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PRAXISUNICO RESPONSE TO BRIDGING THE "VALLEY OF DEATH": IMPROVING THE COMMERCIALISATION OF RESEARCH INQUIRY

Background on PraxisUnico

PraxisUnico makes this submission as a key representative body of the UK's research and development and technology transfer profession. PraxisUnico was formed in 2009 from two separate organisations - Praxis (committed to training for technology transfer officers in universities and research centres) and Unico which was a membership organisation including universities and PSREs (Public Sector Research Establishments). PraxisUnico has over 2600 members from 108 universities and research organisations and 48 commercial concerns, patent agents and intellectual property lawyers are associate members. PraxisUnico holds an annual conference and has delivered professional training to around 2500 individuals from 40 countries. PraxisUnico makes this submission having consulted its board and members.

Although originally focused solely on "technology transfer" (commercial deals involving intellectual property generated by universities), PraxisUnico members are engaged across the whole range of knowledge exchange activities, promoting the transfer of knowledge in all its forms across the boundaries of universities and into society.

Response summary

Our draft response reflects the following themes:

- Difficulties are multi-dimensional but we welcome the Government's commitment to exploring ways in which they can be overcome.
- In PraxisUnico's view, the University Challenge Fund scheme is one of the best examples of a public sector scheme that addressed many of the difficulties in the present environment.
- PraxisUnico would like the commitment shown to the bioscience sectors to be diversified into engineering and the physical sciences if the UK is to re-shape its industrial base.
- Although too early to address the TSB's impact, there is no doubt that its initiatives are providing a much needed stimulus to technology development. Recent changes are likely to

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have a positive impact as they will foster development across the 'valley of death' with closer working relationships to the university sector. PraxisUnico believes that the UK must have an innovation agency but it must take risks to work with new emerging businesses.

- Despite positive signs that the Government's innovation, research and growth strategies will have an impact on the bridging the 'valley of death' we are concerned that none of the recent announcements have specifically addressed the issue that a major stimulus is required to systematically re-shape the technology and corporate venturing market in the UK.

- The UK must seek to encourage private equity investment into science and engineering sectors.

- Investment funds that help to develop the outcomes of research are required that stimulate and avoid fragmentation. PraxisUnico believes that the University Challenge Fund scheme can provide an investment stimulus which can be deployed effectively in a multi-dimensional way.

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

Difficulties

The difficulties are multi-dimensional, and in simple terms there is no way to make it easy. The number of scientific ideas which get successfully into market will always be a small fraction of the total of ideas which are thought to have commercial possibilities. It is not possible at the first steps of commercialising an idea to predict the outcome; insufficient is known. We first need to tolerate failure. Secondly, we need to communicate and celebrate success. What cannot be tolerated is lack of effort and a failure to invest in our country's future.

The second difficulty is already being addressed. The introduction of Impact to the Research Excellence Framework has commenced the process of alignment between university research metrics and university success in both fundamental science and research moving to application in the market. A culture change is underway but it will take time to become fully embedded and this needs to be achieved alongside maintaining the UK's global position in basic science and engineering. PraxisUnico believes the solution offered below presents a further stimulus which would hasten this culture change.

The third difficulty is financial. In 2010 the British Venture Capital Association recorded VC investment as 4% of all VC and Private Equity investment at £313m out of a total of £8.2bn benefitting only 397 companies; of this VC investment, £10m was in seed capital and £46m in start-up. As a consequence of the high rate of failure and the nature of venture capital in the UK it is a significant challenge to secure investment in new technologies. At the same time the in-house research capacity of many companies is being reduced as they commit to open innovation. In many countries it is now clear that public funding is required to de-risk technologies (see the Entrepreneurial State - Demos Working Paper for international comparisons[1]). Research by the Russell Group of universities (published in 2010) has demonstrated that this is a long process, quoting an average of nine years from invention to a commercial deal (from the study of >120 case studies). Funds expended on translational research have increased in recent years but given the time from the emergence of a potentially commercial research finding to application can easily be more than seven years and can often be in excess of 15 years, it is simply too early to judge any particular scheme (but see fragmentation below). We cannot however wait to evaluate recent schemes, if part of the jigsaw is missing we must act now.

The fourth difficulty relates to fragmentation. Each Research Council, the European Commission and each of the major charities are committed to seeing the fruits of their funded research into application, and this is to be welcomed. However, this fails to recognise the nature of research.

