Society of Biology response to the Science and Technology Select Committee inquiry on the commercialisation of research

Released on 25 April 2012

The Society of Biology welcomes this opportunity to comment on the commercialisation of research in the UK and how it can be improved to realise the significant potential for growth that our world-leading research affords. The Society is a single unified voice for biology and is in a unique position to provide perspective on the commercialisation of research from across the breadth of the biosciences. This response highlights the issues surrounding translational research in the life sciences - a typically long-term and complex area that brings risk and opportunity. We have gathered evidence and expert opinion from our membership including in the medical, agricultural, plant, and nutrition sciences, to present the concerns of the community as a whole. The response is prepared with the Anatomical Society, the Association of Applied Biologists, the Biochemical Society, the British Pharmacological Society, GARNet, the Nutrition Society, the Physiological Society and the Society for Applied Microbiology, and with input from a number of individual Members and Fellows.

Summary

- The UK is a world-leading research nation with tremendous potential for science-led innovation and growth. Our leadership position may be threatened by the expanding number of researchers globally and by our relatively declining rate of national investment in research.

- Translational research in the life sciences offers great opportunity for growth but capitalising on this is typically a long-term and complex process for which funding is difficult to secure. Government should incentivize and support investment in early stage development research.

- The Growth Strategy rightly identifies that infrastructure investments needed for the future do not align with amounts available from traditional sources of finances; however the Government needs to set out measures to address these challenges and how this will work with current funding streams to produce economic gain.

- Collaboration helps to reduce risk, shares costs and brings in expertise, key skills and knowledge. This should be facilitated across university departments, between research institutions, and with a combination of government initiatives, industry and charitable support.

- Academics who engage in translational research should be recognised and rewarded appropriately, and supported in respect of filing IP and as founders of spin-out companies.

What are the difficulties of funding the commercialisation of research, and how can they be overcome?

1. Business Development Expertise

Universities differ widely in the expertise and experience of staff dedicated to the successful commercialisation of intellectual property (IP). Personnel (researchers or otherwise) must have the business development acumen to identify ideas with commercial potential from the range of ideas generated by the University, ascertain the true worth of the potential IP and develop suitable business collaborations to realise commercial opportunity. Similarly, SMEs may not have the requisite expertise to deal with IP. High quality commercialisation and IP protection and support should become integrated in the research phase and not just 'tacked on' at the end of the later development phase, and should not be exploitative of researchers, as some academics have found. Institutions such as UMI3, The University of Manchester Innovation Group [1] , provide information and resources for researchers in this respect. Similarly, Auckland Uniservices [2] in New Zealand was cited as a reason for re-location of one academic, who moved spin-out Symansis [3] to NZ from the UK. The Wellcome Trust Technology Transfer provides applicants with expert advice in commercial law and business development to enable funded projects to succeed. It would be prudent to learn from these and other effective models.

2. Academic Recognition

The excellence of a University or academic has until now been judged at review on the basis of scientific achievement, publications and achievement of grant-funding, with less focus on translation and impact. Thus the former have remained academic priorities. Greater recognition for achievements such as filing IP and forming industry collaborations (at a realistic value) could address this deficit and it may be redressed by the REF 'economic impact score'. Knowledge transfer should be recognised as a contribution worthy of academic recognition and reward. Economic impacts in terms of 'spillovers' from research are also important and where possible should be rewarded; the RAND Corporation and others have made some attempt to quantify this [4] .

3. Intellectual Property

It is important that high quality commercialisation and IP protection support should be incorporated throughout the whole process of translational research to commercial product. Across all sectors, the cost of protecting IP can be a major obstacle, and the proliferating need for IP rights can push up IP transaction costs and hinder small, younger firms from entering markets. Hargreaves' recommendations in his review of Intellectual Property and Growth [5] could particularly benefit SMEs, by delivering easier copyright licensing, a single European patent and access to lower cost IP advice. We look forward to the implementation of the Hargreaves recommendations and beneficial effects on innovation and growth in the UK economy.

