Motivation, obstacles and strategies to the industry-university interaction in the British pharmaceutical system of innovation[1]

Subtheme: University-industry-government linkages

Keywords: industry-university interaction, pharmaceutical sector, UK.

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Introduction

The pharmaceutical sector in the UK is one of the most important ones in the UK. It is fifth largest market in the world in sales, the third largest in exports (£12.2 billion in 2005) and in trade surplus (£ 3.4 billion in 2004, being the top three industrial sector in the country in terms of trade surplus consistently). Moreover, the two UK big pharmaceutical companies are among the largest ones in the world and the whole sector employs more than 73,000 people directly (HCHC, 2005; UK pharmaceutical directory, 2009).

In terms of R&D, it is also very representative as the pharmaceutical industry invests some 30% of sales (more than £3 billion a year) into these activities in the UK, which made it the largest investor[2] in healthcare-related research in the country. Not only is it an important investor, but also a R&D performer, conducting 65% of health-rated R&D. Around half of the drugs sold in the country was developed there. More than 29,000 people are employed in R&D departments of drug companies, among these one of the largest percentages of graduates in the private sector (HCHC, 2005; UK pharmaceutical directory, 2009). The evolution of R&D activities in the pharmaceutical sector led companies to look for external partners to improve their innovative capacity. One of the most important partners to pharmaceutical companies is the universities. The industry-university interaction is very well developed in the pharmaceutical sector in the UK, as it has good research universities and research intensive companies. UK Higher Education Institutions (HEIs) have a number of disclosures, more than 3,500, and a cumulative portfolio of 13,978 patents. Many of these patents would be related to this sector of interest to pharmaceutical companies, thus licensed to these companies. Focusing on Sector Skills Councils (SSCs) and Standard Industrial Classification (SIC) health is the third most common sector in which HEIs are engaged in (HEFCE, 2009).

The study about the UK pharmaceutical sector aims to identify the motivations, strategies and obstacles to the industry-university interaction. It will help to understand and learn about the positive strategies undertaken by companies, universities and government that led the sector to a virtuous development.

1. Methodology

The study was preceded by a literature review and secondary data analysis that aimed to contextualise the study showing the UK industry-university interaction numbers and characteristics. It

[1] The paper is based on a field work carried out during the author's PhD exchange programme in the Science and Technology Policy Research (SPRU) in the University of Sussex, which was funded by CAPES (Brazilian Ministry of Education Funding Agency).
[2] Eight times more than the Medical Research Council (HCHC, 2005).

was based mainly on UK reports and surveys about industry-university interactions in the pharmaceutical sector and also on papers about knowledge transfer.

The field work consisted of 12 interviews with the UK pharmaceutical system of innovation actors, e.g. companies, universities, charities and government institutions. Among these there were 2 national pharmaceutical companies, 2 foreign pharmaceutical companies, 2 academic researchers, 2 university liaison agencies[3], 2 TTOs from charities and 2 TTOs from Research Councils. The interviews were based on open questionnaires; most of them were done by phone and recorded. Although the number of interviewees was not very large, all of them are representatives from very important actors of the system. The main topics discussed in the interviews were the motivations and the strategies to interact, the government role and the main obstacles to the interaction.

The main topics discussed in the interviews were the motivations and the strategies to interact; the government role; the activities done in collaboration; the intellectual property rights (IPRs); the role of liaison agencies and the main obstacles to the interaction.

2. Results

2.1. Industry-university linkages in the UK pharmaceutical system of innovation

The pharmaceutical sector, which is a science-based sector (Pavitt, 1984), has the scientific knowledge as a key input for its innovative processes and for that reason pharmaceutical companies have a strong propensity to interact with universities. As a result, the UK pharmaceutical sector has increasing significantly its interaction with research institutions, not only because of Government policies and programmes, but also because of companies' strategies to grow. The propensity to interact and the type of activities performed in collaboration will depend on the level of development of the pharmaceutical companies, especially in terms of R&D; on the level of academic and scientific excellence; and on the business, legal and political environment. In the UK, all these factors are quite positive to enhance the interaction. Albuquerque and Cassiolato (2002) highlight the development of the UK health care system of innovation as a positive environment to industry-university collaborations. Kleyn *et al*. (2007) affirmed the fact that the UK and European government support for collaboration between BioPharma companies and universities has been increasing during the last couple of years. Recent investments from the UK Government in the health sector classified it as a national priority and commissioned a report on "Improving National Health, Increasing National Wealth" that identified investments priorities until 2015 with special attention to university knowledge-transfer groups.

