SCOTTISH LIFESCIENCES ASSOCIATION

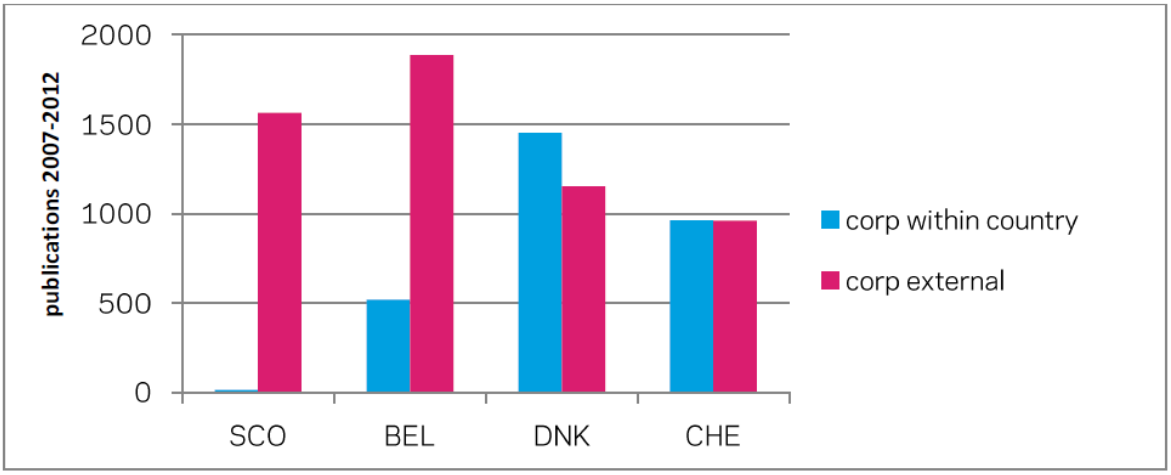
Life Sciences in Scotland - University / Business Issues

Background and Evidence

1. The Scottish Lifesciences Association (SLA) is the trade association for life sciences companies in Scotland, and has over 130 members. Nearly all of the industry representatives who sit on LiSAB are SLA members; Ken Sutherland chairs the Association. The SLA is glad to submit this evidence to the ISF / LiSAB IP hearing on 11 November.

2. Scottish universities perform a vital role in training the many graduates and post graduates which life sciences companies need to recruit each year as they grow their businesses. Life sciences employment in Scotland grew by 15% between 2009 and 2012, with around 640 life sciences companies and organisations employing 33,000 people, many of them in relatively high tech, well paid jobs. The universities have an international reputation for research in life sciences, which is a key sector of the Scottish economy, and are large employers in their own right. University / business links in life sciences should therefore be significant in helping to promote sustainable economic growth, but that promise has failed to materialise in terms of university generated IP driving significant levels of company growth and employment here in Scotland.

3. A report by Elsevier for Scottish Enterprise last year highlighted this. Using the metric of university publications on collaborative research with companies, it compared the performance of universities in 4 countries including Scotland on how frequently they interacted with (a) life sciences companies outside the country and (b) life sciences companies within the country. Universities in all four countries did well on (a), while for (b), the other three countries did well to varying degrees, but Scottish universities hardly collaborated at all with Scottish life sciences companies, as this chart shows:-



Source: International Comparative Performance of the Scottish Research Base in Life Sciences; a Report prepared by Elsevier for Scottish Enterprise May 2013

4. The Scottish university / business interface has been reviewed often as part of a wider issue – that the UK's track record in commercialisation of university research is not good. Many attempts have been made in Scotland to address it, but we submit that there are still significant barriers. Too few life sciences companies are in business in Scotland as a result of the commercialisation of Scottish university research, despite the Scottish Government putting large amounts of money into university-based infrastructure to try to

stimulate economic growth in the sector. The common term used by smaller life sciences companies to describe their interaction with Scottish universities is "nightmare", although many of them (e.g. Axis-Shield in Dundee) interact successfully with universities in other countries, as well as with *some* Scottish universities. The Elsevier report illustrates one of the effects of this issue for Scottish life sciences – a lack of collaborative research with indigenous companies.

What are these life sciences university / business issues?

