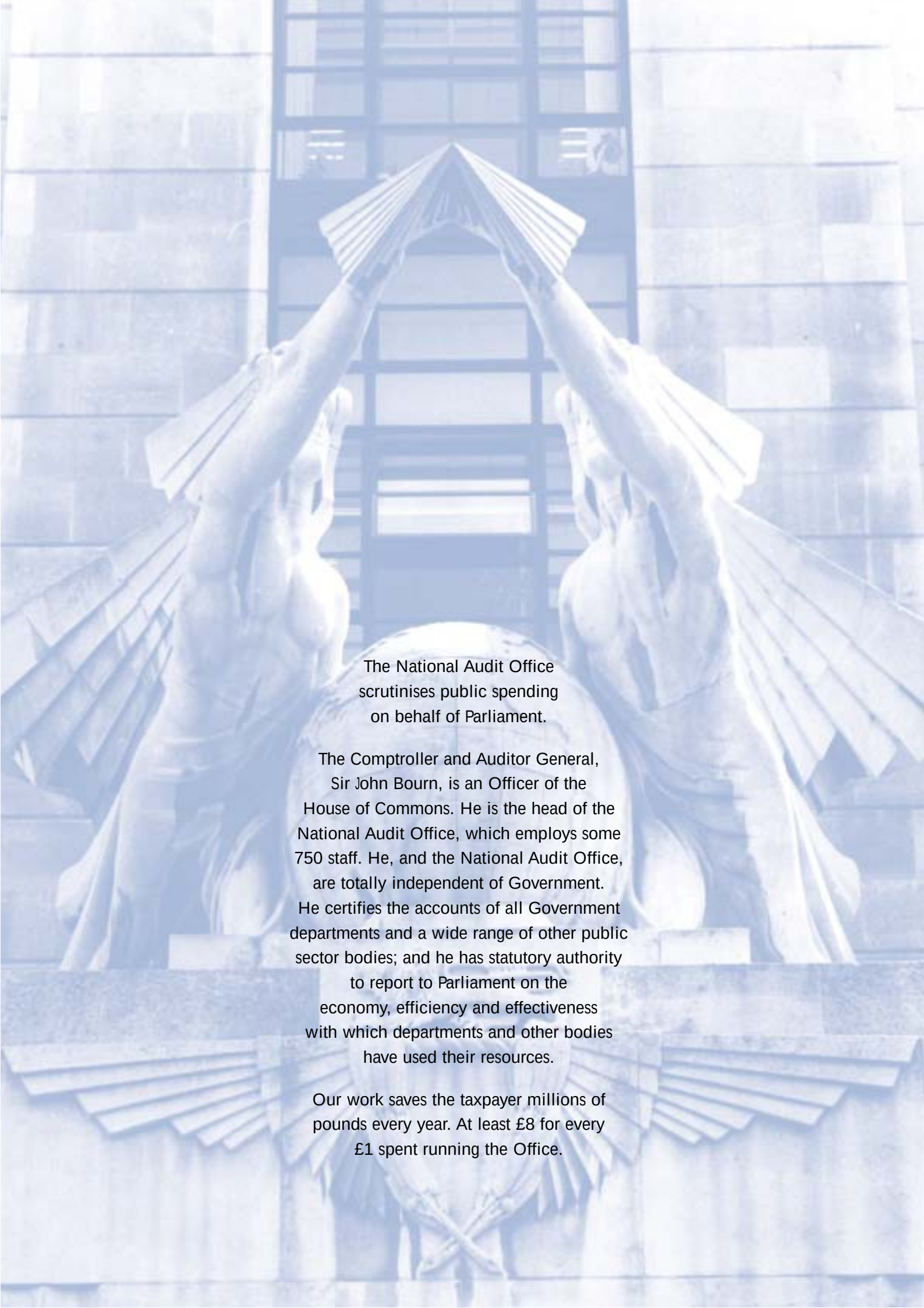
NATIONAL AUDIT OFFICE

# Reaping the Rewards of Agricultural Research

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL
HC 300 Session 2002-2003: 23 January 2003



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***John Bourn***
**Comptroller and Auditor General**

**National Audit Office**
**13 January 2003**

The National Audit Office study team consisted of:

Stewart Lingard, Richard Baynham and Fiona Ashley under the direction of Pamela Thomas.
Morgan Harris Burrows advised us on the commercialisation of nuclear transfer technology.

This report can be found on the National Audit Office web site at www.nao.gov.uk

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# Contents



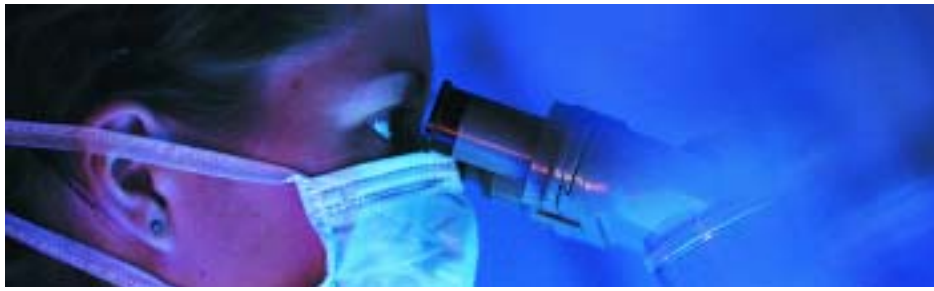
Front Cover: Hybrid leeks demonstrating the uniform quality which can be achieved. Photograph courtesy of Horticulture Research International.

The photograph on Page 43 and extracts from it elsewhere are by kind permission of the Roslin Institute.

# executive summary

**1** In 2001-02, government departments invested some £7 billion in scientific research and development. General responsibility for science policy rests with the Department of Trade and Industry but individual departments are responsible for commissioning programmes of research. The Government encourages research establishments and other public bodies, in co-operation with the private sector, to make commercial use of the outputs from publicly funded science. In 1999 the Government published the Baker Report on "Realising the Economic Potential of Public Sector Research Establishments" which made a number of recommendations on how this could be improved.

**2** This report focuses on one sector of government sponsored research - agriculture - specifically how the Department for Environment, Food and Rural Affairs (previously the Ministry of Agriculture, Fisheries and Food)[1] is responding to the challenges of commercialisation. As part of this review we also examined the commercialisation of the nuclear transfer technology following the birth of Dolly the Sheep, the early research for which had been part funded by the Ministry and where the Department is a part owner of the nuclear transfer patents.