4. Early Stage Investment & Risk

It is widely perceived that a lack of early stage investment and lack of proof of concept funding are common limiting factors of translational research. In the Life Sciences, significant investment is often needed to sustain the translation of basic

research until risks are sufficiently reduced to unlock other funding streams such as equity investment. Historically, schemes offered by the Regional Development Agencies to support proof of concept funding were useful to early stage University spin-out companies where matched funding could be secured. However, small start-up companies often do not have matched funding available and therefore are not eligible for such awards. SMEs can struggle to match-fund or have facilities to match in kind and are therefore less well able to progress a concept to market. This is addressed to some extent by Innovation Vouchers, although they afford only modest financial support. Seedcorn capital is required to plug this gap and enable access to the new schemes offered by the Technology Strategy Board such as the old 'Smart' awards.

Are there specific science and engineering sectors where it is particularly difficult to commercialise research? Are there common difficulties and common solutions across sectors?

5. It is difficult to commercialise research in areas where pathways to production are long. The difficulties of risk and its impact on securing early stage investment are discussed above and apply broadly and detrimentally to the life sciences; this has relevance for developments in food for human consumption and the related agriculture, plant science, plant breeding and health sectors. This is note-worthy not least because of the implications for growth, but also in the light of potential food insecurity associated with climate change, global fiscal uncertainty and habitat loss. Of relevance also are the regulations and restrictions on Genetically Modified Organisms discussed later in our response**.**

6. Developing Pharmaceuticals

The UK has specific challenges and opportunities around development of new drugs. However there is a risk that in the future there will be insufficient programmes to feed through into big development pipelines. Overall, pharmaceutical deal-making activity fell by 18% in 2011, driven by declining R&D productivity and 'blockbuster' drugs coming off patent [6] . The government must address this issue in partnership with universities and industry to ensure our true potential is realised for economic growth and societal health. This can be achieved by incentivising more openness and collaboration, encouraging the stratification of drugs and less concentration on a narrow range of clinical conditions and therapeutic approaches, along with concrete short-term incentives for risk-averse commercial companies to embrace these principles [7] .

7. The British pharmaceutical industry (Pharma) is conservative in the selection of drugs for development. Increasingly, because of the risk and long lead time, researchers must develop a drug to clinical stages before industry will take it on. This not only requires a great financial investment from the institution, but places the risk, at its highest, on the academic and university. As funding for proof of concept is extremely difficult to secure, Universities must 'pick winners' to develop a credible idea from the large number generated by research. At spin-out stage, the University remains liable for costs and must manage the company, ensuring a profit or sale, which may create a conflict of interest concerning the employment and activity of academic staff. Drug development requires large sums of money, and the time taken

for return on investment can be very long; this is not an area that appeals to the majority of venture capitalists (VCs). In addition, the UK pharmaceutical research sector has shrunk because of mergers and losses which means there are fewer companies to approach in search of relevant experience and capability. Given that few pharmaceutical companies are based in the UK, and trade sale or licensing is a key objective, pharmaceutical company start–ups with Angel investment are likely to see that their technology or product will be exploited outside the UK.

8. Drug discovery is a multistep process involving different research groupings, so it is important that the funding schemes are directed at funding groups that can also show a viable plan for commercialising the end product. This change from individual University department control could spread the financial cost and risk across departments, or between universities. The 'Easy Access IP' initiative has allowed a grouping of UK Universities to share early-stage IP in order to further develop opportunities in-house, maximising and simplifying university-industry partnerships [8] . It is important to capitalise on the strength of our universities with the capability to conduct complex early drug development studies in a safe environment and support inter-university technology transfer and knowledge translation in early development. It is also important that funding is provided for a reasonable length of time with appropriate milestones, and to maximise the value of early stage clinical trials. Long term collaborations that are based on in-kind contribution and other innovative non-financial vehicles should be recognised and supported.

What, if any, examples are there of UK-based research having to be transferred outside the UK for commercialisation? Why did this occur?