4. We have sought to analyse the issues in consultation with our member companies through our SLA Innovation Special Interest Group, which is chaired by Dr David Pritchard, Research Group Manager at Axis-Shield. We endorse the need for universities to do pure research, but we believe that there are several significant issues which need to be addressed:-

- The tendency for academia to do too much "me too" research (driven by a focus on research status and the need to publish results) as opposed to commercially useful, practical research is one;
- Overvaluation of underdeveloped university derived IP is another, which creates the consequent difficulty for companies who want to secure exclusive rights to that IP in order to commercialise it;
- The insistence of each university on using its own voluminous legal documentation when dealing with SMEs wishing to license IP, but who do not have the resources to process it, and so often walk away;
- University research sometimes competing with the commercial activities of life sciences companies.

5. We were interested to receive the questions issued to LiSAB members in preparation for the hearing. Dr Pritchard has answered them from his own extensive experience; his responses are at Annex A.

6. There has in our view been a failure of well-intentioned Government moves to address the issues, including:-

- the Intermediate Technology Institute (since closed down);
- setting up Technology Transfer Offices (TTOs) in universities;
- the more recent attempts to embed Easy Access IP into all Scottish universities, under which companies could gain exclusive access to university IP in a quick, simple and cost-free way; and
- plans for an Integrated Knowledge Exchange Office covering all universities, which would have provided a single point of contact for life sciences SMEs to all commercialiseable life sciences research in Scotland, but which has not fully come to fruition.

What should be done?

7. Through the means of the Health Innovation Partnership, NHSScotland is starting to act as a driver of economic growth in Scottish life sciences. The SLA believes that serious consideration should be given to structural reform of the funding of university research to greatly raise the value placed by the HE sector itself on commercially valuable research done in close conjunction with Scottish life sciences SMEs, in order to encourage the transfer of the results into the economy. We are under no illusions about the scale of this challenge, or the timescale, but other countries (e.g. Canada / Korea) have addressed it,

with their universities focussing hard (albeit not exclusively) on commercially valuable research and working closely with local companies.

8. It may be a step too far to make it illegal for Scottish universities to actually own IP. However, we believe that a radical solution needs to be considered, in order to unlock what should be the potential represented by the HE sector as a driver of economic growth in Scottish life sciences. That is why we have proposed to the Smith Commission (see Annex B) that the UK Government's funding to the UK Research Councils should be reviewed, and an appropriate proportion of it devolved within the ambit of the Scottish Government Block Grant, and ring fenced to SFC. At the moment, RCUK funding accounts for 25% of all Scottish university research funding. This funding would be allocated by SFC, along with its own research budget, with a caveat that a specific share of the total is devoted to commercially translatable university research in partnership with companies in Scotland.

9. Meantime, we observe that Scottish Funding Council (SFC) funding comprises even more (34%) of all Scottish university research income, and that this research funding is allocated with no caveats beyond the stipulation that it be used for "high quality" research (and the decisions on what constitutes "high quality" is taken by academic panels). We propose that this should change, and that at least some of this funding should be allocated with the proviso that it be devoted to commercially translatable university research in partnership with companies in Scotland. The metric by which to measure the success of this arrangement would be an increase in the number of Scottish research projects in which companies are collaborating with Scottish universities, as measured by the number of university publications on these collaborative research projects. The outcome would be stronger growth in the life sciences sector and the Scottish economy.

10. We also propose that the Scottish Government should review the objectives it had when it asked the HE sector, via SFC, to implement Easy Access IP and an Integrated Knowledge Exchange Office. These requests were not completely ignored, but in our view, implementation is not achieving the desired results, one of which was sustainable economic growth in life sciences. We propose that these mechanisms should be re-designed and implemented in a way which, inter alia, makes life sciences business growth based on university research an explicit objective. It would help universities to maximise the income generated from successful collaboration with industry – the University of Glasgow earns around £1m a year from licensing IP, and £65m a year from industry collaboration.

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ANNEX A

Questions for discussion

The following views are those of Dr David Pritchard, Research Group Manager at Axis-Shield and Chair of the SLA Special Interest Group on Innovation, given in response to the questions put by Scottish Enterprise.

1. What has been your involvement in and experience of HE / business collaboration?

As head of the Research Group within Axis-Shield I have had extensive involvement with HE organisations around the world. This experience had mainly been in seeking commercialisation opportunities for new diagnostic markers or technologies, but has also been in seeking academic partners to undertake particular programs of work for us.

2. From your experiences, what value have you (seen) secured from HE- business interactions; what has worked well and what barriers have you encountered?