**3** Annual expenditure by the Department on agriculture related research and development has been in the region of £100 million a year throughout the last ten years. In this work the primary focus has been to develop efficient markets in which agricultural industries can thrive; to protect public, animal and plant health; and to sustain rural and marine environments. Research funding normally ceases before the stage at which something to sell might emerge, the primary purpose of the research often being to inform policy making or to provide information for the public good with results widely disseminated, for example, to improve the health of farm animals or benefit the environment. In those circumstances, the Department regards the scope for commercial exploitation of research results as very limited.

**4** Receipts from commercialisation of intellectual property have been generally small. In 2001-02 the five research contractors we reviewed had received in total some £450,000 from intellectual property arising from typical research work for the Department (the nuclear transfer technology "commercialisation" was exceptional), representing just some 2.4 per cent of their total commercial income. The Department received £15,000 in royalty income.

*1 Throughout this report we refer mostly to the Department rather than the Ministry, which ceased to exist in June 2001.*

**5** There are many other aspects of commercialising scientific research, such as winning contracts, collaborative research with the private sector, and consultancy work which have generated income. The resources for commercialisation activities and the commercial income derived from intellectual property - generally from licensing, royalties and 'spin out' companies - may be small but what has been achieved should be commended as a first step.

# Our key findings

## Commercialisation requires active support and management

**6** The research contractors we visited were committed to increasing their royalty and other income from intellectual property, driven in part by the additional revenues this could generate to support their wider activities, the motivational impact for many scientists in seeing products developed from their work, and the greater understanding of customer needs which this can bring.

**7** Nevertheless, contractors face significant challenges in commercialising their intellectual property, including:

a Identifying the best opportunities. This is not easy, and requires active management of intellectual property portfolios. Scientists may have the best understanding of the science involved and the collaboration required to take ideas forward. The experience and expertise of business staff can, however, be key to determining which ideas have commercial potential and should be pursued and which dropped, and to developing exploitation strategies and business plans. Attracting and retaining business staff of sufficient quality for these purposes may stretch resources in an area where income from commercialisation can not be guaranteed to meet the costs.

b Obtaining further funds to develop ideas. Research funding from the Department often ceases well before the stage at which something to sell has been developed. Significant sums are usually needed to demonstrate commercial feasibility, for example to produce prototype products or processes. The Central Science Laboratory, for example, estimates that the technology it develops can cost more than £500,000 to take an idea from proof of concept to prototype product stage. Other technology, for example developing prototypes of machinery, might require millions of pounds to develop to commercial feasibility.

c Winning over scientists to the concept of commercialisation. Many are supportive of commercialisation, recognising the satisfaction and benefits it can bring to them and their research organisation. Others, though, are motivated chiefly by scientific endeavour, their objective being to gain the recognition of their peers through publication of research papers,

perceived as a less risky approach than success through exploitation of intellectual property. They see the confidentiality needed to develop commercial projects as hampering collaboration with other researchers, and hence progress on the research topic, and also as a time consuming distraction from their pure science roots.

d Managing finance and resources to administer knowledge transfer activities, identify commercial opportunities and to file and protect intellectual property, for example, patents. Over its lifetime a patent can cost some £250,000 to file and maintain, more if action has to be taken to defend the patent against challenges and infringements. Expert legal aid and financial advice is often required to support negotiations with outside investors, as generally such skills are not readily available within the research contractor or the Department.

*Stripper Harvester. Photograph courtesy of Silsoe Research Institute*

e Gaining the Department's support where relevant. Some research contractors considered that the Department's approach could be too "hands on", resulting in delays, and putting business opportunities at risk. The Department, however, may be concerned about whether, for example, the research contractor has identified the key risks associated with the proposal, and managed them appropriately so as not to leave the Department with any potential costs of failure. There are other potential conflicts of interest which have to be managed, for example, commercial partners may want their work to be prioritised over core research funded by the Department, and incentive schemes to encourage scientists to look for exploitation opportunities can potentially be divisive.

f Managing risks when making deals including finding a partner, selecting the right type of deal, obtaining sound independent advice and managing conflicts of interest. Licence deals have tended to be the preferred option, but the use of joint ventures and spin-out companies is growing. In seeking partners relatively little competition is applied. This may be due to the difficulty of finding interested and appropriate partners; to the costs of exploring partnership deals or to the reluctance of research contractors to widen their search beyond existing contacts with whom they know they "can do business". This could mean that better deals with other partners are not necessarily being identified but may reflect the limited number of commercial firms willing to invest in agricultural products.

**8** Prior to 2000, the Department tended to adopt a cautious approach to commercialisation but has since taken steps to encourage exploitation in line with, and in part anticipating, the recommendations of the Baker Report. Research contractors are able to retain 90 per cent of net revenues from exploitation of research funded by the Department. The Department has given its executive agencies responsibility for managing intellectual property and is amending contract terms to vest ownership of intellectual property in contractors in line with the Baker Report recommendations. Even so the Department's agencies receive little financial support from the Department to manage their intellectual property.

## Agricultural research can lead to commercial opportunities

**9** Some structural issues exist. Whilst public sector research establishments have the freedom to, for example, set up joint ventures and spin-out companies for exploitation purposes, not all sponsored non-departmental public bodies own their assets, and in those cases their borrowings count against the Departmental Expenditure Limit. As a result any proposals have to be evaluated against the Department's other spending priorities. Executive Agencies have been similarly constrained. However, the Department is now increasing the freedoms of such bodies and seeking to encourage the identification of commercial opportunity.

**10** Despite the difficulties, contractors have successfully developed research into commercial opportunities. A stripper header patented by the Silsoe Research Institute in 1985 has generated more than £1.25 million of gross receipts. A project to develop a robotic mushroom harvester has, however, stalled due to the lack of a partner to meet the funding gap of some £250,000 to develop a pilot laboratory system into a commercial product (mushrooms are the United Kingdom's single most valuable horticultural crop, worth some £300 million a year).

**11** Horticulture Research International negotiated successfully a licensing agreement with a Dutch company to produce, market and distribute commercial quantities of a hybrid leek seed (leads to greater uniformity and quality of product at harvest). And the Centre for Environment, Fisheries and Aquaculture Science has entered into a joint venture with a private sector company to capitalise on its "smart buoy" technology, originally developed to record a range of marine-related chemical and physical measurements over long periods at sea. Probably the highest profile commercialisation in recent years has been that of nuclear transfer technology, used to develop Dolly the Sheep, by the Roslin Institute.

**12** Dolly, its licensing deals and nuclear transfer technology are not representative of the size or significance of discoveries generally made through government sponsored research. Between April 1998 and May 1999 the technology which had led to Dolly was commercialised in two deals.

