific program and not with the person who carried out the program.

• *Ownership of intellectual property.* In most cases, the pharmaceutical company will want to own the intellectual property that is created during the collaboration. This depends upon the type of arrangement. When the work is purely commissioned work (following a previously designed protocol) there should be no problem. When it is established that the academic partner is an inventor, the pharmaceutical partner will still try to obtain the ownership of the intellectual property. In such a case there should be a reasonable compensation linked to that transfer of rights. It is worthwhile to note that problems concerning the ownership of intellectual property mostly arise as a result of arrangements being informal and undocumented.

• *Publications.* Publications constitute a difficult issue. Again referring to the academic freedom, academics want (and are put under severe pressure) to publish. Industry wants to make publication dependent upon the filing of patent applications. In general a 60 day period for the evaluation whether or not there is valuable intellectual property in a potential publication, is considered acceptable. Depending upon the type of invention, the pharmaceutical company will demand the right to withhold publication for a certain time period. For example, in the case where the subject of the research collaboration is a set of novel compounds that could be developed and marketed as drugs, the pharmaceutical company might insist on a publication ban of up to 18 months starting from the filing of the first patent application. The reason for this is that patent applications are published 18 months after first filing and that up until such time the applicant can either amend (during the first 12 months) or withdraw the patent application. Amending and/or withdrawing a patent application are measures that often may be necessary in view of ongoing research.

• *Payments.* Until recently universities were insisting more and more on royalties related to the outcome of the research collaboration, independent upon whether or not the outcome of a research collaboration was a product that could be brought to the market. However, some change in that position is perceived. It has become clear that for both parties royalties are not always the best solution. This depends upon the type of invention. For the pharmaceutical industry, royalties are only taken into consideration when the invention is the actual product that can brought to the market place, e.g. a new molecular entity. The pharmaceutical industry is not readily inclined to grant royalties relating to inventions that only indirectly lead to products on the market, e.g. when the invention concerns a molecular target. However, it is a free market and the forces of supply and demand rule that market. Consequently examples will be found where companies have awarded royalties in cases where the invention was not a sellable end product. Common sense dictates that where the invention does not relate to a product that can be brought to market, royalties are probably not the best solution. First, because in the pharmaceutical business, royalties only "deliver" money 8 to 10 years down the road, certainly when talking about pharmaceuticals. Secondly it is often an uncertain type of income because the attrition rate during clinical development is still very high. Thirdly, in view of the fact that the pharmaceutical industry often has a large project portfolio, the project—unless it is really a breakthrough achievement—will probably be rated lower during portfolio management evaluations because of the "strings" that are still attached to it.

A more preferred solution seems to be offering milestone payments at the different stages of the development of the potential drug linked to the research collaboration. In that way the university gets access to funds in a quicker and more predictable way, yet still shares in the success of the product during the development phase.

CONCLUSION

Although the relationship between industry and university is not based on a common set of expectations, the collaborations between industry and universities are increasing and are maturing, i.e. both parties experience the collaboration as a win-win situation. Serious difficulties often originate from sloppy (legal) preparation of research collaborations. Most universities and pharmaceutical companies have put a lot of effort into educating scientists in the reasons why agreements are so important and what the risks are related to careless preparation of research collaboration. Even more fundamentally, the fact that both industry and universities have created and developed Technology Transfer departments has been a big step forward. It is very likely that the European situation will evolve to resemble more and more the U.S. situation where collaboration between industry and universities have proven to be important seeds for innovation, the basis for further growth.