

## INNOVATION TO IMPACT IN A TIME OF RECESSION

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Whilst most people in developed societies would celebrate the route from innovation to impact, particularly in the context of engineering and biomedicine, it is not often acknowledged that the definitions of the start, mid-points and even end-points of that route vary between groups in society. Since that route requires funding, this variety of opinion leaves regions of the route vulnerable to underfunding, particularly in times of recession. This paper explores how this can lead to failure to foresee problems and underpin solutions on the 10–50 year timescale. Furthermore, policies designed to support the route from innovation to impact can have the opposite effect. The route is illustrated with examples from the author’s research.<sup>a</sup>

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### 1. Introduction: Identifying Innovation and Impact

Research in an economic downturn poses extra challenges. Even at the best of times, the classical route from innovation to successful product is often a long and difficult one. Nevertheless this route is seen by many developed nations as key to economic growth and the ability to manage an expanding population of consumers who expect the best in provision (in terms of housing, healthcare, water and energy supplies etc.) and live to increasing ages.

One widely-recognized challenge is referred to as the ‘valley of death’. In this ‘valley’, a potential product (be it device, methodology etc.) is too far advanced from fundamental research for government research funding, but is also too far from being a cost-effective finished product for the end user (industry, health services, defence etc.) to take responsibility for funding. Faced with this situation, the inventor must find non-standard sources of income to conduct the research, such as loans, or undertake consultancy to raise income. Furthermore, the inventor is faced with more than just the cost of the research. To remain attractive for eventual industry take-up, many projects would require that the inventor

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pay the cost of IPR (Intellectual Property Rights) protection whilst within this ‘valley of death’, which after a few years can increase to an annual charge of over £10k. The less expensive option of keeping technology secret and not protecting IPR whilst touting for industry funding is risky in a time of recession. This is because the price of such secrecy (i.e. not publishing) can be redundancy for those academics who appear not to be publishing. Furthermore, lack of IPR could be exploited by some industries, and deter others from investing (because if the inventor has no IPR, then they in turn would have no proxy IPR compared to their competitors).

In a time of recession, the two sponsors at the ends of this route from innovation to impact (government at the start, and industry at the end) face drivers to take on less risky (and hence less adventurous) projects, and so opt for safer (and hence more incremental) projects. Industry funding must take into account the fact that the eventual profits or cost savings for each product that succeeds must also cover the lost investment in those which do not. Whilst government might understand that adventurous research runs a significant risk of generating no ‘pay-off’ in the lifetime of that government, nevertheless it understands the need to justify tax spend on research to voters. This means that basic research is concentrated into themes which can easily be justified to voters (such as energy, transport, counter-terrorism etc.), or go into projects which are safe, incremental, and offer pay-off on the 3–5 year timescale.

However there are subtler problems than those associated with the ‘valley of death’ contained within the route from innovation to impact. Such problems occur with the definitions of the start and end-point of this route.

One problem comes from the assessment of what constitutes impact, a successful outcome from research. It is too simplistic to base the criterion for success on wealth creation. Other criteria are important, such as establishing a service or a pioneering dataset, or advancing and disseminating knowledge sufficient to support innovation in the years to come. It is vital to recognise that impact may be very long term, such as the prediction of problems that will arise 10–50 years in the future. Classic examples include climate change, population growth, the provision of energy and water, and the mitigation of problems associated with ageing, epidemics, developing nationhood, identity, and the requirements for information and communication technology. Predictions on the 10–50 years timescale can allow measures to be put in place on the 5–10 year timescale to offset the risks, or provide the foundation for solutions that will be available when the problems eventually become critical. However the difficulty here is the limited ability to foresee which predictions will come about, and which will simply consume current resources where no critical problem will arise. Successful mitigation can avert the problem and make the original measures seem unnecessary or excessive. Genuine problems, predicted early, can consume a disproportionate amount of research income, denuding other sectors and aggravating other threats. The problem is more than that of identifying the long-term issues that require current resource and distinguishing those which do from those which do not. It is one of supporting the broad base of disciplines which will develop and maintain the skills to allow these predictions in

the first place (the first climate change warnings, for example, did not come from climate change centres — see Sec. 3). Underpinning this question, at a time of limited resources, is the decision of how much we can afford to let fundamental studies decline, and in which disciplines. The UK response in recession for engineering has featured two main strands. The first strand has been to select a few already-identified issues for support by research teams focused on those issues (such issues include energy, environment change, and the needs of an ageing population). The second strand has been to support wealth creation through engineering for product development on the shorter timescale as part of a series of measures to improve the economy on the 3–10 year timescale (a pre-requisite for expanding further research). The problem here is that this is paid for by reducing allocations to fundamental research across the wider spectrum of topics. The latter is vital because, in the prediction and mitigation of the long-term problems, it provides a pool of ideas outside of the groups focused on the favoured topics. Furthermore, the research and development that leads to wealth creation in the 3–5 year timescale usually relies on research a decade or more earlier at a time when that particular impact could not have been predicted. The two problems underpinning this are: first, an inherent inadequacy in accurately predicting where research might lead; and, second, an inadequacy in distinguishing the genuine predictions from the population of predictions in circulation, most of which are probably over-optimistic. The first is inherent in the nature of research, and there are many cases where the future impact was not identified at the time of the research; and the second stems from the requirement placed on those proposing research to demonstrate that it will lead to impact (usually wealth creation) in the  $\sim 3$ –6 year timescale. These inadequacies answer the question often asked in the media as to why any public money should be used to pay for research, given that if research is genuinely going to benefit an industry, then that particular industry should pay for it.