- The first deal was a partnership between the Roslin Institute and venture capitalists, 3i Group. This created a spin-out company, Roslin Bio-Med. The shares in Roslin Bio-Med were owned 42 per cent by the Roslin Institute, 42 per cent by 3i Group, and 16 per cent by the company's management team and two scientists at Roslin.
- The second deal involved the sale of Roslin Bio-Med to the Geron Corporation (Geron), a biotechnology firm based in the United States.

## Private sector involvement in Dolly achieved a number of outcomes

**13** Deals with the private sector were essential as the value of the technology was in its potential and not in the original purpose of the research (to explore the scope for identifying and disseminating genetic improvements in livestock of benefit to the agriculture industry). Developing the technology had cost some £3 million of which the Department funded about £2 million. The Roslin Institute funded the final steps which resulted in the major breakthrough leading to Dolly. The Biotechnology and Biological Sciences Research Council increased Roslin's core funds to strengthen the basic biology of nuclear transfer, and also invested about £1.5 million over three years to a national effort involving Roslin, four universities and the Babraham Institute to improve the efficiency of cloning mice as part of the Council's initiative in gene technologies underpinning healthcare. Nevertheless, Roslin felt it needed additional funds for developing the research further (bio-medical rather than agricultural applications were seen as having the most commercial opportunity). Competitors in the United Kingdom and abroad were developing similar technologies, and the risk for the Roslin Institute was that its intellectual property would become outdated and worthless and its ongoing research would become uncompetitive.

**14** Roslin's deal with 3i Group to create Roslin Bio-Med provided the necessary investment to continue the research. The allocation of shares to two scientists (at a cost to them personally of £20,000 in total) and the management team (at a cost to them of £204,000 in total) was a requirement of 3i Group in order to ensure those individuals were involved and to improve the chance of success in the next development stage. The subsequent transaction with Geron (a US company with net assets of some $64 million in 2000) arose because Roslin, Roslin Bio-Med and Geron recognised their respective research was complementary, and that an early partnership would increase the potential for commercial exploitation. Again, there was a risk that other companies or research teams in the United States or elsewhere on their own would develop the technology, leaving Roslin's work without any value.

**15** The Roslin Institute's financial advisers for the transaction with 3i Group, KPMG, told the Institute that in the absence of competition, it was difficult to know whether the partnership offered the best value for money. Roslin chose 3i Group due to its history of investing in biotechnology companies and as a United Kingdom group with a strong focus in Scotland. In Roslin's view, the alternatives were unsatisfactory and could have lost valuable time when rivals were working on similar technologies. Our consultants, Morgan Harris Burrows, advise that the funding of research for three years, and the equity given to the Institute, was higher than usual for a deal involving such an early stage of research into unproven technology.

**16** Roslin did not seek any independent valuation of Roslin Bio-Med at the time of the Geron transaction. Instead they accepted a valuation undertaken by Geron's financial advisors, J P Morgan (of approximately £29 million). 3i Group had also expressed an aim to obtain at least double their planned investment in Roslin Bio-Med, from £6 million to £12 million, or a 100 per cent return on their planned investment. As 3i Group owned 42 per cent of the shares in Roslin Bio-Med this would have implied a value on the company as a whole of £28.6 million. At the time of the deal, shares in Geron allocated to the vendors were worth some £16.8 million, and the Institute also received research funding of £12.5 million.

**17** The value of the shares in Geron allocated to 3i Group at the time of the Geron transaction (4 May 1999) was some £2 million lower than their expressed aim. It represented a gain of just over half of their investment. The two scientists and the Roslin Bio-Med management team received shares worth £3.7 million at that date some 16 times their original investment of £224,000. The commitment of individuals was required by Geron, as it had been by 3i in the earlier deal. Roslin took Geron shares worth some £3.3 million at the time of the transaction and, spread over six years, £2.5 million of undirected research funding, and £10 million of research funding to be directed by Geron on nuclear transfer technology. In the event of successful exploitation of the technology, Roslin will be entitled to a share of royalty payments and joint ownership of intellectual property rights. The Department also received £120,000 of research. Therefore the public sector received some five times the value of a research investment of £3 million over a ten year period.

**18** The transactions relating to nuclear transfer technology ensured its further development thus helping in the search for radical new treatments for disease, and hence of benefit to the public and the United Kingdom economy. The outcomes are set out in **Figure A**.



## A Outcomes from the deals to commercialise nuclear transfer technology

- The nuclear transfer patents (applied for and granted between 1995 and 2000) are co-owned by the Roslin Institute, the Biotechnology and Biological Sciences Research Council and the Department.
- In 1998, the Roslin Institute granted PPL Therapeutics, a British company based in Scotland, a licence to develop and commercialise nuclear transfer as a better way to create transgenic animals producing theraputic proteins in their milk. From 1998 the Roslin Institute received some £100,000 a year in licence fees from PPL Therapeutics.
- 3i Group, the venture capital company, planned to invest some £6 million into developing the Dolly technology at Roslin. Roslin Bio-Med - a spin-out company - was set up by Roslin and 3i in 1998 to commercialise the technology and was granted a licence to exploit nuclear transfer patents.
- When Roslin Bio-Med was sold in 1999 to Geron, a United States company, the Roslin Institute received 400,000 Geron shares worth some £3.7 million. Some 60,000 shares were later sold by Roslin for over £1 million. Other United Kingdom based shareholders received Geron shares worth some £13.1 million.
- The Roslin Institute received £12.5 million in research funding from Geron over a six-year period from 1999-2005 of which £10 million was to be used on developing nuclear transfer technology. New intellectual property arising from the nuclear transfer programme is co-owned by Roslin and Geron and some royalties will accrue to Roslin if any products are developed.
- Geron was granted an exclusive research and licence agreement for six years to exploit the nuclear transfer technology for all human-based biomedical applications, excepting PPL Therapeutic's interests. Geron and Roslin would become joint owners of all intellectual property arising from future research (except that arising from a specialist pigs project, the rights to which belong to Geron).
- The Department for Environment, Food and Rural Affairs received £120,000 worth of research to be carried out at Roslin and a share of any royalties.
- Nuclear transfer research continued to be carried out by Roslin staff at the Roslin site in Scotland. Over the past two years the focus of research at Roslin directed by Geron has changed to stem cell technology.

**19** To sum up, significant additional financing was needed to develop the nuclear transfer technology to any commercially usable level, and others around the world were working on similar projects. It is unlikely therefore that government funded research would have been an option for the longer term, apart from basic underpinning research funding. There were clear benefits for the United Kingdom from the deal done with Geron but the lack of really independent advice on the value or about the potential market at the time of the transaction with Geron means that we cannot say conclusively whether the best sale value was obtained. In crude terms the public sector received about 5 times the value of their investment in the initial research, 3i received a return of 1.7 times their investment, and the scientists and management 16 times their investment. They were, however, essential to the deal. No one would have realised past investment without them, and the scientists were clearly essential to the future as well.