9. Asterion, a successful spin-out from the University of Sheffield developing novel therapeutic proteins was heavily funded by Beaufor-Ipsen, a French Pharma business, and by USA-based Genzyme when no UK-based funding or a joint research and development deal was forthcoming. As mentioned previously, Symansis was moved to New Zealand because of the decline of Pharma in the UK, and the beneficial IP protection support available there. Big Pharma's own recent retraction within the UK means that much UK research in this field must now be commercialised elsewhere.

10. Few large plant biotechnology companies exist in the UK. Recently, leading chemical company and GM plant specialists BASF stopped developing and marketing genetically modified crops in Europe to concentrate on the American and Asian markets this year [9] . The assumption that GMOs carry a higher risk than other types of novel foods from regulatory authorities and media alike has led to slow progress, increased development, trialling and registration costs, and high consumer scepticism. Government should base GMO legislation on sound science with a proportionate response to risk, and adequate support for GM research.

11. Regulatory barriers in the UK/Europe, especially around the conduct of clinical trials, along with GMO legislation mean that other countries are becoming more attractive as sites for commercialisation of research. The government should not only encourage other countries to have high standards and controls around ethical

concerns, but help simplify legislation in the UK to address this imbalance. For instance, transposition of European Directive 2010/63/EU should be harmonised across Europe, whilst maintaining high standards, to ensure that the UK is not at a competitive disadvantage in either in the fundamental or translatable research using animal models.

12. Research and development investment in a group of Asian economies (including China, India, Singapore, South Korea, Taiwan and Japan) has tripled in the past 15 years, and has now collectively reached the US level of investment (higher still than the UK's investment) [10] . Journal articles have tripled, high tech industry is being fostered, and China particularly is opening up research to external collaborations. Meanwhile UK applications to the European Patent Office fell by 9.4% between 2010 and 2011, while Sweden, Germany and France all increased their applications and China's patent applications grew by over 27% since 2010 [11] . Emerging markets in India and China have proved attractive to Big Pharma, with AstraZeneca and Bayer HealthCare forming partnerships with companies in the East in the face of declining Western sales growth [12] . A report by BIS on the International Comparative Performance of the UK Research Base states that while the UK is a leading research nation in terms of annual publications, and is far more efficient than larger countries (such as the US and China) in terms of output per researcher, our leadership position may be threatened by the declining share of researchers globally and by our declining share of global spending on research [13] , [14] .

What evidence is there that Government and Technology Strategy Board (TSB) initiatives to date have improved the commercialisation of research?

13. While it is still too early to quantify the tangible effects of the Government and TSB initiatives, some initiatives have been welcomed, the Knowledge Transfer Networks for instance showing some dividends. For example, in 2011 Medical Research Scotland changed focus and replaced its Project Grant with a new grant for PhD funding to support collaboration between industry and academia [15] . Novel elements in this approach include the company taking the lead in finding academic collaborators, and PhD students taking part in a Commercial Training Programme.

14. TSB funding is often provided at a near-market level research translation and not available to support early-level research translation. Defra initiative LINK provided support for translational research in the agriculture and horticulture sectors; bringing together researchers and industry and providing early-stage funding. However this level of support has been largely unavailable since LINK halted applications and its work was incorporated into the TSB.

15. Regarding Pharma, the Wellcome Trust 'Seeding Drug Discovery' initiative has been helpful in progressing early drug discovery programmes because it offers suitably large funds and allows both small companies and academics to apply. BBSRC Industrial Partnership Awards provide funding for early stage development [16] , and the MRC also has some good initiatives, for example the Developmental Pathway Funding Scheme/Developmental Clinical Studies scheme (DPFS/DCS), which provides funding for small proof-of-concept clinical studies. TSB funding streams could be reviewed to provide interdisciplinary support of this type for sufficient lengths of time; reflecting that different industries move at different speeds.