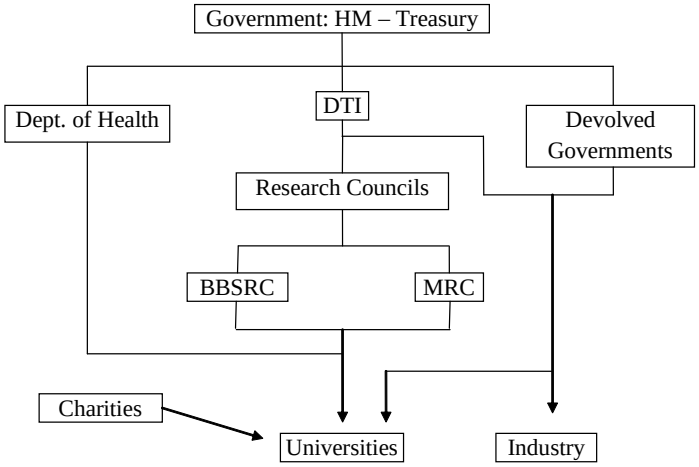
Most of the attention to the sector is expressed by several different government funding schemes, especially to research, development and innovation. The biopharmaceutical basic research is funded basically by the Medical Research Council (£450 million a year) and the Biotechnology and Biological Sciences Research Council (£300 million a year) which have schemes like studentships, fellowships, research grants, special initiatives and interdisciplinary research collaborations. Mission-oriented R&D and industry-university interaction, on the other hand, are stimulated by several different schemes, such as: a) LINK and Faraday Partnership: to foster collaborations between academic and industrial sectors; b) Small Firms Merit Award for Science and Technology (SMART) and the Knowledge Transfer Partnership (KTP): to lower the commercial and technological risks of investments in R&D and innovation, specially for SMEs; c) the Higher Education Innovation Fund (HEIF): to build university's capacity for knowledge transfer activities. Some of these schemes rely on other government departments as well, like the Department of Education and Skills (DfES), regarding education in England; the Higher Education Funding Council for England (HEfCE), when it is specific to higher education funds to facilities and staff to carry out undergraduate and post-graduate teaching and basic infrastructure to research; and the Department of Health, regarding the design and funding

[3] Liaison agencies are technology transfer offices (TTOs) and business development teams (BDT).

of science and research policies to the health sector. The Department of Trade and Industry (DTI)[4] is responsible for funding basic and mission-oriented research, and it also works to stimuli the commercialisation and exploration of the knowledge and technology generated from the research. In this sense, many DTI schemes are made to enhance the interaction between industry and university.

Besides Government funding, university research in the UK also counts on a variety of other funding sources. Industry represents about 5% of total university funding, overseas funding, specially the EU, about 8% of the total and the UK charities have been increasing their contribution to about 15% of the total. In the health sector, specifically, the UK has some traditional and very relevant charities that fund the research significantly, such as the Wellcome Trust, the Cancer Research and The British Heart Foundation (D'Este *et al.*, 2007). Figure 1 below summarises the UK national system of biopharmaceutical research funding.

Figure 1: The UK national system of pharmaceutical research funding



Source: developed by the author based on D'Este *et al*., 2007.

Some evidences confirm the increase in industry-university relationship in the British pharmaceutical sector. Between 1981 and 2000, the number of co-authorship between companies and universities had a significant growth in Chemistry, Medicine and Biology[5] (Calvert and Patel, 2003). The CIS 4, the fourth edition of the Community Innovation Survey with company information from 2002 to 2004 (Eurostat, 2008), shows that universities and other higher education institutions (HEIs) are the third most important collaborators for the manufactures of chemical and chemical products (DG 24)[6] sector in the UK only behind clients (1st) and suppliers (2nd). D'Este and Patel (2007) showed that 67.4% of 754 academics researchers from Chemistry[7] interact with industry in meetings and conferences, 58.9% through consultancy and contracted research, 46.8% interact in joint-research, 45.2% in training and 17.3% in creation of physical facilities.