The uncertainties in predicting the outcomes of research (and even knowing if we need to wait another 50 years to see an impact we cannot envisage) therefore compromise the oft-cited aspiration to fund adventurous research with impact. They also compromise our ability to recognize innovation at the start of the innovation-to-impact route. Innovation in engineering is more than simply the suggestion of something new. ‘Brain-storming’ sessions which produce a surfeit of suggestions, without assessment of their validity or details of a mechanism, do not constitute innovation, but instead either go nowhere or consume resources following the majority of unsuccessful false leads. Imagination alone will enable suggestions linking, say, use of computer games or sci-fi stories to defence, criminology, biomedicine, future products etc. Even if one suggestion from this miasma of ideas leads to an output, its suggestion did not constitute innovation. The innovative stage incorporates the judgement which filters the promising possibilities from the resource-wasters, and establishes the mechanism by which development to impact can be made. Here again, whilst impact on a three-year timeframe allows us to identify the innovation, impact on the 50-year timeframe will rarely do so in the lifetime of the innovator. The identification of innovation requires hindsight.

## 2. What to Fund?

Given that our assessments of both innovation and impact are necessarily compromised, there is therefore a need to support a wide topic base. However there is also a difficulty paying for it with the current funding structures. The resolution is to celebrate and promote the ability to undertake fundamental innovation efficiently, producing very large output (in terms of rigorous ideas, validated and published for all, number of PhD students trained etc.) for modest funding input *per project*. This ability has been feature of science and engineering in the UK in the 1800–1990 timeframe, but it is under threat by current policies. These include measures to focus Government funding by topic. They also include the shift in the assessment of university staff away from output (examples of which are listed above) in favour of input (i.e. funding won). Such shifts are understandable on a local scale, given the local need for administrations to attract sufficient overheads to run their institutions. However they conflict with the national need to enhance efficiency, generating more valuable output for less cost. Somewhere between this input and output, between publication and secrecy, are the knowledge transfer and enterprise activities, the formation of spin-out companies and the filing of patents, activities which sit uneasily between input and output as a short-term cost and a possible longer-term benefit. In a national recession, if all universities compete in terms of input (winning funding), there will be few winners. Celebration of efficiency (high quality output at low cost per project) preserves the research base for future years.

Championing the broad (in terms of topic) and shallow (in terms of funding for individual projects) approach is not to denigrate the needs of administrations striving to keep universities solvent. Neither is it to disparage the achievements of large research groups focused on societal problems, or of researchers using major facilities, or of Governments which devote large sums to specific individual projects. Instead, it is to note the need to take active measures not to starve the primordial soup of research, from which the ideas and trained researchers and leaders required in 20 years will emerge. The ingredients of that soup are supplies of studentships and small projects. Supplying these will mean compromise. It means, for example, that the administration of a large number of small packages of funding can only be afforded if assessment of impact is less probing than the current peer-review methods (peer-review nevertheless must be maintained for output). It also means that any investment in this soup takes funds away from the groups that directly study societal themes, and furthermore that any small ‘soup’ project runs the risk of not generating impact. Nevertheless, broad and shallow support of high risk projects in the primordial soup without assessment of topic or impact is vital to the health of engineering in the 15–30 year timescale. Whilst peer review of outputs is vital, peer review of research proposals in a time of recession becomes unaffordable. The UK is responding by focusing new funding via large grants to a small number of investigators who already have existing large grants, reducing the need for peer review. Other investigators can no longer apply for studentships within standard grant proposals. Instead the government has awarded ‘Doctoral Training Centres’ to specific universities. These Centres are restricted to fund studentships only in a

small number of prescribed subjects (such as transport). This article advocates the opposite approach, of reducing the peer review burden by distributing small amounts across diverse fields with minimum administration. If the investor lacks detailed knowledge, as here, then a broad and balanced investment portfolio (with low administration costs) makes as much sense to the funding of science and engineering as it does in the stock market.

In summary, the benefits of much research often take years to appear, may be unexpected, and require input from diverse strands. The foundations of such strands are often fundamental, adventurous, and (even where the benefits can be foreseen) it would have been difficult for Government at the time to persuade taxpayers of such long-term benefits.

In a recession this leads to tensions between four conflicting drivers: First, the need for Treasury to reassure taxpayers that tax revenue is invested wisely; Second, the need for Research Councils to balance the requirements of government (who are reassured if wealth creation from research occurs by the end of, say, a 3-year grant) with the recognition that the country needs fundamental and adventurous (high risk, high gain) research to engender innovation; Third, the need of academics to ensure that their response to financial downturn (and the resulting policies) enables them to spend more time on core research activities, not less (a real possibility if, in their field, the success rate of research proposals diminishes, or the assessment and auditing of their performance become more onerous); Fourth, the needs of industry to remain financially viable when the monies available for research are significantly reduced. Section 3 of this paper explores these tensions, and Sec. 4 provides specific examples illustrating these features by discussing four case studies of innovation in the author's research into bubble acoustics.

