Report on twinning

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Florin Zubascu and Shane McCollam joined Pharma Day on 25th April 2015 within task 1.11 of BASTION project. They have prepared a summary of event and they ran two interviews with Pharma Day participants. The materials were published on Science|Business web site.

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Poland making moves to lift barriers to investing in drug discovery

Shortcomings in the framework for clinical trials, little knowledge of intellectual property law and a dysfunctional relationship between scientists and technology transfer offices are holding backscience-industrycollaboration, but work is in hand to change things

Florin Zubascu

Medical researchers in Poland have plenty of good ideas and the intellectual capacity to pursue them, but they are having a hard time building effective drug discovery partnerships with industry.

In Poland, scientists show “huge resistance” when it comes to working with industry, said Duncan Holmes, head of Discovery Partnerships with Academia (DPAc) at GlaxoSmithKline. “But I come here open minded,” he told delegates at a meeting held to highlight the barriers to effective collaboration between research and industry, in Warsaw last month.

The meeting of medical scientists, IP specialists and representatives of big pharma was organised by BASTION, an EU funded project that aims to reduce the time from scientific discovery to clinical application.

Poland has got great scientific heritage and Holmes said that is one of the reasons why big pharma is still looking for investment opportunities there. However, Polish scientists have got to be open to this interest. “Big pharma will not keep coming unless you are willing to stand up and talk about the research you are doing,” he said.

Overcoming this reticence would allow scientists tocapitalise on the economic potential of their research and meet the industry halfway.

In recent years big pharma companies have put significant effort into setting up dedicated units with a brief to improve interactions with academics, Examples include the Johnson & Johnson innovation centres, Pfizer’s Centres for Therapeutic Innovation (CTI) and GSK’s DPAc programme.

GSK’s DPAc programme is looking around the globe for 10 to 15 partnerships with researchers that “undertake the best science” and “are focused on drug discovery,” said Holmes. These partnerships can be set up across any geography and in any therapeutic area, with the researchers sharingboth the investment and the rewards with the pharma company.

Another example is Pfizer’s CTI. These centres are separate research units with a focus on entrepreneurship which, “serve as accelerators for projects in academic research,” said Olga Krylova, Senior Director for External R&D Innovation at Pfizer. Researchers can tap into Pfizer’s know-how in regulation and commercialisation. Since 2010, Pfizer’s CTIs have, “evaluated over 1,000 proposals of which two have already reached the clinical development phase,” Krylova noted.

For the moment, there are obstacles on the road to fruitful collaboration between science and industry in Poland, including an incomplete legal framework for clinical trials, little awareness of intellectual property law, and the dysfunctional relationship between scientists and technology transfer offices.

Incomplete legal frameworks

“The Polish law on non-commercial clinical trials is very poor,” said Ewa Rutkowska, anexpert in pharmaceutical law, healthcare law and product liability. “But there are sparkles of hope,” she said. The Polish government is in the thick of preparing an amendment to the pharmaceutical law that open the door to non-commercial clinical trials.

Researchers complain about not being able to use equipment paid for by the EU in clinical trials sponsored by industry. This is prohibited by the rules of the funding. “These kind of situations block science-industry cooperation and the progress of science,” said Rutkowska.

Some of these obstacles could be avoided if Poland was more engaged in EU funding mechanisms and programmes such as Horizon 2020 and the Innovative Medicines Initiative, argued Janusz Bujnicki, head of Laboratory of Bioinformatics and Protein Engineering at the International Institute of Molecular and Cellular Biology. Poland,“Is not involved in designing EU funding mechanisms,” he said.

Another hole in the Polish legal framework is a lack of special provisions to ensure thetransparency of science-industry collaborations. In healthcare, “cooperation is inevitable, but let’s do it in a fair and transparent way,” said Rutkowska. To achieve this, stakeholders should be more proactive and “encourage decision makers to implement lawsthat offer incentives and not obstacles,” Rutkowska recommended.

Last but not least, the Polish tax law lacks key provisions relating to the fiscal status of research grants coming from industry.

No IP, no commercialisation

Until last year the Polish IP law was not clear about who actually owns a patented invention, causing much confusion between scientists and research institutions. A new law, “is a good direction, but it’s still not perfect” said Rutkowska. There should be more flexibility, enabling scientists to earn money from their inventions.

In addition, a low level of IP awareness can be a barrier in the drug development process, said Magdalena Tagowska, patent attorney at PATPOL. Scientists in Poland overlook many important details. They “do not look into the patent database and many get heartbroken when they find out their ‘invention’ has already been registered,” said Tagowska.

At the same time scientists are drowning in paperwork and do not have enough energy to do their research and take care of the legal stuff as well,Tagowska said, suggesting this is a burden which could be relieved by technology transfer offices.

Piotr Kaminski, managing partner at Kaminski & Partners, warned scientists about the dangers of publishing research results before legally protecting the IP.Once the results are published scientists will not be able to find partners or investors from the industry. “Publish and be damned,” he said.

Kaminski echoed Tagowska's view on the low IP awareness of scientists in Poland, arguingscientists musteducate themselvesabout the importance of IP if they ever wish to commercialise their research results.

Technology transfer offices are waiting for scientists to catch up

Tech transfer offices have a crucial role in oiling the wheels of science-industry collaborations. Theyknow about the expectations and the needs of the industry and have the ability to advise scientists on commercialisation opportunities.

However, as things stand"Mostdrug development projects are at an early stage and are not mature enough to show to investors," said Maciej Wierzbicki, head of technology transfer at theBioTechMed cluster.