The industry-university relationship has been increasing and developing in the UK. However, most of the studies and policies still concentrate on specific structures and activities done in collaboration, such as, patent ownership agreements, academic spin-outs and income streams from license and royalties, as if there were no other ways to interact. D'Este and Patel (2007) show that actually other activities as consultancy, joint research, contracted research and training are much more common and spread in more universities than the activities mentioned before. The data from the HE-BCI survey showed above corroborate the authors' assumption showing the amount of income from each of the

[4] The main UK government actor for manage the system of innovation.
[5] Those are the main research fields to the pharmaceutical sector as showed in Klevorick *et al*. (1995) and Cohen *et al*. (2002).
[6] NACE Rev 1.1 classification. There are no data to pharmaceutical manufactures separately (DG 24.41 and DG 24.42) in the Eurostat database.
[7] As said before, among the disciplines analysed Chemistry would be the most related to pharmaceutical sector.

collaborative activities. In other words, knowledge exchange or is larger than technology transfer, which is one way of doing it. The narrow view of many studies was a stimulus for the field work carried out to this paper. Therefore, interviews were conducted with important actors of the pharmaceutical system of innovation in the UK to have a better understanding of the industry-university interaction and to get a deeper, wider and systemic view of the collaborative activities. The results from these interviews are discussed in the next section.

2.2. Motivations, obstacles and strategies to interaction

The interviews in the UK brought up a lot of interesting new information and also confirmed others. Certainly, the conclusions based on the interviews are limited, as the number of people interviewed is relatively small to be used as a proxy to the whole sector. However, the interviewees were experts in the field and in the topic representing important actors from the British pharmaceutical system of innovation. In other words, important companies, universities, research institutes, charities and government organisations were interviewed, for that reason it is possible to believe that the results are valid and consistent to the reality. The section is divided in 6 sub-sections that represent the main points discussed in the interviews: motivations, Collaborative activities and fields of science, strategies, government role, liaison agencies role and obstacles.

2.2.1. Motivations

The main motivation to interact with research organisations for all the 4 pharmaceutical companies interviewed was to access researchers' knowledge and expertise. Universities researchers are always moving forward in the understanding of some technology or some disease and this knowledge is very important to the drug development of pharmaceutical companies. The knowledge can generate new ideas, new technologies and new potential products. Moreover, new technologies can reduce the costs of developing a new drug; make the process faster and more successful.

Both researchers from universities had the same answer when they were asked about their motivations to interact with pharmaceutical companies. It was related to the possibility of the development of the invention into an innovation. In other words, it is the possibility to take the technology or molecule from the early stages through the development till it gets to the market. It actually means that the researchers are also looking for the company expertise and capability to develop drugs.

It is interesting to highlight that both university researchers gave the same reason to establish links with industry, even though the way they interact is completely different. One of them has been doing it exclusively through joint-research, while the other one interacts with industry basically through licensing, not establishing contact to the development of the research. Nevertheless, the later also has a seat in a company's advisory board, which is a position as a scientific consultant for the main strategies of the company. The researcher said it does not have influence on his work, even though it is also a way to interact with the industrial sector, but is an interesting and different activity.

Among the liaison agencies representatives the answers about the motivations to interact were more diverse. The only factor that the 4 of them agreed, even though not in the same level of importance, was that the collaboration with industry is a good source of funding to the university research, which complements the funding available and increase the capacity to do more research. Other motivations were good reputation to the university, which means that if the university interacts with industry it is acknowledge as one with high level of research; and source of knowledge, people and materials to the research. It was mentioned that the industry knowledge would help academic researchers to have a better understanding of "the real world".

2.2.2.Collaborative activities and fields of science

Licensing is the most visible way to identify industry-university interaction and the easiest way to measure technology transfer, through license incomes. For that reasons it is the most stimulated and acknowledge activity done in collaboration. However, it was not identified by interviewees as the most relevant one. They were asked to order in terms of frequency and importance five types of activities – joint-research, contracted-research, technology transfer, services and human resources training. The top three were joint-research, consultancy and licensing. 5 out of 9 interviewees that answered this question ordered joint-research as the first and most important activity performed in collaboration between industry and research organisation. Through joint-research the learning process tend to be more effective to both sides of the collaboration. The less relevant activity among the five, tough still important, was human resources training.