### **3. The Assessment of Research**

'Research', in the context of this article, can be classed into four categories. The first two (product development and applied research) usually have identifiable routes for exploitation which, it is hoped, would benefit the public who pay for much of it (either wholly or in part). Such benefits might, for example, be provided in terms of products and processes for industry, healthcare, government, or tools and guidance for the monitoring, regulation and engineering of society. In an economic downturn, both product development and applied research benefit from the ease with which researchers, sponsors, government and media can explain the benefits of this tax spend to the public, and the ease with which the public can grasp those arguments. Industry too can see the benefits and can justify part-funding of some product development and applied research (the extent varying from sector to sector, e.g. geophysics, pharmaceuticals etc.). At the other extreme there are those projects which remain as basic research for many decades. The main output of such research is in the discovery of new knowledge. With the exception of themes held in general public and media esteem (such as climate change), this output provides only a difficult argument to make to the public for use of tax revenues in an economic downturn. Seemingly perpetual basic research themes are often justified to the public in terms of the number of people trained, or by highlighting example domestic products resulting from it. However when such cases

are made, the justification is denuded by omission of the most compelling argument, that of discovery. Justification based on products from long-term basic research often sound hollow, and ridiculed in terms of “we sent men to the moon and all we got was the nonstick frying pan”. The public can appreciate the gap filled by many others in taking, for example, particle physics discoveries into products in the home or hospital. Such exploitation paths suffer from the perception by nonscientists of a genealogical route for the exploitation of research, whereby (with the exception of a few famous figures) credit is given to the product development prior to delivery rather than to the more fundamental research of earlier workers. We may remember da Vinci, Mendel, Rayleigh, Watson and Crick, but behind every cathode ray oscilloscope and aircraft engine there are too many names to recall, and explanations of their web of contributions may require considerable insight and effort for the public and policy makers to grasp.

This article considers the fourth type of research project, which sits midway in the above list, where basic research is followed through to an identifiable product by a single research team. Such a route is not, as product development or applied research often are, based on modifications to existing technologies or techniques. As such, it can be a recognizable channel for groundbreaking innovation to reach the point of public service. In Sec. 4, cases are considered where this development is done by a single research team, for one important reason: where the route diverges to different teams, the connections can be lost. Such loss of connections can occur, for example, as products appear through use of code written and passed on either informally or commercially, code which itself was based on groundbreaking equations by earlier workers; or when researchers fail to recollect all the comments, questions, conversations and presentations which in retrospect were key to the solution. The fact that no clear genealogy exists for many end-products undermines a current drive to assess ‘innovation’ and ‘research’ through their ‘impact’.

What we call ‘research’ has been subtly redefined in recent years in the UK. The definition used in the 2008 UK national assessment of the way core funding for research should be distributed as Universities compete with each other (the Research Assessment Exercise, RAE), was that research was “original investigation undertaken in order to gain knowledge and understanding”.<sup>1</sup> This did not differ significantly from the definition used in the 2001 RAE. However in 2009, for future assessment exercises (the so-called ‘Research Excellence Framework’, REF) the definition of research was changed to “a process of investigation leading to new insights effectively shared”.<sup>2</sup> This change, which is aimed at emphasizing the benefits that research brings to markets, reflects the meteoric rise of the perception that good research has ‘impact’, a concept which encompasses the extent to which an item of research makes a positive difference. Since such potential differences are manifold, assessors of impact usually prohibit certain types of impact from assessment. For example the guidelines for the REF pilot exercise<sup>3</sup> state that “we define impact as any identifiable benefit to or positive influence on the economy, society, public policy or services, culture, the environment or quality of life. It follows that for the purpose of assessing the impact element in the REF *we do not include impacts within the academic sphere or the advancement of scientific knowledge*”. These two exclusions from the definition of impact risk not crediting

an academic study in one institution which, through publications, led to an academic study in another institution, which then led to a product in industry. There are surely many cases of this, often unknown to the original researcher. It is not easy to follow an item of research through academia, and then through confidential work in industry, in order to link the original research to the creation of new businesses, or to wealth creation in current business, or to the delivery of the same level of healthcare more cost-effectively, or to major benefits to the ‘UK brand’ by, for example, enhancing UK performance in the London 2012 Olympics.