16. The Wellcome Trust Technology Transfer has several commercialisation initiatives in progress based on this model; the Stevenage Bioscience Catalyst [17] for instance operates as a partnership between Wellcome Trust, GlaxoSmithKline, the East of England Development Agency and the TSB, whilst Orthox [18] is supported jointly by the Wellcome Trust and TSB. It will take time to see if these partnerships translate into real products, however collaborating with industry, government and charities spreads the financial risk, and has the benefit of buy-in from experts with a variety of key skills and knowledge.

What impact will the Government's innovation, research and growth strategies have on bridging the valley of death?

17. The innovation, research and growth strategies recognise the role of SMEs for job creation and wealth, and we welcome initiatives targeting support for small companies and spin-outs. The additional £75m promised to TSBs is also welcome, as is the proportion of new funding made available for the Biomedical Catalyst Fund. The growth strategy rightly identifies that infrastructure investments needed for the future do not align with amounts available from traditional sources of finances; however the Government needs to set out measures to address these challenges and how this will work with current funding streams to produce economic gain. With the Science budget effectively cut by 15%, there is a need for smart investment by government to match that of our competitors and to encourage private investors to choose UK research and development. We need to make the most of UK's potential for growth not only in the biomedical sector, but also the high tech and agri-sectors that are not addressed in the Strategy for UK Life Sciences.

Should the UK seek to encourage more private equity investment (including venture capital and angel investment) into science and engineering sectors and if so, how can this be achieved?

18. Private equity investment could be encouraged through larger tax breaks and more opportunity to partner with government initiatives. However the government should also encourage longer term return expectations for life science research, and help bridge the gap in early stage funding at the pre-commercialisation stage when costs and risks are high. For early stage projects a step-wise investment based on early milestones may be helpful as it limits initial investment but then increases for investors who are progressing with the product. Funds could be made available for SMEs where job creation is high, not only to multi-nationals. Clear ethical frameworks and agreements must be in place for private investment in spin-out companies, and tax break rules should apply to research founders so they are treated as if they were employees (whilst remaining employed by the University), otherwise at each stage of investment, founder shares become diluted.

19. A successful example from Scotland is the Angel investment group in the Scottish Borders (TriCap) which have provided funding for several life sciences start-ups including MGB-Biopharma Ltd, Actual Analytics Ltd & Sphinx Biomedical Ltd. In the case of MGB over £2m was raised through Angel investment. A key element in setting up the ventures has been the Scottish Investment Bank which provides matched funding on the same terms as private investors. There is, however, a challenge to these companies in sourcing follow-up funding.

20. A major issue is the incompatibility between the Angel investment model (based on the single class of common shares necessary for investors to take advantage of the Enterprise Investment Scheme) and the venture capital model which has complexities designed to ensure the priority of the capital investors over common shareholders (including founders). This means that the start-ups have to be set up with business plans designed to lead to trade sales or licensing deals generating follow-on financing within the boundaries set by the original Angel investment. There are exceptions to this rule where follow-on rounds are raised by Angels but these are sometimes challenging.

What other types of investment or support should the Government develop?

21. The Government should not lose sight of the importance of basic research and allow for creativity that fuels innovation. Research in the fundamental or basic sciences, whilst not necessarily leading to commercially viable products in a linear fashion, are vital. This research is crucial for production of knowledge that may subsequently be fundamental to the future development of commercial products, and ensures that the UK maintains absorptive capacity relating to research from other countries. It also has use in terms of creating skilled graduates and post-graduates, as well as new scientific methodologies and instrumentation, all of which are key components of the process of innovation. A reduction in funding of basic research across all UK institutions will simply precede the loss of future commercialisation opportunities. With real-term cuts in the Science budget, we look to Government to not only recognise that innovation is the key to growth, but to invest strategically and with enough capital to ensure the UK is at least matched with, if not ahead of, our competitors.