All the 4 interviewees from companies could not indicate precisely the percentage of products that had counted on research organisation collaboration to be developed, but most of them affirmed that this amount has been increasing in the recent years. One of them guessed that the activities in pre-clinical stages probably rose from around 10-15% to about 25% of development of products that has had activities done in collaboration with research organisations, nonetheless, at clinical stages 100% of the activities count on research organisations collaborations.

The main field of science at research organisations that interact with pharmaceutical companies usually are Chemistry, Pharmacy and Pharmacology, Biology and Physiology. This question was only made for companies and all of them (4) mentioned Chemistry as an important field of science for their R&D and innovation search. The other three fields of science were identified by 3 of the 4 companies in different orders.

2.2.3.Strategies

In terms of strategies to build links with research organisations, 2 out of 4 interviewees from companies affirmed that it is a company's strategy to go out and look for academic researchers for consultancy, services and collaborative research. In one of the companies, there is a great stimulus for inside researchers to publish and participate in conferences, where they can have contact with academic researchers. This company has increased from 10% to 30% the amount, in terms of finances, of research performed outside the company in the last five years. The strategy of another company is to go to conferences to meet academics and not only to establish contact to joint-research, but also to invite them to give lectures inside the company. This same company also finance PhD entirely or partially with government sponsoring the other share, as part of its strategy to interact with the academic world.

It is also important to highlight that those companies are not anymore concentrating those actions in the country where they are established. The strategy now is to interact with universities and research institutes worldwide and to build a global network. Although there is still an enormous concentration on interactions with European and US research organisations, it has been expanding to India and Asia. The interviewees from the companies affirmed that Latin America would also be an option if they were able to be more aware of the science developed there and knew about any expert in the area they are interested in. There was a consensus that Latin American country governments should have an effort in helping companies to find out what is going on in their scientific systems.

Research organisations' strategies to promote interaction with companies occur in two levels. Either it can occur directly through personal's contacts that happen both ways. Companies' employees contact researchers and researchers contact companies' employees in conferences, meetings or because of their publications. Or it takes place through the liaison agencies from the research organisations that were created to build a network to future interactions, to market out the research, to promote events with companies and academic researchers and to deal with contractual agreements and IP rights that

will come up from the interactions established. One of the interviewee from a liaison agency has a three phase programme to establish these interactions. Phase I is exchanging ideas and information, phase II consists in homing a research project proposal, and phase III is the development of transaction and contract. It is a gradual process of establishing a relationship, changing ideas and information through a period of time and then finding a project to be developed in partnership.

Both companies and research organisations nowadays have strategies to contact outside partners. 3 out of 5 interviewees questioned about this issue affirmed that the movement to build links would occur from both sides, industrial and academic. The other two interviewees stated that the liaison agencies have the role of contacting potential partners to the development of the research. It was commented that the liaison agencies sometimes organise a brief document about the invention to market it out, other times, companies go directly to the liaison agency to ask if they have something related to the area they are interested in.

2.2.4.Liaison agencies

The liaison agencies at the universities and research institutes have the mission to manage the IP developed from the research activities. To manage the IP means to identify promising research that has translational potential that could file for patent protection and then help researchers to find follow on funds so they can develop their research till a stage where companies might be interested in invest. The agencies will then keep a pool of candidates or pre-clinical opportunities to find the best partner to carry out clinical tests. They work together with researchers since the beginning of the collaborative research to identify and monitor the IP, and help with material transfer agreements. They also keep records of the technology transfer function and a database of patent filings; and do the finances and manage the income from the licenses.

One important and difficult activity reported by two interviewees from the liaison agencies was the selection of potential credible candidates to exploit the IP. It is major that the company which license the patent has a good condition to develop it into a product that will get to the market. A lot of elements can interfere in the drug development, to try to increase its possibilities the liaison agencies try to select the most reliable, appropriate and structured company to license the patent. Nevertheless, they say it is very difficult to do it all the time, because there are not many companies interested in the license and it is a difficult selection itself. These interviewees affirmed they select case by case considering diseases areas of interest, record in the area, and availability of resources to develop the drug. Another way to increase the security of the transaction is putting into the agreement safeguard clauses to ensure that the company will develop it further, take it to clinical trial, authorisation approval and sell the product. Other times they include clauses saying that if at some point for whatever reason the company want to drop the project the rights would go back to the liaison agency, which will be able to license it to another partner.