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Very rarely is research in any research team funded by a single source. The commercial outcome emerges from groups with diverse funding sources, and increasingly from inter-disciplinary and multi-institutional teams. Each funding source has different rules which, in turn, increase the complexity of moving forward into the commercial domain. This is further exacerbated as it is also very rare that a single research idea will succeed without adding other technologies. Collaboration across the research community not just in research but in commercialisation will become increasingly critical.

The fifth difficulty relates to the absorptive capacity of the UK industrial base. There are two sub-components to this difficulty. First, overall business investment in R and D (of 1.15% of GDP for UK in 2008[2]) is very low by OECD comparison. Secondly, where we do have strengths the trends to globalisation are significant and few business R and D decisions are made in the UK from the perspective of benefit to UK - we would contend that this significant international dimension to UK BERD, whilst a strength in one way is a massive weakness in another. UK researchers looking for commercial partners will therefore increasingly turn to overseas partners with the consequent flow of benefits outside the UK, unless further action is taken.

The sixth difficulty relates to the shape of the UK industrial base which is dominated by large and small companies, but with few medium-sized businesses (CBI Future Champions report, October 2011[3]). This absence of medium-sized companies in part means that the businesses which could gain substantially from new technologies are few in number by comparison to other developed economies.

The seventh difficulty has also been addressed in recent years and this relates to UK Technology Transfer Offices in universities and public sector research establishments. PraxisUnico has now trained over 2500 professionals in the UK research base over the past ten years. However, staff churn means that this is a continual process. Income to universities from industrial R and D is now £900m per annum and income from intellectual property has been rising year on year. However, to evaluate outcome by examining income to higher education is the wrong perspective; the correct approach is to start considering the return to companies from acquiring university technologies. One possible metric is to look at the capital value of companies as they go through IPO or trade sale. Since 2003 the valuation of university spin-out companies which have come to market or trade sale is well in excess of £13bn (many trade sales are private and undisclosed). These figures are derived from 50 companies (see appendix insert list) and there are a further 1400 spin-out companies trading which will continue to feed this pipeline. Opinions on the role of spin-out companies in the economy vary but given the absorptive capacity of the UK industrial base (see above) spin-out companies over the next ten years could make a significant cumulative contribution to the re-shaping of the UK economy when combined with other actions addressing the overall venturing environment.

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The final difficulty is 'short-termism'. What is required is a sustained solution, delivered over sufficient time to assist in the re-shaping of the UK economy. Many public sector interventions are hampered in achieving a major impact as a consequence of being short lived interventions with limited cumulative gain. This 'short-termism' was true of the original UCSF as well as for other sub-national interventions through regional or European funding.

Solutions

Some of the solutions are not easy in the present environment but the future growth of the UK economy and its re-shaping will require public investment combined with public sector interventions to stimulate changes in the private sector environment. We must reinforce successes, address fragmentation, stimulate collaboration and invest in our research bases' capacity to support commercialisation.

In PraxisUnico's view one of the best examples of a public sector scheme which addressed all of the points made in the previous paragraph was the University Challenge Fund. This scheme was relatively short lived but its successes are still being celebrated. £65m was invested in a series of experimental funds across the UK run and managed, for the most, by, or on behalf of, consortia of universities. This scheme assisted the development of Imperial Innovations, the development of seed funds in universities, supported the creation of SET squared and enticed the emergence of private sector investment in university companies, as well fostering collaboration between major universities. Over a period of nine years to 2009 these funds leveraged seven times their public sector investment from the private sector to £433m. By any measure this scheme was a success. It promoted the development of technology transfer, it built on the strength of the university sector and fostered collaboration. PraxisUnico has campaigned on numerous occasions for this scheme to be reinvigorated and we believe that the time is right, and much of the original infrastructure is still in place. The scheme should be rekindled, new bids invited and the scheme broadened to support technologies capable of being de-risked for development by existing companies as well as supporting new company development. Unlike the previous versions of the Scheme the successful funds should be 'open for business' to all universities, thus ensuring that high quality technology arising in an institution with low volumes of activity would not be deprived of access to investment funds. The scheme should have a ten year duration in order to provide a major foundation and to build time for traditional VC funds to emerge from the private sector as the deal flow will then be fully established.

The scheme would not be competitive to the MRC DPFS scheme or the new Biocatalyst Fund but would be one of the mechanisms which could provide support for their implementation. The original University Challenge Fund was co-funded by the Wellcome Trust, The Gatsby Foundation and the Government and a multiple sponsor scheme could re-purpose individual funds held by

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different public agencies for early stage follow-on into a single coherent investment based solution delivered through universities covering the proof of concept, seed and first round funding environment stage.