Making such links is clearly vital if a researcher wishes to win public funds for a specific project, or help their institution to receive core funding through a research assessment such as the REF, or to justify their work to employers or the media. However the character of those links reflects the fact that there are manifestly two types of impact. The first is ‘retrospective impact’. This is a respectable concept that can be attributed to those innovations which generated some proven benefit, where some current product, process or service can be credited in part to a recorded (and usually published) item some years earlier. Many, perhaps most, of these links are not recorded, and not recognized by the original researchers, who may refrain from publication to protect IPR. However, difficult as they are to find, verified accounts of such hindsight-driven impact can be genuine and valuable. The second type of impact is ‘prospective impact’. This, in contrast, consists of works of optimism and the imagination. They are given credibility only when they are accompanied by a quantitative assessment of likelihood and are placed in the context of a track record of ‘retrospective impact’. In 2009 the UK Engineering and Physical Sciences Research Council (EPSRC) introduced the mandatory requirement that grant applicants provide statements of ‘prospective impact’, which would be assessed when considering whether to fund a project. This requirement needs to be balanced to offset the already inbuilt advantage that product development has over more adventurous fundamental research. This advantage is that product development can not only produce a more concrete prospective impact statement, but it can more easily attract support (including matching funds) from the industries which would otherwise need to fund product development in its entirety. The methods for providing reviewers and sponsors with evidence of the merits for adventurous fundamental research projects should be qualitatively different from the more concrete and quantifiable measures that are available to product development and applied research. Adventurous fundamental research should therefore be assessed differently to avoid the assessment being based upon their low scores in these concrete measures.

The encouragement for researchers to emphasize prospective impact when applying for research funding reduces the imagination needed by government and public when the argument is made that those tax revenues spent on research have been wisely invested. However, the impact of fundamental research does not follow the simple genealogical lineage to which this model applies. We know from spectacular examples of retrospective impact (such as the 1859 publication<sup>4</sup> of the geologist Charles Darwin following his circumnavigation of the globe in 1831–1836) that impact may take many years to become apparent, may still be ongoing, can be unpredictable, and often occurs in fields outside those of the original researcher (or, to put it another way, impact in one field often requires input from other disciplines). With

today's proliferation of information exchange, the researchers themselves may be unaware of the use made of their research. Similarly, the user may be unaware of the original research that was key to the exploitation. If the wealth-creation event ever cites a source, it may cite an obvious applied paper, but the genius may be owed to an equation presented 100 years earlier and embedded in the commercial code used in the more recent applied paper. The emphasis on short-term impact places a driver against fundamental research and towards the product development that previously went on in industry. This model can be easy to sell to business and public, but without Faraday's benchtop experiments or Maxwell's equations, and contributions from many scientists and engineers whose names we would not recognize, how much of the equipment in a current intensive care ward would exist?

Not all topic areas for fundamental research are difficult to justify as constituting a wise spend of taxpayers' money. This has led to the ring-fencing of large tracts of funding for specific topics. By 2009 UK Research Councils were doing this for: energy; living with environmental change; ageing (life long health & wellbeing); global uncertainty (security for all in a changing world); nanoscience through engineering to application; and the digital economy.<sup>5</sup> In moderation, this is a sensible way of ensuring that the public funds spent on research tackle major societal issues. However, it must be undertaken with the awareness that it reduces the funds available for other studies. In an economic downturn, this reduction can eradicate some centres for research in other topics. The argument that funding by topic places monetary support in the topics from which the 'big solutions' will come, is undermined by the fact that innovation frequently requires the cross-fertilization of other disciplines. Furthermore, failure to maintain critical competency in fundamental topics outside the favoured group not only prevents this cross-fertilization, but also reduces the ability to anticipate future crises. For example, early warnings of climate change came from a spectacularly gifted electrochemist (by training) in 1896<sup>6</sup> and a steam engineer in 1935,<sup>7</sup> who stated that "By fuel combustion man has added about 150 000 million tons of carbon dioxide to the air during the past half century... approximately three quarters of this has remained in the atmosphere... the increase in mean temperature, due to the artificial production of carbon dioxide, is estimated to be at the rate of 0.003° C per year at the present time". The overwhelming argument for research funding should not be the ease with which the public can be convinced that the funds are well spent. If this is the priority, product development and global crisis topics themselves will suffer in the long term by the loss of expertise in the wider topic field upon which, in the long term, both depend. The issue is of how much funding must be preserved for truly adventurous fundamental research in the 'primordial soup' described in Sec. 2. The survival of research groups depends on funding exceeding threshold values (at a minimum, that required to keep one staff member, although a critical mass of researchers represents a more realistic threshold size). As a result, reductions in the proportion of funding reaching research groups (i.e. after overheads are subtracted) will lead to group/departmental closures in an economic downturn in a way which would not occur in better economies. This is a particular problem when economic hardship for universities causes income generation by individual researchers to be a major feature in assessing redundancies. For individuals, a clear survival response



would be to move from basic research towards product development, and to try to compete in the favoured topic areas against established groups, some of which shape the calls for proposals. This reduces the time a researcher spends on core research in their expertise. It can also increase the time spent to little effect writing unsuccessful proposals in areas in which they have less expertise and training. Persistent nonproductivity will hasten the closure of research groups and departments. Once expertise is lost, the cost of restarting it is much greater than the year-on-year maintenance. Furthermore, the economic savings in the interim must be offset against the loss of cross-fertilization to other disciplines, loss of education and training in the topic, and loss of the prescience of future needs. The loss of nuclear power expertise in the UK in the 1980s, and the current imperative for new build, provides one such example. Loss and new build did not arise from a model as simple as the alternating supremacy of opposing groups: both were given impetus in part by political response to changing perspectives in the environmental lobby, fuelled by deeper public appreciation of the fundamental science.