What has worked particularly well has been:

- Primarily within USA, Canadian and Scandinavian Universities, the Tech Transfer Offices are good at proactively discussing and understanding the types of opportunity that our business is seeking, resulting in early, focused and relevant communication of potentially interesting opportunities.

- Many (but not all) universities are starting to have a more realistic view on the value of their IP, and on how much work is required to take this from concept to a full commercial product.

- Some geographical areas have a single portal to view IP and initiate licensing discussions.

Things that work less well are:

- Many universities within Scotland (and within the wider UK) are not particularly effective in highlighting opportunities to relevant companies. I have 'inadvertently' come across technologies arising within Scottish Universities that they should have been banging on my door about. This contrasts with for example some parts of the USA, where I receive very targeted and frequent communications.

- Within the UK (and particularly Scotland) where an academic moves from one institution to another the IP status becomes complicated or even completely lost. 2 specific examples.

    i, A research group moved from one English university to another; both universities are seeking rights to the IP produced by this group, which is greatly complicating agreeing commercial terms (and indeed is producing a very real risk that the IP will not be licensed and commercialised at all).

    ii, An academic who had filed patents for an interesting new diagnostic marker moved from one Scottish university to another. On contacting the original university, we were told that the IP had moved with the academic to

the new university. However, despite several attempts to contact the new university regarding this opportunity, no response was obtained and therefore the potential to commercialise this work was lost.

This issue could be overcome by having a common portal for all IP within Scotland (although as shown in example i above this a UK wide problem and a UK wide portal would be even better).

- There are too many small public sector groups working on innovation, IP commercialisation and HE-Business interactions within Scotland. At a recent meeting of the Scottish Lifesciences Association Innovation Special Interest Group, all of the attendees were aware of some of these public sector groups but it was evident that no-one knew of them all and in particular did not have an understanding of particular roles and responsibilities of these groups (there was a perception that there was a lot of overlap between them). It should be noted that this SLA SIG is composed of people within industry that are likely to have most interaction with and understanding of these public sector organisations.

- The full economic cost model applied by UK universities to interactions with business is a considerable barrier to establishing collaborations. It is often more cost-effective for businesses to work with universities outside of the UK even when grant funding is available. A specific example is a project that we wished to undertake with a Scottish university. This was eligible for KTN funding but even with this support, the cost of the project to the company was double that of getting the same work performed by a university in Spain.

- It is often the case that 'university academics' only look to engage with industry when seeking support for grant funding (and require a letter of support from industry etc.), This can engender a view that their concern is only in 'research' and that end-products are of little interest.

3. How can (the treatment of) intellectual assets, including IP a) facilitate university-business engagement b) support business innovation

Much of this is addressed in answers to other questions, but I believe that overall a more collaborative approach would be beneficial. This collaboration and business engagement should be from an early stage and would result in stronger and more valuable IP that would benefit academia, industry and Scotland as a whole. For example, I have seen IP (originating in Scotland) that was essentially worthless whereas it could have been transformed in to valuable and effective IP had industry been consulted about what claims were commercially important. However, I should note that on several occasions a major Scottish university has approached me seeking guidance on the commercially important aspects of IP and how to structure the patent and claims accordingly.

4. Does the treatment of intellectual assets, especially IP, support the success of universities and businesses? How does the approach in Scotland compare internationally?"

The success of our company is based upon IP, and how it is managed is a key component of our strategy. In my experience, innovation within Scottish universities ranks among the best in the world, but the biggest difference that I observe with some other countries is the desire and framework that universities in these countries have to translate this in to a

commercially viable end-product. To some extent, this is driven by academics within Scotland being rated by their publications and grant funding rather than industry engagement. I often find it frustrating that it is easier for me to identify and discuss opportunities in Massachusetts or California universities than a Scottish institution that is tens of miles down the road.

5. Should companies have free access to all University IP? What are the pros and cons of such an approach for universities and businesses?

Our view on this is rather ambivalent. An advantage could be that it would remove the sometimes unrealistic expectations of a substantial up-front fee for what is still a high-risk undertaking. On the other hand, universities need to guard against companies acquiring free-of-charge IP in order to block others developing products that challenge their own (i.e. obtaining IP so that it sits on a shelf but blocking others from entering the market). For many companies in life sciences, the substantial investment required to commercialise a product is only financially viable if they have an exclusive licence to the IP and this needs to be taken in to consideration. My personal view, is that in general, free access to University IP is worthy of consideration if the University has failed to obtain commitment to a more traditional licensing arrangement within 6 to 12 months of filing the application.