**20** The deals with the private sector avoided the risk that the technology would be overtaken before any benefit could accrue to the public sector. They ensured that research could continue in the United Kingdom. It is not possible at present to put a valuation on this aspect. The research and the successive deals were in many ways ground-breaking, requiring robust leadership and personal commitment. Each new venture required lessons to be learned and shared in the handling of commercialisation.

# Our recommendations

**21** Our principal recommendations are set out below. While our focus has been on the work of those public sector bodies carrying out research for the Department, the recommendations may also apply to others.

i To increase awareness of exploitation opportunities, and to reduce the risk of staff inadvertently compromising intellectual property, public sector research organisations should provide regular expert training on the stages and good practice involved in commercialisation.

ii Furthermore, the Department should facilitate the sharing of good practice between its research establishments on matters such as:

- assessing ideas for exploitation potential;
- how pre-seed financing may be obtained (particularly within the public sector, for example the University Challenge Fund, the Regional Development Agencies and other sources);
- the nature of deals best suited to particular circumstances; and
- identifying and working with partners.

iii Public sector research establishments should assess intellectual property systematically for commercialisation opportunities, documenting for future reference and transparency the key reasons for pursuing or dropping ideas.

iv Public sector research establishments should develop exploitation or business strategies, identifying key risks, and how these are to be managed.

v Sponsors should review progress by their research contractors in exploiting research funded by the public sector. Reports by contractors might outline exploitation strategies and demonstrate the extent to which intellectual property has been reviewed for commercialisation opportunities, been exploited commercially, or benefits derived in other ways, for example knowledge shared in the public interest. The Department will in future require its contractors, through revised standard contract terms to report on exploitation activities regularly. Where similar reports are produced for other public bodies, for instance Research Institutes, or where similar reviews are undertaken by Research Councils, every effort will be made to avoid duplication.

The following recommendations arise from the key findings from our review of the commercialisation of nuclear transfer technology but take account of subsequent changes as a result of the Baker Report, for example, that responsibility for and benefits from commercial exploitation should fall increasingly to the research provider. It can be difficult to demonstrate whether the maximum return has been achieved in the commercialisation of intellectual property. However, where public funds are involved, research providers and sponsors should explore how best to satisfy taxpayers that the best returns all round have been achieved.

vi When making commercial deals appropriate expert advice should be obtained. This can be expensive and the cost will need to be justified by the risks and benefits involved. Expert independent advice in the private sector in the relevant field and Partnerships UK, a joint private/public sector organisation, may provide a source of practical guidance and can provide more in-depth support. Specialist legal advice may also be required by research contractors to review compliance with legal requirements and detailed terms and conditions of agreements.

# Our recommendations

vii Where a commercialisation opportunity carries significant risks, or deals are likely to be novel or the potential costs/income are large, research contractors should make sponsor bodies aware (even though no prior approval is required) at an early stage. If consultation with sponsors is appropriate (as applied at the time Dolly was commercialised), the nature and timing should be agreed at the start. This consultation can run in parallel with other expert advice to avoid delay.

viii Detailed negotiations with potential commercial partners should be carried out by research contractors (as was the case with nuclear transfer technology), supported by experts as appropriate, rather than the sponsor, as they are better placed to understand the nature of the underlying science and who is key to a successful outcome (such as the scientists), and as they will be the ones working day to day with the commercial partners.

ix Whilst recognising that the ability to work together and the need to protect new technologies are important in choosing a partner, potential partners should in principle be subject to competitive pressures to obtain the best deal for the taxpayer. However, in exceptional circumstances a single partner approach might be appropriate to avoid potential damage to the value of new technologies by revealing information to too many people in applying open competition. Where only one possible partner exists it is particularly important to obtain expert independent professional advice on the terms and conditions of the deal to ensure maximum value.

x Commercialisation deals may require research contractors to consider trade-offs between cash and non-cash considerations such as guaranteed research funding, royalties, taking equity. To ensure any deal meets wider public sector interests as well as those of the individual research contractor, contractors should consider the options at an early stage and seek expert advice on the risks and benefits of each.

xi When a spin-out company is being sold on, the public sector shareholder(s) should obtain an independent assessment of the spin-out company's value prior to entering negotiations and not rely on the valuation offered by their potential partners. Specific valuations of intellectual property may be difficult to assess but equally important are independent assessments about the market in which the spin-out operates, who the buyers might be and why, and how much they might be willing to pay for it.

xii Where a public sector research organisation is offered non-cash (e.g. equity) consideration for a spin-out company, then the risks, alternative options and the implications of such offers and conditions attached to them should be evaluated in detail by expert advisers.

xiii In setting up a spin-out company, representation of shareholder interests should take account of public sector involvement. In addition the management team of spin-out companies is crucial to their success. It is essential to choose a team with the requisite skills, experience and knowledge of the industry they are working in. Specialist recruitment agencies can help in this regard.

xiv All research contractors should put in place procedures to cover the disclosure of interests by staff, and the monitoring and handling of conflicts of interest. Guidance on these matters has been issued by the Office of Science and Technology[2]. Where the Department has funded the originating research, it may need to be satisfied that its contractors apply appropriate procedures on potential conflicts of interest, without interfering with the freedom to exploit research in the public interest.

2 *In July 2000*

# Part 1

# Introduction

1.1 Those funding and conducting research at public expense have responsibility for ensuring good value for money is achieved. Some research may be for the wider public good where dissemination of results, and access to the results may deliver benefits, for example leading to improvements in the environment. In some cases, scope may exist for 'commercialisation' of an output from research. Commercialisation may generate public revenues, and assist industry in the creation of jobs and prosperity to the benefit of the community. Examples range from the sale of services or data to the business sector, licensing of technology, to start up or spin-out companies.

## The Baker report identified how commercialisation could be more effective in public sector research establishments

1.2 In August 1999 the Baker report - *"Creating knowledge, Creating wealth: Realising the Economic Potential of Public Sector Research Establishments"* - concluded that more could be done to overcome a "risk avoidance culture that inhibits entrepreneurial behaviour." The report's recommendations focused broadly on:

- purchasers and providers of public sector research should have commercialisation as a more explicit part of their objectives;
- departmental research establishments should have more control of intellectual property and more financial freedoms;
- scientists should be allowed incentives or rewards, subject to proper systems for ensuring probity, in order to encourage commercial activity;
- research establishments should have access to commercial expertise and share best practice in knowledge transfer.