Whilst the original University Challenge Fund was a useful part of the funding environment a softer money alternative, where innovation can remain an internal project run by the research team for longer, feels more appropriate in some cases. Therefore a basket of funding options to drive projects to commercialisation is required rather than relying on just one route. In early stage development 'fragmentation" of support routes can be seen as being more of a positive than a negative.

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

There are no easy sectors. The technologies emerging from the research base are the foundation for new industries and will always be challenging. The bioscience sector has the benefit of major corporate R and D in the UK, as does large scale mechanical engineering thus providing considerable commercial insights for the research community. However, even in the bioscience sector the challenges are substantial as the entire business models are changing from traditional drug discovery to personalised medicine, with new models arising from genetics and cellular therapies - the UK must foster the new and not simply sustain the strengths it has which may well be under threat from major disruptions (who could have foreseen the demise of Kodak, for example). A review of BERD statistics by sector demonstrates the challenges faced if the future of the UK rests on building the past. There are huge opportunities in renewable energy and major opportunities in construction and by simply reinforcing the importance of manufacturing to the UK. PraxisUnico would make one plea; the commitment shown to the bioscience sector needs to be diversified into engineering and the physical sciences if the UK is to re-shape its industrial base.

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

One of the most long standing examples relates to magnetic resonance imaging. The original patent portfolio emerged from three universities in the UK (Oxford, Nottingham and Aberdeen) over more than twenty years generated only royalty income to the UK of circa £300m in total for an industry generating hardware sales in excess of $2.5bn per annum for licensees in Japan, US, Korea and Germany. One of the primary inventors sought to gain investment in the UK, unsuccessfully. The importance of these decisions is huge as it is not merely the loss of the major manufacturer but the subsequent supply chain development and investment in further investment in innovation which, in turn, assists the re-shaping of a country's economy. More recently (Jan 2012) the sale of Inhibitex Inc developed in the US (check) to Bristol-Myers Squibb for $2.5 billion

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relates predominantly to technology developed at Cardiff University. The company migrated to the US early in its development as a significant early stage, higher risk investment could only be secured in the US.

Founded in 1996 by graduate student Mike Lynch and utilising a unique combination of technologies borne out of research at Cambridge University, Autonomy has experienced a meteoric rise. The company was bought by HP in August 2011 for £7.1 billion, producing a several hundred million dollar fortune for Mike Lynch. Autonomy is a global leader in infrastructure software for the enterprise that helps organisations to derive meaning and value from their information, as well as to mitigate the risks associated with those same assets.

Campath® (alemtuzumab) is a monoclonal antibody treatment for B-cell chronic lymphocytic leukaemia. Based on a monoclonal antibody, Campath-1 discovered in the Cambridge University Department of Pathology by Herman Waldmann and colleagues, the treatment was improved by Greg Winter and others at the MRC Laboratory of Molecular Biology in Cambridge, using a process that became known as “humanisation”, to create Campath-1H. The initial commercial development was undertaken by the Wellcome Foundation, under licence from the British Technology Group, but after £50m investment, Wellcome dropped the project, it was licensed by BTG to LeukoSite in the USA. LeukoSite merged with Millenium Inc. who then sold the rights to ILEX, later acquired by Genzyme, who now produce and market the drug. Wellcome was a British company (now part of GSK); the others are all American.

Helen Lee developed diagnostics technology primarily for diseases in developing world countries at the University of Cambridge and was seeking financial support to start up a company at the turn of the century. It was not possible for Helen to identify readily accessible funding in the UK and she turned to the USA when setting up her company "Diagnostics for the Real World". She managed to secure funding from NIH through the SBIR scheme and set up her company in California in 2002. Helen is a supporter of SBIR which has three calls a year and has very clear rules and guidelines for engagement. She received nine rounds of SBIR funding. The company currently has 15 employees in California and its first two products are on the market and licensed through Thermo Fisher.

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

It is probably too early to address the TSB's impact, but there is no doubt that they are providing a much needed stimulus to technology development. Recent changes to TSB funding schemes are likely to have a positive impact as they will foster development across the ‘valley of death’ with closer working relationships to the university sector. In a recent TSB study it found that outcomes

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from its programmes were enhanced by university involvement. PraxisUnico believes that the UK must have an Innovation agency. There are examples where TSB funding has been used to pump-prime spin-out companies; for example, in the field of tissue engineering at Cardiff University and it would have been difficult (very early stage) to get this off the ground without the TSB funding. The challenges for the TSB are first, to avoid a naive separation between market-pull and technology-push. Increasingly, new markets will emerge through a dynamic environment bringing together technology push, market-pull alongside science-pull and entirely new market creation. Secondly, the TSB must champion the linkages for companies they support into the venture funding communities both corporate and private funds. Thirdly, the TSB must take risks and work with new emerging businesses and not confine action to well established industrial partners.