The importance of liaison agencies to the development of industry-university links has increased the number of these agencies in research organisations, also as a result of government stimuli as mentioned in the last section. Not only has it increased in number of agencies, but also in relevance, especially in some specific and very active research organisations. Among the 6 liaison agencies interviewed from universities, government funding and research institutions and charities, 3 are a separate company established to manage the IP, own it and help researchers to find partners and deal with contracts. Two of them are also starting to act in a broader way and work with other research organisations apart from the one they are directly related to. One of these performs an important activity to the pharmaceutical sector. It has its own laboratories with high throughput screening facilities to carry out follow on research and take the invention from the researcher laboratory till the proof-of-concept, a stage where companies would be more interested in licensing it.

Both academic researchers had positive views about the liaison agency's work. They affirmed that now they take care of all the contractual, IP and business agreements and it is much easier for them

to count on specialised assistance. However, from the companies' point of view some liaison agencies can make the transaction even harder. One of the problems of these agencies pointed by two companies was the high level of expectation of these offices about the return they can get from the IP license what makes them overvalue the IP. Another company related the problem when they are inflexible and want to own the whole IP without trying to negotiate it, most likely because of the metric they are measured by (licensing income). Nonetheless, it is not a rule to all of them, neither to all the cases of interactions, because three of the interviewees from companies reported that the good liaison agencies do help and make the interaction much easier. They said that most of the times the first contact and agreement will take longer to be negotiated, but the other times after that it becomes a smoother process.

2.2.5.Government role

Most of the interviewees (7/12), especially companies' representatives and university researchers, did not identified government policies and programmes as a stimulus to them to carry out collaborative activities. The motivations described above where actually the main drives to the interactions. At the research institute, most of the collaborative activities are self-financed together with the industrial partner, not by government schemes. However, 2 out of 4 companies reported to have some studentship grants together with universities, but it was explained that it is an action from the university that look for companies to established partnership to be able to apply for the grant. This money will fund PhD candidates to work in the laboratory. The company can collaborate financially and intellectually.

The interviewees from the liaison agencies from the universities, on the other hand, have a different opinion. They believe that the government has important programmes that stimulate the industry-university relationship, and, according to one of them, it had occurred in waves since the 1980's.It was also highlighted that recently the government is interested in the impact of the research, which can be social, economical, financial, etc. For this reason, it is strongly encouraging activities in collaboration with industry, so it can have a large and easier impact on society. One important scheme in this direction is the follow on funds that allow early stage research to get to a stage where industry would have more interest in license it.

The government has also set up a technology developing funding group called the Technology Strategy Board[8]. It is money that goes to the university to work in collaboration with industry. It may require an industrial partner or not, but in both cases the university is who receives the grant. This would be the main government programme to promote the industry-university relationship, but even though it was not mentioned by any of the interviewees from companies or research organisations as a stimulus to build interactions. Moreover, the UK government has also a very relevant role carrying out research through the laboratories from the Research Councils. The MRC has about 60 institutes all over the UK and the BBSRC has 5 institutes, most of them related to agriculture and food, but one of them is more medically focused.

2.2.6.Obstacles and ways to overcome them

A number of interviewees (3 from the companies and 1 from a liaison agency out of 9 questioned about this topic) identified the decision and negotiation about the IP as a frequent obstacle to the industry-university relationship. As a reason for this difficulty the achievement of an effective contract was also frequently mentioned by interviewees (2 from companies and 2 from liaison agencies). Publication was cited by 3 interviewees (2 from companies and 1 from a liaison agency) as a common problem on this kind of collaborative activities. Other problems also mentioned were difficulty to build a network, funding of the activities, learn how to work with a company, timing of delivery, diligence obligations and uncertainty about the future of the company.

[8] In the same way that the Research Councils fund research, it funds technology development.