Hence the focused support for an impactful research programme must be balanced with enough support for academic freedom: the three high impact studies cited above<sup>4,6,7</sup> were all considered, to a greater or lesser extent, to be outside their main fields by the researchers in question, and indeed Callendar's research is recognized as having been a spare-time hobby.<sup>8</sup> There are no simple arguments to convince a public that tax funds have been wisely spent supporting a critical mass of research characterized by academic freedom. However, since such free research has less explicitly promised short-term impact, it can be conducted with reduced monitoring and control. If government accepts this, such adventurous fundamental research should require reduced overhead for administration. This is crucial: total UK expenditure by research councils in the UK has nearly doubled in the last ten years, but included in this is a very significant increase in overhead paid to universities by research councils. The increased overheads reflect the Full Economic Costs (FEC), which were introduced by UK Government in 2006 in response to the assessment that about a third of the costs universities attributed to research were not covered by research income, leaving a £2 billion "research deficit" in the sector.<sup>9</sup> Despite the extra income from FEC, the deficit remains around £2 billion. Whilst Universities are not obliged to charge FEC to industrial sponsors, the perception is that research proposals attracting less than 80% of FEC are loss-making and are therefore discouraged. The position is clearly not sustainable, as high overheads deter sponsors and reduce the money available to research (and reduce the number of grants that can be awarded), and yet the full costs of infrastructure and support services need to be covered or the deficit will increase. A reduction in the administrative tasks required by government policies would leave a greater proportion of funds in universities for core research.

#### **4. Case Studies in Bubble Acoustics**

This section illustrates the processes of innovation by reporting on four studies, following them from the initial idea through to their current status through a single research team. The detailed knowledge required for this exercise restricts this to the author's own team, since

even when only a single researcher and a single link with industry are involved, the innovator can be ignorant of the impact. With the exception of the conical bubble project, all the projects identified at the outset their eventual impact (which was at that time prospective impact), but (except in the case of the cleaning project) this was not sufficient to secure research funding. The bulk of the research time in all four projects progressed without external financial support. Although this is beneficial to the taxpayer in the short term, and promotes entrepreneurship, it does delay progress. For example, the author undertook consultancies, and hired out equipment, to gain funds which were then used to pay the salaries of researchers, detracting from the time he and the equipment could be used in the research. In the longer term, self-funding is not sustainable, and greatly reduces the ability of research groups to initiate future projects. This is particularly the case in a recession when industry is less able to pay for consultancies and equipment hire.

Whilst all four projects resulted in devices, a large proportion of the research came in the form of equations. For such theory, the public and policy makers are poorly equipped to verify claims that these were key to the development of the devices. Scepticism may not be the biggest problem: the audience may be open-minded, but the claims may be spurious, illustrating how difficult it is to assess research by impact.

The four studies are linked by the fact that the technologies rely on nonlinear response of gas bubbles in liquids when driven by pressure fields. Such bubbles are probably the most potent naturally occurring acoustical entities in liquids, and are highly nonlinear when they pulsate in response to a driving sound field. The first example is that of the conical bubble, which at first glance might appear wholly without use. The second example describes a passive acoustical sensor which is placed on the skin of a patient undergoing shock wave lithotripsy (SWL). The third example uses the nonlinear oscillations of bubbles to produce enhanced ultrasonic cleaning, with applications for hospitals, industry and defence, and domestic use. The fourth example is a sonar system designed to detect objects in bubbly water, which lays down the foundation for a wealth of other detection technologies (e.g. of improvised explosive devices (IEDs)). Partial contributions of these projects into other areas (the monitoring of cancer therapies, osteoporosis and ‘greenhouse’ gas budgets) are noted.

#### **4.1. *Conical bubble collapse***

The author conceived of the possibility of making a practical conical gas bubble in water which would collapse, momentarily producing intense conditions (pressure and temperature) at the end of the collapse. Applications for Research Council funding were rejected, so the work developed unfunded through the late 1980s and the 1990s, resulting in publications on the theory of the conical bubble collapse, and measurements of such collapses achieved in practice.<sup>10–14</sup> A conference presentation<sup>13</sup> sparked off academic research in other countries<sup>15–17</sup>] and, when combined with other studies on the inertia associated with bubbles in tubes and how these might relate to bubbles in blood vessels,<sup>18,19</sup> provided models for bubbles in such biomedical conditions.<sup>20–23</sup> Although the main output by the author in the first decade of this work was its use as a vehicle for training students and source of

the above publications, around 15 years of unfunded research after the first studies and failed grant applications, the project was taken up by industry. The following text is a direct quote from Toby King (formerly R&D Director of Weston Medical, currently CEO of Moog Insensys Limited): “Fundamental published work on conical bubbles by Dr Leighton informed Weston Medical in the development of a needle-free injector (for subcutaneous drug delivery). In 2002 the business was worth £6 million, but development was stalled by performance issues. Weston Medical contracted Dr Leighton to address performance. His solution enabled further development, such that in 2006 the company Zogenix was formed around this technology, and has now raised a total of over \$150 million of Venture capital and loans, primarily to fund approval (successfully achieved in the USA last year) and marketing of the product with a migraine drug, now called Sumavel Dosepro. The current global market for just this one drug (Sumatriptan) is over \$1 billion per year”.