1.3 The Baker report also recommended that the National Audit Office had a role to play in supporting a less risk averse approach to commercialisation in the public sector; and in November 1999 we published a statement confirming our support for well thought through risk taking and experimentation in the exploitation of research. In July 2000 the Government accepted the thrust of Baker's recommendations, and required departments and public sector research establishments to develop action plans in response. To assist public sector research establishments with commercialisation, in July 2000 the Office of Science and Technology produced guidelines on managing the conflicts of interest which can arise from commercial activities, and in December 2001 the Patent Office published guidelines on how public sector purchasers of research and research providers were to implement the Baker recommendations. Also in December 2001 Partnerships UK, which was set up by the Treasury to assist government departments in setting up public private partnerships, published detailed guidance on setting up joint venture companies.

1.4 In February 2002 as part of its response to the Baker report the National Audit Office reported on *Delivering the Commercialisation of Public Sector Science (HC 580 2001-02)* which focused on the Department of Trade and Industry's research councils and public sector research establishments they sponsor.

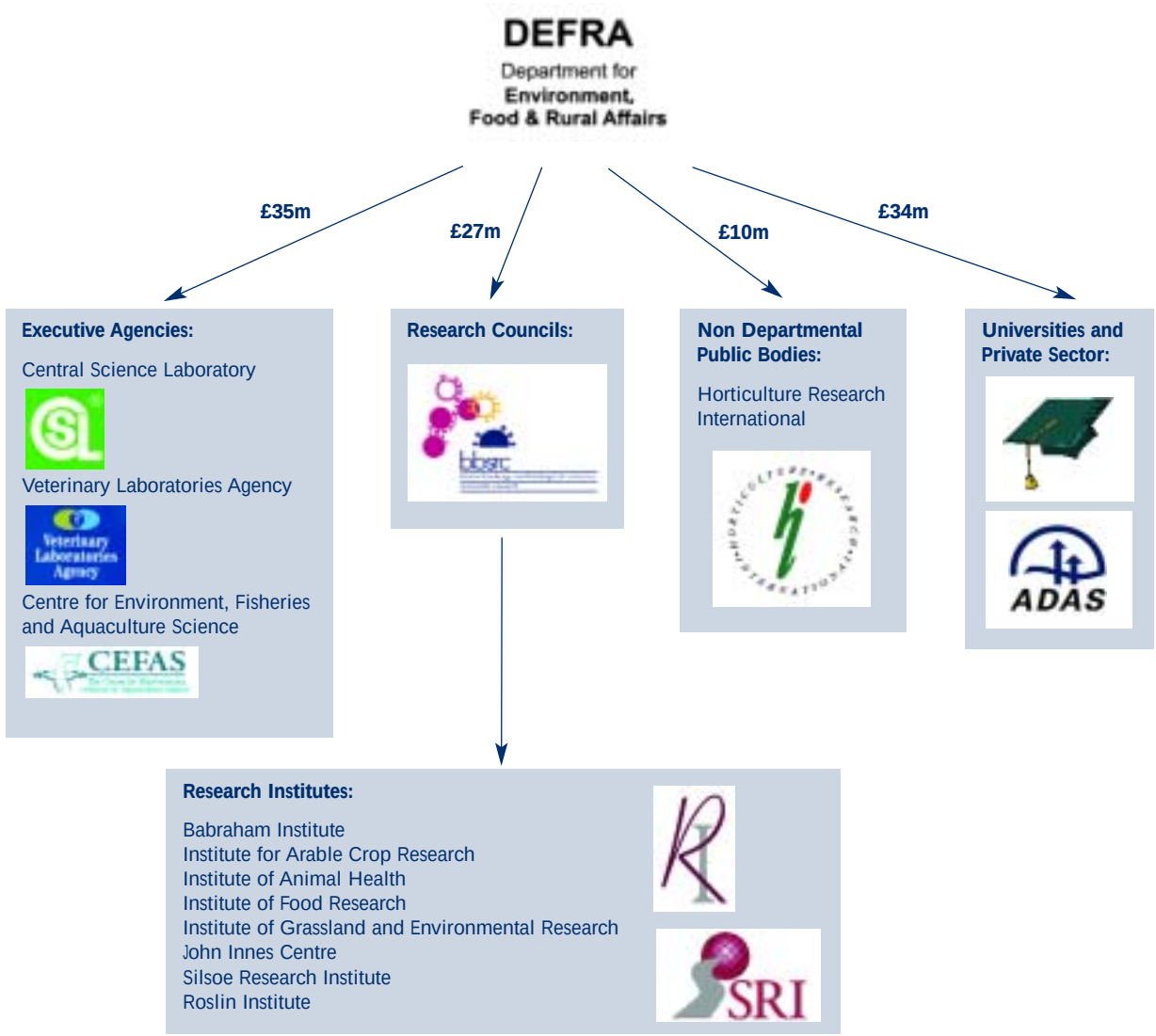
## Our examination focused on research funded by the Department for Environment, Food and Rural Affairs

1.5 In 1995 the Committee of Public Accounts published its report on *The Management of Intellectual Property in the Ministry of Agriculture, Fisheries and Food (HC 237, 1994-95)*. The Committee questioned the attention given by the Ministry to commercialisation, the identification of potential for exploitation and the effectiveness of the arrangements for protecting intellectual property. The Committee's recommendations and the government's responses are set out in Appendix 2 of this report. This report reviews the changes made by the Department as a result of the Committee's recommendations, and how the Department and its research contractors have responded to the call for greater commercialisation following the Baker report.

1.6 Throughout this report we refer to the Department for Environment, Food and Rural Affairs (the Department) which was established in June 2001, and subsumed the Ministry of Agriculture, Fisheries and Food. Our report does not examine environmental research acquired by the new Department in June 2001 from the old Department of the Environment, Transport and the Regions. Our recommendations will, however, have wider relevance.

1.7 The Department commissions some 1,500 agriculture related research projects through a diverse range of contractor organisations involving more than 100 bodies, examples of which are shown in **Figure 1**. The Department's executive agencies received some 35 per cent of total Departmental expenditure on research in 2000-01. But the Department also commissions research from research institutes, non-departmental public bodies, universities, and private companies.

**1 The Department funds research at a range of bodies**



## We decided to examine five research contractors funded by the Department

1.8 We examined commercialisation of research by five of the Department's research contractors comprising:

- two research institutes: Roslin Institute and Silsoe Research Institute;
- a non-departmental public body: Horticulture Research International; and
- two executive agencies: the Centre for Environment, Fisheries and Aquaculture Science; and the Central Science Laboratory.