Under UK patent law the employer of the researcher own the intellectual property rights. That means if a university researcher receives a grant from a fund institution, the university will be the owner of the IP. If it generates a patent and it is licensed, then there is going to be a share of revenue with the fund agency and the researcher that will get a small amount of the income generated. However, in industry-university collaborative research the rule is not applicable, because there will be employees from both institutions[9]. Therefore, it will vary according to who brought more knowledge to the collaboration. Companies affirmed to be quite flexible in this negotiation, agreeing with university ownership and co-ownership of patents, for instance. Nevertheless, 2 interviewees from companies also stated that if the researchers are being too radical and difficult to deal with they would establish their clear position and if necessary change the partner to a more flexible one.

Although companies affirmed to accept co-ownership, it was also said by an interviewee from a company and one from a liaison agency to be something quite complicated. The former affirmed that sometimes they would prefer that the university owns the IP and licenses it exclusively to the company. They would also establish an agreement that the company would have rights over any IP that could come out from that particular research. To solve this kind of problem the contractual agreements establish 100% of the IP to the university with company accessing it via licensing, or 100% to the company which pays royalties to the university. Despite all the difficulties, it is an obstacle that can be overcome. One of the researchers interviewed has 20 joint-owned patents with companies.

The IP negotiation problem is not only related to the ownership of it, but also to the costs of licensing. Two interviewees from companies and on from a university liaison agency commented on the unrealistic expectations and overvalue of the IP, from universities specifically. They tend to include overheads that raise the price of the license considerably. It means that universities sometimes are not only expecting to receive too much money from the licenses, but also that they are including the costs of maintaining the buildings, the labs, the computer equipments, employed staff, etc. This overvalue turns the university price of technologies and services non-competitive comparing to the market. In some cases, this is the only place where you can get it and universities take advantage of the absence of competitors.

Another problem cited by 4 out of 9 interviewees that is much related to the first ones is the achievement of effective agreements that would be able to satisfy the company and the research organisation. They said to be very hard to set up a contract that establishes the amount and source of fund, the ownership of the IP and the activities carried out by each party. TTOs had become a great help in these cases, but companies' background and understanding of research are also very relevant.

Publication was also cited as a frequent problem to be worked out in industry-university collaborations, as a premature publication can destroy any intellectual property that the company may wants to protect. However, interviewees from companies showed to understand academic freedom and their need to publish. The academic researcher stated that publishing is something that can be done, if you learn the rule about how to do it and if you are able to show its relevance to the company.

The way research organisations and companies try to overcome all those problems is mainly trying to be flexible, discuss and negotiate case-by-case, explaining to the other part its motives and points of view. One of the researchers highlighted that it is also very helpful when the company's representative that will deal with the research and the collaboration is someone with long-term academic experience. The liaison agencies affirmed to have some steps and routines to help the interactions. Moreover, it helps researchers to put together projects that might work, to build network and to be careful with publication that can affect IP rights.

[9] When the collaborative activity is a service the IP generated will belong to the company.

Conclusions

After carrying out those interviews, it was possible to get a better idea about the specificities of the industry-university interaction in the pharmaceutical sector in the UK. First of all, it is clear that a well developed industry in terms of research and development activities is extremely necessary to build an industry-university relationship. Only with a good in-house research structure and a well trained and experienced team, it is possible to communicate and work together with the academic world to achieve relevant results. It was clear that the establishment of a global network of scientific researchers is a strong strategy from the pharmaceutical companies and that they are acting pro-actively to build this network.

It was also interesting to see that the universities and researchers institutes are very open minded about this topic and are trying to improve their own structures and rules to become more able to build new links and to develop the ones already established. Those institutions are as well establishing ways to market out their pool of opportunities, to show their scientific capabilities and to have close contact with industry.

It is important to highlight the government support for the development of the academic research in the areas related to the pharmaceutical sector, not only funding university research, but also performing research in its own research institutes. Moreover, the government also supports and finances the establishment of new positions at research organisations to build the interaction between industry and university, and follow on projects to stimuli the interaction between these actors.

One issue that still seemed to be a very relevant obstacle to a smoother interaction between industry and university in the pharmaceutical sector is the intellectual property rights. Both sides say that they are working to become more flexible, but it may still have a long way to go.

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