6. Do universities and businesses value IP differently? How do they determine that value? What value is realised from IP by universities and businesses?

In general the answer to the first question is 'Yes', although there are differences between countries, regions and individual universities and we are starting to see university valuations become more 'realistic'. Unsurprisingly, university assessments of value may be based on best case scenarios (e.g. assuming that everyone in the total available market will use the product 5 times a year at £50 a time) whereas the business assessment of value is often based on a (frequently single figure) percentage market penetration with a lower unit price. In our experience, universities can fail to appreciate that there is frequently still considerable risk for companies that acquire IP and that a very substantial effort is required to produce a commercial product. It is worth noting that changes in the marketplace and in patent law in major territories are almost certainly having a detrimental value on IP, for example the US Supreme Court ruling on 'patenting of natural phenomena' means that US patents are now not likely to be granted in many areas of the life sciences. My personal preference is to base agreements mainly around royalties upon sales as that seems to be fairer to all parties with the return being based upon actual market uptake rather than trying to predict (and basing license fees etc. on) what might happen.

7. Would the economy benefit from a single set of terms and a common process used to spinout companies/license IP from all Scottish universities? Are there limits to standardisation given the wide diversity of contexts?

In our view such a system would be advantageous as it would facilitate more effective and rapid discussions. We believe that flexibility would be required to adapt to particular circumstances and requirements but that starting with a *pro-forma* set of terms would be a good way forward.

8. Scotland appears to suffer a failure to grow "companies of scale" across the board, [but particularly in the life sciences sector]. Why don't [lifescience] companies grow to a larger scale in Scotland & are there any changes you might suggest to address this?

One factor here is that the life sciences are generally a highly regulated environment, and therefore it is difficult for a small organization to proceed past a certain stage due to the investment and resources required to pass these regulatory hurdles. Sometimes, universities seem to proceed down the 'spin-out' route without giving adequate consideration to licensing to an existing organisation (although this may just be that appropriate business have not been approached). One option might be that smaller companies might partner with larger organisations, which could bring their experience, knowledge and resource to assist with particular elements of the project. It is likely that any dilution of the small organisation's potential profit (e.g. from a royalty payable to larger organization) will be outweighed by the reduction in risk and facilitation of reaching the market.

9. What impact does the current level of resourcing and prioritisation (people/time/training/experience) – from universities, companies and support agencies - have on the success of negotiations, including those for IP licensing?

In my experience the levels of resourcing and prioritisation are adequate for negotiations including those for IP licensing.

Dr David Pritchard

Research Group Manager at Axis-Shield, Dundee and
Chair of the SLA Special Interest Group on Innovation