1.9 **Figure 2** describes the main areas of research carried out by each of these five public bodies. The executive agencies are part of the Department and may therefore face different commercialisation challenges to the more independent institutes. All five face similar challenges commercialising work in the agricultural research area.

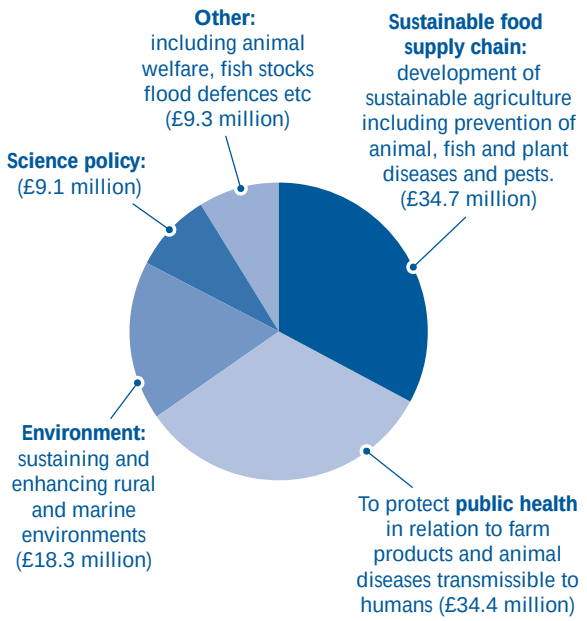
## The Department spends over £100 million a year on research

1.10 Research on agriculture related programmes for which the Department (or its predecessor) has been responsible throughout the last 10 years has amounted to some £100 million a year. In 2001-02 the three main areas of activity, accounting for some 80 per cent of the total, were: development of a sustainable food supply chain; protecting public health; and sustaining rural and marine environments **(Figure 3)**. In 2001, the Department acquired responsibilities for the environment and rural affairs which have not been examined in this report. Its annual expenditure on research and development is now estimated to be some £130 million.

**2 The main areas of research at five bodies working for the Department**

| Research organisation | Type of organisation | Nature of research |
|---|---|---|
| **Roslin Institute** | **Research Institute** Sponsored by the Biotechnology and Biological Sciences Research Council | Genetics of farm animals, biology of reproduction, developmental biology and growth, animal welfare and behaviour |
| **Silsoe Research Institute** | **Research Institute** Sponsored by the Biotechnology and Biological Sciences Research Council | Engineering, physics and mathematical research for agri-food industries across crop production, environment, livestock, food |
| **Horticulture Research International** | **Non Departmental Public Body** sponsored by the Department for Environment, Food and Rural Affairs | Horticulture |
| **Centre for Environment, Fisheries and Aquaculture Science** | **Executive Agency** of the Department for Environment, Food and Rural Affairs | Fisheries science and management, marine environmental protection, aquaculture, fish and shellfish disease and hygiene |
| **Central Science Laboratory** | **Executive Agency** of the Department for Environment, Food and Rural Affairs | Agriculture, environmental management and conservation, analytical services in food safety and quality |

**3** **Agriculture related research and development funded by the Department in 2001-02**




## The primary aim of the Department's research is to inform policy but the Department seeks to transfer knowledge

1.11 By mid 2002, the Department was working on a science and innovation strategy covering its new responsibilities, taking account of the spending review of 2002. Generally, its funding of science focused on the development and delivery of policy objectives; risk management; analysis of future problems; and dealing with statutory and regulatory duties. It also sought:

- to secure information for public policy purposes, including advice and guidance to consumers, producers and other stakeholders;
- to monitor, survey and analyse a substantial range of indicators, including those relating to animal health and welfare, marine resources, the impact of farming on the environment, aspects of the food chain and the state of the United Kingdom's river and coastal defences; and
- to help, and where appropriate, to encourage increased efficiency and market competitiveness, and wealth creation among the Department's sponsored industries through policy instruments and effective knowledge transfer.

1.12 Although the focus is on informing policy, the Department seeks to ensure that the results from the research it funds can be readily transferred to the agricultural industry. It encourages knowledge transfer though best practice publications, scientific papers, conferences, technology clubs, newsletters and road-shows. In many cases the Department distributes its intellectual property or advice free of charge.

1.13 A key objective of the Department, for example, is to protect the public's interest in relation to environmental impacts and health, including in relation to diseases which can be transmitted through food, water and animals and to ensure high standards of animal health and welfare. Examples of research and development expenditure in these areas include:

- research into Transmissible Spongiform Encephalopathies (TSE) with major efforts focussed on developing a sensitive diagnostics test for TSE infection that can be performed on live animals;
- research into possible use of bovine tuberculosis vaccines; investigating ways in which the disease is transmitted and improving existing controls aimed at minimising cattle-to-cattle transmission;
- research on the use of animal manures to reduce the need for fertiliser has resulted in the development of the MANNER decision support system. This assists farms and advisers to use the nutrients in manures (in particular nitrogen) more effectively and to reduce the risks of water and air pollution. MANNER is also used for modelling scenarios in river catchments to assist in the formulation of government policies on environmental protection;
- funding the production of a CD-ROM of published research on organic farming, a directory of current research across Europe and the preparation of a CD-ROM compendium of the management of animal health and welfare within organic systems.

1.14 The Department also engages in the LINK programme to which it commits some £6.5 million a year. LINK promotes partnerships between industry and research bodies to develop commercial products and services **(Figure 4)**. Each LINK programme consists of several research projects that typically last between two and three years. In each project financial support from industry is matched by the government department or research council partner.

**4 The Department's involvement in LINK**


| There are seven programmes led by the Department: | Total funding[1] (£ million) | Number of[1] Projects | Number of contacts[2] |
|---|---|---|---|
| Sustainable livestock production | 9.7 | 39 | 84 |
| Sustainable arable production | 19.2 | 29 | 60 |
| Horticulture | 15.0 | 31 | 137 |
| Technologies for sustainable farming systems[3] | 3.4 | 24 | 32 |
| Food safety and quality | 2.7 | 17 | 97 |
| Aquaculture programme[3] | 2.9 | 36 | 124 |
| Advanced food manufacturing | 8.1 | 54 | 170 |

**NOTES:**

1. Since the start of the programme
2. Includes companies and academic institutions
3. These programmes are now closed

## The opportunities for identifying and exploiting commercial potential are relatively small but need to be protected

1.15 In the 1980s many government departments withdrew from sponsorship of "near-market" research. As a result, funding of research often ceases well before the stage at which something to sell might emerge. Commercial exploitation may also be limited because:

- The agricultural sector is diverse and farmers have a tradition of sharing information about good practice, new farming methods and products.
- Research on environmental protection or animal welfare issues may not generate intellectual property for commercial exploitation but instead bring benefits through publication of the results or by providing guidance to farmers.
- The depressed state of the agriculture sector has led to fewer industrial partners coming forward to contribute to the commercialisation of research.