While early stage drug discovery projects in Poland have attracted interest from big pharma there are no successful spin out companies. "I hope that in a few years there will be this very famous Polish biotech company," said Andrzej Kusmierz, founder & CEO, Idea2Business. Then, "We will be able to say this is the place to come for early stage drug discovery projects."

A survey of scientists, experts, tech transfer officers and investors conducted by Idea2Business, suggested that to speed things up, Warsaw needs an independent biotech incubator. "Leaders of the best research teams said they have many ideas and would like to have a place where they can go freely without being defined collaborators ofexisting institutes," said Kusmierz

How Poland can play to its strengths

"Poland should play to its strengths and find its competitive advantage" said Marcin Makowski, associate director for Centralised monitoring at AstraZeneca. "[Poland] has the capability to recruit a lot of patients in early phase clinical trials," said Makowski. "Our biggest asset isthe quality of human resources."

To tackle the shortcomings in science-industry collaboration in drug development projects, Bujnicki suggested there should be more interchange with Polish scientists and business representatives from abroad.

This view was echoed by Duncan Holmes. "More dialogue between the different groups involved is really valuable," he said. Big pharma companies will not invest in universities where there is no, "form of engagement to drug discovery," said Holmes.

Patents can make or break drug discovery in Poland

Florin Zubascu, Science|Business

There are several barriers holding back science-industry collaboration, but the most urgent one is the reluctance to protect intellectual property in advance of publishing research results, according to two of Poland's leading patent attorneys


Magdalena Tagowska, patent attorney at PATPOL


AgnieszkaŻebrowska-Kucharzyk, patent attorney at PATPOL

As delegates at Pharma Day last month in Warsaw agreed, a lot of Polish scientists are not aware of the benefits of intellectual property (IP) protection. And even if they are, they choose the publishing path instead.

As Poland is making moves to lift barriers to investing in drug discovery, convincing scientists to choose IP protection over publishing their results is of utmost importance, the meeting held to highlight the barriers to effective collaboration between research and industry was told. Without IP, the much coveted big pharma investments in drug discovery projects are unlikely to materialise anytime soon.

To find out more about the reluctance of Polish scientists to patent their discoveries and why they prefer to publish, Science|Business interviewed Magdalena Tagowska and AgnieszkaŻebrowska-Kucharzyk, patent attorneys at PATPOL, one of Poland's top patent law firms.

Many scientists seem to be discouraged after a failed first attempt, as filing in an application requires a lot of effort. "Sometimes you have to do more than one application in order to get some kind of success," said Tagowska. Unfortunately, that is when scientists decide it is easier for them just to publish and forget about patenting altogether.

Filing a national patent application is quite easy because the costs are low. However, it gets harder once scientists decide to register abroad, with many steps required to get their application ready, Tagowska said. "There is too much burden on the scientist to do everything."

Technology transfer offices (TTOs) can help out in this process, taking on some of the administrative burden. But, the relationship between scientists and TTOs varies across universities and it depends on the people working there. "Some do a great job and really help scientists, but others don't," said Żebrowska.

First, scientists have to first convince their transfer office they have a good invention. Second, scientists need to secure the funding for the application costs, then they have to deal with a lot of paperwork, inspections and reviews. “It is very difficult,” Tagowska said.

It is also the case that not all universities are interested in commercialisation and patent applications. “In Poland we need more regulation in this area,” said Żebrowska. Governments should encourage commercialisation of research, but at present scientists in Poland are not used to being involved in innovative projects. “They are doing science just for the sake of it and they are not looking for something that can be applied,” said Żebrowska.

Some universities offer little or no incentive for scientists to get their discoveries commercialised. “There is no point in making a patent if you don’t plan to do anything with it,” said Tagowska. “There should be some mechanism helping scientists go further to commercialise their invention,” she said.

However, change may be coming, with EU funding educating students in IP management and free-of-charge tools such as the IPR Helpdesk now available. “We think these are very useful and we hope that the next generation of scientists will realise how useful it is to know more about patenting, said Żebrowska.

But while the system works elsewhere, “here we have some problems with it,” said Tagowska.

“We need some examples to show the system can work,” she said.

Getting the right IP expertise

Very often researchers are disappointed to find out that their “invention” is already patented. In other cases, they may succeed in registering the patent but it turns out there is no interest from investors. “I think the decision-making process should be simplified and made by people who have a feel for the industry and actually know what is needed,” Tagowska said.

However, there are not many patent experts who can help scientists with the evaluation of their projects. Poland has fewer than 1,000 patent attorneys of whom only about 300 are active. And not many of them have technological background. “Most of them are lawyers and deal with trademarks and designs and litigation,” said Tagowska.

But interest in the profession is growing with more and more attorneys are following international patent databases to learn the best way to help out Polish scientists. “We followed the progress of international patents and we learned from that,” Tagowska said.

Is big pharma ready to invest in Polish IP?

In the past five years the number of patent applications in biotech and pharma has grown on the back of increasing levels of public funding, with Polish science projects attracting money from the EU. As a result, “We observed a great change in the way scientists are thinking and their attitudes towards patents,” said Żebrowska.

But while scientists may think their projects speak for themselves, to attract interest from big pharma they need to be more proactive. Big pharma is not yet ready to acquire Polish IP. “We do not see of that kind of cooperation,” said Tagowska.

Making progress will require a change of mind-set. In Poland, the government and the universities are not encouraging scientists to commercialise, preferring them to publish instead. Being granted a patent is seen as a lesser achievement than doing the science. “If you want to get recognition in the scientific world you should not patent. This has to change,” Żebrowska said.