#### **4.2. A passive acoustic sensor for lithotripsy**

During shock wave lithotripsy (SWL), thousands of shock waves are directed into the patient at a rate of about one per second, in order to fragment kidney stones or reduce them to a size whereby they can subsequently be dissolved using drugs.<sup>24</sup> With current apparatus the clinician is ill-equipped to determine in-theatre whether the treatment has been successful, with the result that 30–50% of patients need to return for re-treatment, and an unknown number receive a greater exposure to shock waves than is necessary for stone fragmentation. Overexposure carries the potential for adverse side-effects.<sup>24–28</sup> The research project described here led to the development of a new passive acoustic sensor, which is placed by a nurse on the patient’s skin, and passively monitors the scattering and reverberation of the SWL pulse in the body.<sup>29</sup> In the clinical trials, the automated output from the device during treatment could correctly predict successful treatments 94.7% of the time, compared to the 36.8% per cent scored by the clinician in theatre using the best currently-available equipment,<sup>30</sup> although statistics from current clinical trials on how use of the machine affects retreatment rates will be more meaningful.

Development of the device required theory, computational fluid dynamics (CFD) simulation, laboratory and human tests, and clinical trials with the associated issues of patient safety and confidentiality.<sup>31</sup> The research for this device began in the late 1980s and early 1990s, with Coleman and Leighton using the correlation of cavitation luminescence with passive acoustic emissions from a benchtop lithotripter, to infer that the passive acoustic emissions could be used to monitor the lithotripter performance.<sup>32,33</sup> These unfunded studies were followed by more unfunded work, characterizing the spatial resolution of the passive acoustic sensor and correlating it with cell lysis, luminescence and the sound field<sup>34–39</sup> and determining the extent to which the quantitative passive acoustic output correlated with (and so might be used as a proxy measurement for) other effects produced by cavitation (e.g. sonochemical effects, erosion etc.).<sup>40</sup>

However, to use these findings in a clinical device, the researchers would need to understand how the far field acoustic emissions (detected by a sensor placed on the patient’s skin) were related to the interaction of the shock wave, tissue and stone in the body. Modelling

techniques for such emissions at the time were not up to the task. By the early 1990s, the Gilmore model was usefully being used to predict the far field emissions of the lithotripter-induced collapse in an infinite body of fluid from a bubble which remained spherical at all times.<sup>41</sup> However, during lithotripsy the bubbles do not remain spherical at all times, and indeed are likely to undergo fragmentation and coalescence, their dynamics being affected by structures around it (for example, as formulated in the earlier studies described above in Refs. 10–21). By the mid 1990s, Boundary Element Methods<sup>42</sup> and Arbitrary Lagrangian Eulerian simulations<sup>43</sup> had been used to simulate the collapse of a bubble to produce a liquid jet which passes through the cavity, but not the moment where the jet impacts the downstream bubble wall to generate the blast wave which would dominate the far field passive acoustic emissions. Therefore in the late 1990s, funds were sought from EPSRC for two PhD studentships (awarded in 2000), one to produce appropriate simulations<sup>31,44–49</sup> and the other to conduct experimental work. This experimentation began by identifying the initial bubble size to be used as input in the simulations,<sup>50</sup> and then progressed through prototype design in a successful collaboration with Guys and St Thomas’ Health Trust (GSTT) and Precision Acoustics Ltd. (PAL).<sup>51–57</sup> This was followed eventually by clinical trials in 2004, but the data for these could not be used, and the submitted papers were withdrawn before publication, because although the data were taken with formal ethical approval and in compliance with the guidelines in place at the time, these guidelines changed prior to publication. One year of further funding was applied for, and granted from EPSRC in 2005, to repeat the clinical testing such that successful clinical trials were published in 2008.<sup>29</sup> During the research, the team contacted established lithotripter manufacturers for support and to discuss incorporating the technology into the sensor suites already sold with commercial lithotripters (featuring X-ray and active ultrasonic technology). However, the team could not gain support from established lithotripter manufacturers (perhaps related to the mature stage of lithotripsy as a medical procedure<sup>24</sup>), and so the decision was made to produce a stand-alone device instead for a few thousand pounds. Units have been sold in the UK and US.

The UK National Health Service (NHS) is currently trialling the device as a technology to achieve its key of reducing the ‘patient pathway’.<sup>24,58</sup> The patient pathway describes the route taken by the patient through the health-care services. Condensing this pathway (e.g. by reducing inaccurate diagnoses, ineffective treatments, waiting times, and the number of times that the patient needs to visit the hospital to see different people) was a key aspiration in the 2004 NHS improvement plan.<sup>59</sup> By determining within the first hundred or so shocks (i.e. before the inception of most adverse affects) whether the stone is of a type that will fragment during lithotripsy, or whether the patient needs instead to be sent for ureteroscopic stone removal, the passive sensor is an innovation aligned with this aspiration. The device was awarded the 2008 ‘Medical & Healthcare’ award by ‘The Engineer’.<sup>60</sup> In the years since the original correlation of the acoustical emissions with cavitation<sup>32</sup> that correlation has been used by several laboratories around the world to develop ingenious ways to exploit it to characterize responses as a result of lithotripsy,<sup>61–65</sup> and analysis of these far field passive acoustic emissions in the frequency domain has also been explored to provide a potential diagnostic for the efficacy of lithotripsy shock waves.<sup>51,53–56,66</sup> Applications for

dental ultrasound have been investigated.<sup>67</sup> This fundamental research has therefore stimulated research elsewhere and generated a product, but the time lag between the first research to the current date is nearly two decades, only four years of which received external funding.