1.16 The Department has funded relatively little research generating intellectual property or other assets suitable for commercial exploitation. Whilst the Department currently holds 7 United Kingdom patents granted or filed, the five research contractors we examined hold more than this **(Figure 5)**.

1.17 The underlying nature of much of the Department's research is to inform policy-making, perform regulatory functions, conduct "horizon scanning" or provide information for the public good. Given this the Department does not expect that there would be many opportunities for commercial exploitation or scope to set meaningful targets for commercialisation. The Baker principles reinforce the importance of freedom for research contractors to pursue commercial exploitation of the intellectual property they develop.

## Revenue from exploitation of intellectual property has been relatively low but is expected to grow

1.18 In 2001-02 the commercial income of the five research contractors we reviewed was nearly £21 million **(Figure 6)**. This income includes, however, consultancy advice and laboratory testing. Royalty and licensing income from commercialising intellectual property was just under £450,000, only 2.4 per cent of total commercial income. Individual projects often earned only a few thousand pounds a year. In rare cases they were larger, for example a stripper header **(Figure 7)**, patented by the Silsoe Research Institute in 1985, has generated more than £1.25 million (gross receipts, before deductions for patenting and other costs of maintaining intellectual property).

## 5 Number of patents managed

| | Number of patents managed | |
|---|---|---|
| | Granted[2] | Filed[3] |
| Central Science Laboratory | 29 | 19 |
| Centre for Environment, Fisheries and Aquaculture Science | - | 1 |
| Horticulture Research International | 6 | 12 |
| Roslin Institute | 8[1] | 3 |
| Silsoe Research Institute | 34[1] | 1 |
| **Total** | **77** | **36** |

**NOTES:**

1. 5 Roslin patents and all of Silsoe Research Institute's patents have been assigned to third parties to manage
2. Granted: These patents have been awarded and recognise the intellectual property rights of the applicant
3. Filed: These patents are still being reviewed and assessed by the Patent Office and are yet to be granted

**Patent:** Patents are intended to cover new processes and products which are of practical commercial use. For an application to be successful, the invention must be novel and involve an inventive step. In exchange for public disclosure, the inventor receives a limited monopoly for a period of twenty years. Fees are payable to the Patent Office at the time of registration and annually thereafter.

## 6 Commercial income in 2001-02 at five research contractors

| Research contractor engaged by the Department | Income from commercialising Intellectual property (Royalties and licence) | | Total commercial income[1] |
|---|---|---|---|
| | £000 | % of total commercial income | £000 |
| Roslin Institute | 100 | 4.8 | 2,066 |
| Silsoe Research Institute | 69 | 3.6 | 1,910 |
| Horticulture Research International | 111 | 1.9 | 6,000 |
| Centre for Environment, Fisheries and Aquaculture Science | 142 | 4.7 | 3,047 |
| Central Science Laboratory | 27.5 | 0.49 | 5,641 |
| **Total** | **449.5** | **2.4** | **18,664** |

**NOTE:**

1. There is no precise definition of commercial income and these figures may not be consistent. However, in general terms the amounts shown are for income from non-United Kingdom government sources.

**7 The Stripper Header, patented by the Silsoe Research Institute in 1985**

Instead of cutting the crop at ground level, a combine harvester fitted with a stripping header removes the grains and heads from the stalks, leaving about 75 per cent of the length of the stalk standing in the field. The harvesting rates of many crops have been increased by 50-100 per cent. The overall harvesting period can be reduced and timed for maximum advantage which means that the farmer only needs one machine rather than two, or just a smaller harvester. Crops can be harvested even if the straw is too wet for conventional harvesting and to better effect if the crop has been flattened or damaged. Over 2000 machines are now operating in thirty countries around the world.

1.19 The Department is entitled to a proportion, previously 40 or 60 per cent depending on the type of contract, of royalty income earned by its research contractors. The Department's entitlement is now 10 per cent of royalties, but it has passed to contractors the responsibility for the costs of protecting intellectual property. Between 1988 and 1998, the Department collected royalty income of about £150,000, less than 0.1 per cent of research spending. In 2001-02 the Department received £15,000 in royalty income: by way of comparison other bodies with a greater capacity to generate intellectual property have earned more. For example, the Medical Research Council had an average annual income of some £12 million to September 2001 from sales of equity in spin-out companies, licensing and royalties. The Natural Environment Research Council has annual licensing and other commercial consultancy income including income, from the sale of data related products, totalling £2.45 million.

1.20 The five research contractors expect royalty and other income derived from their intellectual property to grow in future years due to:

- Lower government research funding which has increased the drive to find alternative income. At Horticulture Research International, for example, income from the Department, the body's main source of funds, declined from under £13 million in 1995-96 to £10 million in 2000-01. Over the same period income from non-government sources (not exclusively from commercialisation of intellectual property) rose from £3 million to £6 million.
- More efficient use of assets, including intellectual property, as a source of revenue.
- The Baker report and the government's response, which have encouraged contractors to re-examine and audit their intellectual property portfolios and identify commercial potential.
- Introduction of the Wider Markets Initiative which has led to Departments relaxing their rules on holding receipts from commercial activities.

1.21 ADAS Consulting Limited is one of the largest private sector agricultural research companies in the United Kingdom, being an executive agency of the Ministry of Agriculture, Fisheries and Food until privatised in 1997. Privatisation had made relatively little difference to the scope for commercialising intellectual property in the company's view.

1.22 Their turnover includes up to £19 million a year in research contracts. Some are small projects using new technology to meet specific market needs but these are not expected to generate royalty revenue for some years to come. Whilst creating new technology may be difficult, the company considers that there is scope to generate future revenue through the use of information technology to present intellectual property in useful forms, for example computer programmes and data to assist decision making (as in the case of MANNER, for optimising use of nitrogen fertiliser paragraph 1.13), and charging for access to data derived from scientific research, whether from usage payments or indirectly by securing new research contracts. For example, ADAS Consulting is considering making commercially available on CD-ROM the identification and control of pests and diseases found in cereals. Several of the research establishments we examined were also considering exploiting their intellectual property in similar ways.