20 October 2014

ANNEX B

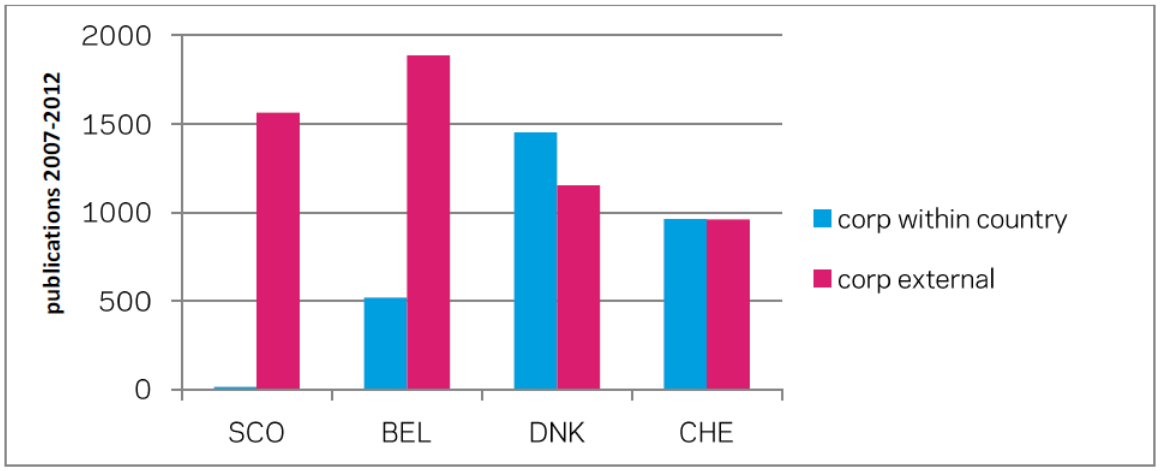
SLA SUBMISSION TO SMITH COMMISSION

Generating economic growth from Scottish university research in life sciences –

Proposed devolution of UK Government Science and Research Budget

1. **Background**: Scottish universities perform a vital role in training the many graduates and post graduates whom life sciences companies need to recruit each year as they grow their businesses – life sciences employment in Scotland grew by 15% between 2009 and 2012. They also have an international reputation for research in life sciences. A key sector of the Scottish economy, the life sciences sector comprises around 640 life sciences companies and organisations employing 33,000 people, many of them in relatively high tech, well paid jobs. University / business links in life sciences should therefore be significant in helping to promote sustainable economic growth, but that promise has failed to materialise in terms of university research and IP driving life sciences company growth in Scotland.

2. **Evidence**: This assertion is evidenced in a report for Scottish Enterprise last year by Elsevier. Using the metric of university publications on collaborative research with companies, Elsevier compared the performance of universities in 4 countries including Scotland on how frequently they collaborated with (a) life sciences companies outside their countries and (b) life sciences companies within their countries. Universities in all four countries did well on (a), while for (b), the other three countries in varying did well degrees. However, Scottish universities hardly interacted with Scottish life sciences companies at all:-



Source: International Comparative Performance of the Scottish Research Base in Life Sciences; a Report prepared by Elsevier for Scottish Enterprise May 2013

3. **Issues**: The Scottish business / university interface has been reviewed often as part of the wider issue of the success or otherwise of UK commercialisation of university research. Many of Scotland's successful life sciences companies interact frequently and successfully with universities in other countries (e.g. Axis-Shield in Dundee with University of California). However, few life sciences SMEs are in business in Scotland as a result of the commercialisation of Scottish university research, despite large amounts of Government money going to universities to stimulate economic growth in the sector. Issues include:-

- A tendency for academia to engage in research driven by a focus on research status and the publication of results, as opposed to doing commercially valuable research in collaboration with and for companies;

- Overvaluation of underdeveloped university IP, which creates a difficulty for companies wanting to secure exclusive rights in order to commercialise it.
- University research sometimes competing with the commercial activities of life sciences companies.

4. **Outline Proposal**: In many economically successful countries (e.g. Canada / Korea), universities work closely with companies in their countries on commercially valuable research. Many of the SLA's member companies believe that a new mechanism is needed to encourage those engaged in research in Scottish universities to raise significantly the value placed on commercially translatable research done in close collaboration with Scottish life sciences SMEs, with the specific aim of the company commercialising the results. We believe that this would unlock the potential for Scotland's world class universities to stimulate sustainable economic growth in Scottish life sciences, in addition to the research they already do with international life sciences companies.

5. **Proposed Mechanism**: Scottish Funding Council (SFC) funding comprises 34% of all Scottish university research income, with a further 25% coming from the UK Research Councils (£242m in 2012/13). These are average figures; certain universities get far more than 25% from the Research Councils, and others (e.g. Strathclyde) get very little. We propose that the UK Government's funding to the UK Research Councils should be reviewed, and an appropriate proportion of it devolved and brought within the ambit of the Scottish Government Block Grant, then ring fenced to SFC. This funding should then be allocated by SFC along with its own research budget, so that a specific share of the total is devoted to commercially translatable university research in partnership with companies in Scotland. The metric by which to measure success would be an increase in the number of Scottish research projects in which companies are collaborating with Scottish universities, as measured by the number of university publications on these collaborative research projects. The outcome would be further growth in the Scottish economy.

6. We believe that decisions on university research in Scotland should be taken in Scotland, and based at least in part on its commercial value. From a UK and Scottish Government point of view, the proposed change in Scottish university funding would be cost neutral, and would be aimed at strengthening growth in the Scottish economy. From the universities' point of view, accepting the proposed change and making it work well would justify their claim that they are the seventh key sector of the Scottish economy, a claim which we believe is difficult to substantiate on the evidence available, at least in life sciences. It would also help them to maximise the income generated from successful collaboration with industry – the University of Glasgow earns around £1m a year from licensing IP, and £65m a year from industry collaboration.

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