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

There are positive signs both in recent policy statements and speeches by Ministers and it is too early to say two years into an electoral term. The announcements relating to TSB, Bioscience Investment and NHS Innovation are all welcomed. We are concerned however, that none of these have specifically addressed the topic of this investigation which requires a major stimulus to bring together all of the investments in translational research, with those in the TSB into a new economic policy which has at its heart a systematic re-shaping of the technology and corporate venturing market in the UK.

We also feel the commercial imperatives of a venture capital fund and the need to form a limited company and associated management team do not seem to fit easily with the early stage innovations with long lead time to market. By the time that a business case and project team have been put together, that is getting close to where the investment community can understand a project and invest in it. That's where the challenge funds are really operating, and by then we're climbing out of the valley. If a university spends on patent protection, then it should be able to deploy some associated concept development money.

6. 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?

Yes, absolutely. Models such as Fusion IP, IP Group and Imperial Innovations have helped bridge the gap between City investors and universities. Relationships such as these also bring a professional, business-like culture into universities, helping to embed entrepreneurial culture. The

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further stimulus provided by a major university challenge fund scheme as suggested above can build on these early successes, fostering university collaboration, creation of critical mass and support the re-shaping the UK economy.

In addition there exist solutions such as Alumni Angel networks, the sale of "first look" options, specific fundraising/sponsored research or the establishment of a proprietary fund by universities.

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

There are many different calls on funds and the simple answer is that all investment funds that help develop the outcomes of the research are required. These vary from the costs of IP protection (there seems to be a real lack of funding for this activity, budgets are required), undertaking effective market research, bringing in design and engineering expertise earlier into the process, professional advice/advisors and lawyers, investment readiness, expansion of technology transfer training for young researchers, proof of concept funding, entrepreneurs in residence etc. But the answer is to stimulate these areas and avoid fragmentation by initiatives which tackle only one component at a time, which seems to be the present policy dynamic. PraxisUnico believes that the University Challenge Scheme proposed in this submission has the further beauty of providing an investment stimulus which can be deployed effectively in a multi-dimensional way with a clear focus on commercial goals without narrowly defining an inappropriate target for an intervention.

Across all sectors we are concerned about the early stage problems, where nobody really knows if something is worth supporting. Best for the possible means to be fragmented in this case, because then perhaps someone will pick something up as worth doing. Also it's very difficult to apply systems and measures to events or timeframes at this stage. We recognise that support at this level.

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Prepared on behalf of PraxisUnico Board and Committees

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Declaration of Interests

Dr Douglas Robertson is directly involved in the operations of university research commercialisation functions.

DWR, 22 January 2012

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Appendix 1 – University spin-outs and acquisitions since 2003

(as extracted from PraxisUnico publication *The Review*, June 2011)

2003
Wolfson Micro

2004
ARK Therapeutics
OHM
Vectura
Summit
Synairgen
Ceres Power

IDMos

Microemissive Displays

Andor
Cambridge Display Technology

2005
FusionIP
Proximagen

Provexis
Stem Cell Sciences
Oxonica
ReNeuron
NeuroDiscovery
GETECH
SPI Lasers
Celoxica
Toumaz

2006
Lipoxen
Syntopix
ParOS
Renovo
Oxford Catalysts
Avacta
Imperial Innovations
ValiRx

2007

Epistem

Modern Water
Tracsis

e-Therapeutics
Oxford Advanced Surfaces Group

2008
Scancell

2009
Nanoco Group

2010
Ilika
Tissue Regenix

2011
Microsaic Systems

Acquisitions
Kudos Pharma

NeuTech

Cambridge Antibody Technology
Domantis
Solexa

Arrow Therapeutics
Daniolabs

Plasso Technology
MTEM
Cambridge Display Technology

Meridio
CamFPD
OMD
SIW
Transitive
Thiakis
Phototherapeutics

Biotec Laboratories
APT
Inforsense
BioAnaLab
Orthomemetics
Reactivelab
Apatech
MET
Im-Sense
Exosect (Bee Health Division)
Artemis Intelligent Power
Biovex

Lab901
Chameleon Biosurfaces

Pending Acquisitions
Astex Therapeutics