### 4.3. *Ultrasonic cleaning*

Products for ultrasonic cleaning are being developed from fundamental research undertaken by the author in collaboration with Dr Peter Birkin of the School of Chemistry at the University of Southampton. The collaboration began in the late 1990s and received EPSRC support from 1999 until 2006. Although the projects have led to current products, these were not identified until recently: the stated goal of the first seven years of the research was to address identified problems in technology by increased fundamental understanding, in the hope that this would lead to an exploitable solution (as indeed it did). As an indication of how times have changed, whilst this vision was sufficient a decade ago to obtain funding, the more precise impact statements associated with development of clearly specified and patented products were in 2009 judged by EPSRC to be too close to fundamental research to warrant funding by a ‘follow-on’ scheme.

The research began with parallel studies of high energy cavitation (bubble collapse) and low energy bubble shape oscillations. The high energy cavitation collapse can generate a range of effects, including luminescence, chemical and biological effects, and erosion, and these have been exploited for years not only in research laboratories, but also in the practical application of the ultrasonic cleaning baths. However characterization of the cleaning performance of such baths was (and still is) rudimentary, industry favoring a check based on the insertion of domestic aluminium cooking foil into the bath to see whether the cavitation is capable of generating small erosion ‘pits’ and ‘holes’ within the foil. This has numerous disadvantages, the main one being that the effect on the foil may be very different from the effect on the object to be cleaned when it is inserted into the bath, because insertion of such an object can disturb the ultrasonic field which causes the cleaning.<sup>40</sup> Indeed, even insertion of the empty mesh tray (which is normally used to hold the object to be cleaned) into the bath can disturb the sound field sufficiently to compromise the cleaning of any object that would be placed into the tray. The research began by investigating techniques to monitor cavitation of the type which occurs in cleaning baths.<sup>40</sup> This included a novel trial whereby the author invited proponents of different cavitation monitoring techniques to visit the UK National Physical Laboratory (NPL) where they would each be assigned a 2-day period in which to test the effectiveness of their favored technique.<sup>40</sup> Erosive, chemical, acoustic, and luminescence techniques were tested. The results showed that, whilst all the users could get their own technique to work to their satisfaction in their own laboratory under controlled conditions, all techniques in some way performed less well when deployed in a strict 2-day time limit in an unfamiliar laboratory.<sup>40</sup> This study stimulated development work on a number of sensors, such that three of the collaborators (NPL, the University of Southampton, and the University of Belarus) are now able to provide, for sale,

commercial sensors for cavitation detection. The study also provided a step in the development of a reference cavitation facility at NPL.<sup>68,69</sup> An off-shoot of the technique was used in a collaborative experiment between the Institute of Cancer Research and the University of Southampton, to provide *in vitro* cross-calibration for monitoring equipment for tumour therapy by high intensity focused ultrasound.<sup>70,71</sup>

The author and Dr Birkin, and their students, developed a range of sensors for such cavitation.<sup>72,81–83</sup> These sensors were then deployed to monitor their efficiency when transducers couple to vessels to generate cavitation,<sup>84–88</sup> including examination of the cleaning that could be achieved with commercial ultrasonic cleaning baths and ultrasonic horns.<sup>89,90</sup> Studies were also undertaken on the bubble activity which leads to cleaning, such as bubble collapse and the formation of high-speed jets as bubbles involute during collapse.<sup>91,92</sup> This combined experience led to the development of cleaning apparatus which is currently under discussion for commercialization in a University of Southampton spin-out company.

The second aspect of bubble activity which was researched, and fed into the development of products for the spin-out company, was acoustically-generated surface wave activity on a bubble. This activity generally occurs at lower driving pressures than the cavitation activity discussed above, and so leads to mass flux in the liquid and at the surface, and shear which can be used to clean, but does not lead to erosion. Indeed the researchers developed a dual microsensor which could simultaneously monitor for mass flux and erosion, and so find the cleaning regimes when one, both, or neither could be generated.<sup>93</sup> This is particularly important for the cleaning of surfaces which must not be eroded (such as delicate surfaces, or surfaces where the generation of a crack would make decontamination more difficult the next time cleaning is attempted). The research covered the underlying theory for the stimulation of such waves which allowed the driving conditions to be tuned to generate this activity,<sup>94–98</sup> the monitoring of such waves through acoustic,<sup>99–106</sup> photographic and electrochemical<sup>107–111</sup> techniques. A side-study of this work indicated that the technique could greatly increase the efficiency of electrodeposition processes in industry.<sup>112</sup>

This fundamental science behind the ultrasonic cleaning project received good research council support from 1999 to 2006, but then with focusing of research into particular themes and the economic downturn, applications were rejected to develop this fundamental research into wealth creation. These two strands of research into the high-energy and low-energy bubble activities which produce (respectively) strong cleaning, or cleaning without erosion, were utilized in a project sponsored by the UK Defence Science and Technology Laboratory, which developed a successful prototype cleaning device. The author and Dr Birkin are trying to raise support for a spin out company from the University of Southampton.