22. The Government should support industry placements and secondments for early career researchers and students so that they have suitable industry experience [19] . The Society of Biology has developed a Degree Accreditation Programme to recognise academic excellence in the biosciences, strongly emphasising research experience and critically, time spent in an active research environment [20] . Industry experience is valued across the biosciences, but particularly where the UK is in danger of losing skills where we have excelled; skills in medicinal chemistry, *in vivo* pharmacology, plant sciences and agriculture-based skills. Government should engage in discussions with Learned Societies and their members about what actions they are taking to conserve these skills. In addition, talented international students with the potential to support commercialisation and growth should be supported and not hindered by immigration policy.

23. There is a disparity between the commercialisation of research in South East England compared to the rest of the UK [21] . SE institutions have better additional knowledge infrastructure and industry involvement, making them more competitive. Figures show that for spending on research programmes also varies widely across the UK. In 2010-11 for example London and the South East secured £748m and the North East just £94m [22] . These regional differences should be addressed, and networks built to improve knowledge sharing and to learn from existing models of successful translational research.

February 2012

1. The University of Manchester I3 (UMI3) was formed after the integration of the University's business incubation services provider, UMIC, and its Intellectual Property commercialisation company, UMIP. http://www.umi3.co.uk/

2. Auckland Uniservices manages the University's intellectual property and is responsible for all research-based consultancy partnerships and commercialisation. http://www.uniservices.co.nz/

3. Symansis https://www.symansis.com/aboutus/default Symansis is a company that produces high quality reagents for the use of researchers in the field of cell biology. The company was founded by a group of leading cancer research scientists from the UK, USA and New Zealand. The company is situated in the South Island of New Zealand.

4. Medical Research What's It Worth? : Estimating the Economic Benefits from Medical Research in the UK http://www.wellcome.ac.uk/stellent/groups/corporatesite/@sitestudioobjects/documents/web_document/wtx052110.pdf

5. Digital Opportunity. A review of Intellectual Property and Growth. An independent report by Professor Ian Hargreaves http://www.ipo.gov.uk/ipreview

6. Data from Pharma Ventures research drawing from its PharmaDeals database which follows, analyses and records deals world-wide and contains over 43,000 deal records. http://www.pharmaventures.com/aboutus/press/news/1698

7. Science Question Time: The Future of Drugs http://www.biochemist.org/bio/03401/0054/034010054.pdf

8. Easy Access IP http://www.easyaccessip.org.uk/

9. BASF to concentrate plant biotechnology activities on main markets in North and South America http://www.basf.com/group/pressrelease/P-12-109

10. Research in Asia heats up http://www.nature.com/news/research-in-asia-heats-up-1.9885

11. UK applications for Euro patents down 9 per cent http://www.researchresearch.com/index.php?option=com_news&template=rr_2col&view=article&articleId=1154750

12. PharmaVentures http://www.pharmaventures.com/aboutus/press/news/1698

13. International Comparative Performance of the UK Research Base – 2011. A report prepared for the Department of Business, Innovation and Skills. http://www.bis.gov.uk/assets/biscore/science/docs/i/11-p123-international-comparative-performance-uk-research-base-2011.pdf

14. Global Research Report United Kingdom http://researchanalytics.thomsonreuters.com/grr/

15. Medical Research Scotland
http://www.medicalresearchscotland.org.uk/funding.htm

16. BBSRC Industrial Partnership Awards
http://www.bbsrc.ac.uk/business/collaborative-research/industrial-partnership-awards.aspx

17. Stevenage Bioscience Catalyst http://www.stevenagecatalyst.com/

18. Orthox http://www.orthox.co.uk/

19. All together now: Improving cross-sector collaboration in the UK biomedical industry. NESTA Report March 2011
http://www.nesta.org.uk/publications/reports/assets/features/all_together_now

20. Society of Biology Degree Accreditation
http://www.societyofbiology.org/education/hei/accreditation

21. Higher Education Institution Knowledge and its Impact on Regional Competitiveness. ESRC Report http://www.esrc.ac.uk/my-esrc/grants/RES-171-25-0023-A/read/reports

22. Science: Finance Written Ministerial Answers
http://www.publications.parliament.uk/pa/cm201212/cmhansrd/cm120123/text/120123w0004.htm#12012339000022