#### ***4.4. A sonar that will penetrate oceanic bubble clouds***

The fourth project is the development of a sonar system which can function in bubbly waters, where dolphins are able to echolocate but where the best currently-available man-made sonar cannot. Although gas bubbles in the ocean confound man-made sonar, some cetaceans must deal with bubbles as a result of their location (for example as occurs with those species restricted to coastal regions): others actively generate bubbles to aid their feeding.

Indeed it was seeing video footage of this in 2003 which first inspired the suggestion.<sup>47,113</sup> Data is scarce as to what extent, if any, cetaceans have exploited the acoustical effects of bubbles, or have undertaken tactics to compensate for their deleterious effects. The absence of data provides a fruitful opportunity for hypothesis. Having evolved over tens of millions of years to cope with the underwater acoustic environment, cetaceans may have developed extraordinary techniques from which we could learn.<sup>114–118</sup> This idea was developed through simulation,<sup>119–123</sup> laboratory<sup>124–128</sup> and sea trials (with parallel studies to measure the ocean bubble population to use as input to the modelling,<sup>99,100,102–104,129,130</sup>) to develop practical sonar technology for use in bubbly waters. The first (and only to date) sea trials were finally completed in February 2008, using internal funds and borrowed equipment, and successfully distinguished between bubbles (from ship wakes) and the seabed (which was being used as a target).<sup>131</sup> The fundamental technology has also been proposed for use in the detection of improvised explosive devices (IEDs), detection of surveillance equipment, detection of combustion products and use with MRI.<sup>119,126,131</sup> Despite over a dozen applications for research funding, no funding has ever been granted (the studentship, travel and equipment requirements were paid for by consultancy earnings on other projects by the author). The first IPR protection was filed in 2005,<sup>119</sup> but by when approval was given in 2009 to grant the patent<sup>119</sup> there were insufficient funds to meet the >£10 k annual cost of maintaining the patent. The work linked with two other projects (the first on seabed acoustics,<sup>132–137</sup> and the second on the ultrasonic assessment<sup>138–140</sup> of bone health and osteoporosis) to generate proposed methods for monitoring the populations of climatologically significant methane bubbles in the seabed. Such bubbles can also make the seabed unsuitable for civil engineering works.<sup>141</sup> These studies in turn led to new hydrophone calibration techniques (developed in collaboration with NPL).<sup>142</sup> The background work on methods to monitor oceanic bubble populations led to measurements of the interactions between atmosphere and oceans, particularly in the transfer of greenhouse gases between them,<sup>143,144</sup> and to sensors for use by the ceramics and neutron generation industries.<sup>145–147</sup> The study also led to a proposed explanation of how acoustic calls of humpback whales are used in feeding with bubble nets (proposed in 2004<sup>114</sup> and since developed,<sup>115</sup> and featured in TV Nature documentaries).<sup>148,149</sup>

## 5. Conclusions

It is vital to maintain, across a wide topic base, research that is sufficiently adventurous that it is impossible to foresee the impact of some of it on the 10–50 year timescale. The necessary penalty for doing so will be the funding of a proportion of research that has no impact within the time window used for the assessment. The unavoidable uncertainty about what future impact might occur, and when, not only compromises our ability to make such determinations, but also compromises our assessment of when successful innovation occurs.

Such limitations undermine the philosophy of using impact to assess the value of a research project (in particular, in assessing which projects to fund). Reference 150 surveys the time it takes from the initial innovation to wealth creation through innovation. It records

a one-year study into the economic benefits of the UK's public and charitable investment in medical research. It found the benefits to be high: a £1.00 investment in public/charitable cardiovascular disease (CVD) research produced a stream of benefits equivalent to earning £0.39 per year *in perpetuity*. However, it also records that the time lag between research expenditure and eventual health benefits is around 17 years: it infers "a mean lag between research and impact for CVD treatments of between 10 and 25 years, with a central estimate of 17 years".

The four projects described in Sec. 4 (conical bubbles; lithotripsy; cleaning; sonar) have so far progressed for many years (20;20;11;7 years respectively) of which only a small proportion of the research was funded (0;4;7;0 years respectively). The remainder of the time relied on the investigators supporting the work themselves through unpaid overtime or by spending (on student stipends, equipment and travel) funds they earned through consultancy work. Hence all the projects were either wholly or significantly dependent on unfunded work by the investigators and students, maintaining the momentum for years at a time when no funding could be obtained. Self-funding is a laudable ingredient within a research project, but must not be the sole ingredient. It is rarely sustainable, and becomes less feasible in a recession, when the required entrepreneurship is hampered by fewer industrial funds and greater restriction and taxation of such activities. The four projects required over 100 papers of fundamental research, noting that the work that is closer to market has been held back from publication to protect IPR. These publications detail how much of the work for the eventual project took place in other topic areas. The projects have between them produced several commercial products, and been the vehicle for the training of over a dozen students who will contribute to the next generation of research and development in the UK.

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