## The licensing of the "Dolly" technology was different in size and scope

1.23 One of the most prominent examples of commercialising intellectual property was the Roslin Institute's commercialisation in 1998-99 of the technology which had led to the birth of Dolly the Sheep, nuclear transfer technology. The Department had funded two thirds of the early research which eventually led to the birth of Dolly. The commercialisation of Dolly was greatly different in size and scope to other examples of commercialisation of research funded in part by the Department. We have therefore examined Dolly separately in Part 4 of this report.

## What we examined

1.24 In this study we examine:

- whether the Department and its research contractors have encouraged commercialisation (Part 2);
- how the risks arising from commercialisation have been managed (Part 3); and
- how the nuclear transfer technology which led to Dolly the Sheep was commercialised (Part 4).

1.25 Our main methods are described in Appendix 1. Broadly they involved:

- A review of the intellectual property generated by the five research contractors and any action to commercialise it.
- Interviews with staff in the Department and at its research contractors.
- Case studies of items of intellectual property that have been commercialised.
- Discussion groups to obtain the views of scientists on commercialisation.
- Reviews of key issues at other public sector organisations, such as research institutes sponsored by the Biotechnology and Biological Sciences Research Council; the Defence Evaluation and Research Agency[3]; and universities; and in the private sector, ADAS Consulting Ltd.
- Advice from consultants Morgan Harris Burrows particularly on the commercialisation of nuclear transfer technology (Dolly the Sheep).
- Drawing on the work done by colleagues in the study of *Delivering the Commercialisation of Public Sector Science* which reflects good practice based on reviews of public and private sector organisations. Appendix 3 includes the key recommendations from that report.

*Robotic Mushroom Harvester. Photograph courtesy of Silsoe Research Institute.*

3 *The Defence Evaluation and Research Agency separated into two organisations in July 2001: QinetiQ (a private sector technology company) and the Defence Science and Technology Laboratory (an agency of the Ministry of Defence).*

# Part 2

# Encouraging exploitation

2.1 This part examines how the Department and its research contractors encourage the identification and exploitation of intellectual property and the constraints they face. In particular, we consider:

- the steps being taken to encourage a positive attitude;
- the freedom given to research contractors to exploit intellectual property; and
- funding the costs of exploitation.

## Steps to encourage a positive attitude

### Commercial objectives for contractors are to be introduced

2.2 The Baker report recommended that research establishments and their chief executives should have commercialisation as an explicit part of their mission statement and objectives to encourage identification and exploitation of opportunities for realising the economic value of intellectual property. Horticulture Research International, the Centre for Environment, Fisheries and Aquaculture Science and the Silsoe Research Institute have incorporated knowledge transfer into their corporate objectives; and at Roslin the promotion of commercialisation is a personal objective of each of the thirty-two principal scientific investigators.

2.3 The Department's executive agencies do not have knowledge transfer as an explicitly stated part of their mission. The Department has, however, made knowledge transfer an explicit responsibility of senior management, including Chief Executives, at the research contractors it sponsors. These are reflected in personal work objectives as appropriate. For example, the Horticulture Research International Mission Statement is "To innovate and communicate for the benefit of producers and consumers of horticultural and other plant-based products".

### Awareness about exploiting intellectual property varies between scientists

2.4 The Baker report found that the lack of staff awareness about exploiting intellectual property, and a belief by scientists that dissemination of information in the public sector was more important than exploitation, were the main barriers to commercial exploitation.

2.5 We explored with discussion groups of scientists at each of our sample contractor organisations their understanding of potential for exploitation. Individually, the more experienced and senior scientists had a better awareness whilst those scientists who had previous experience of projects with commercial potential were most aware.

2.6 Across an organisation, the level of awareness depended on the body's success in raising the profile of its commercial activity and on the level of contact that scientists had with private or other research sectors. At the Roslin Institute, for example, publicity surrounding the licensing of nuclear transfer technology had raised the profile of commercialisation and scientists seemed well aware of what could be achieved as a result. Elsewhere the level of awareness has been lower but significant efforts have been put into training over the last two years. The Centre for Environment, Fisheries and Aquaculture Science, for example, raised scientific staff's awareness of intellectual property through seminars to:

- encourage the identification of potential commercialisation opportunities; and
- avoid the risk that staff may inadvertently compromise options for exploiting intellectual property by making statements in public or writing about their work.

2.7 Discussion group members involved in commercial ventures in the past had not had the benefit of prior training, but thought that training, for example in how to license patents, would have been helpful. Whilst our sample of contractors all offered some general awareness training in intellectual property issues, further

training would improve scientists' understanding of the basic business skills needed for commercialisation and to protect options for exploitation. Training is also required on when scientists should or should not publish their research finds, since this can conflict with commercial considerations which require keeping their ideas and inventions confidential.

## Attitude and commitment amongst scientists towards commercialisation vary

2.8 The organisation's culture can influence a scientist's search for commercialisation opportunities. We found three distinct sets of views amongst scientists we met. Of the three, the largest group were generally supportive of commercial exploitation of their work as involvement in a commercial venture enabled them to get closer to the existing or potential needs of their research customers, and to benefit from contacts with business. Increased job satisfaction can follow from successful commercial work, and commercialisation can be a significant motivator as scientists see the direct results of their work being sold as useful products.

2.9 The second group comprised a small, but significant number of scientists who were less committed to commercialisation because:

- They were motivated more by scientific endeavour than potential financial rewards. Some scientists believed that career progression was dependent upon publishing research papers and gaining the recognition of peers in their field. Unless scientists' involvement in commercial work could be recognised as part of their performance review there was a disincentive to participate in commercialisation of their research.
- Involvement in the exploitation of intellectual property was viewed as risky because even the best ideas can fail. Writing research papers was viewed as relatively risk free.
- Involvement in commercial projects meant that scientists were asked to work under confidentiality agreements, which they felt could hamper collaboration with others and impact on their ability to progress their research.
- Some were concerned that association with a commercial product could damage their reputation for independence and scientific standing.
- Some saw commercialisation as time consuming, involving out of hours working, and which was sometimes unsuccessful or failed to progress the science. Not all scientists saw it as their job to pursue commercialisation, particularly where the organisation had its own business unit and personnel dedicated to exploiting commercial potential.

2.10 A third group of scientists were uncomfortable with commercialisation because it took them away from their pure science roots. However, they recognised that if their organisation were to maintain its current level of research activity, it would need to increase its income from sources such as commercialisation, as a substitute for a predicted decline in central government funding.

## As well as awareness and commitment, financial incentives too have a role in promoting commercialisation

2.11 Participation of scientists in commercialisation is necessary to provide scientific advice and to take a continuing role once a commercialisation project is underway. Incentives may therefore be required. These might include schemes to provide a scientist or inventor with a personal share of the royalties from licence agreements or an equity stake in a spin-out company. Equally, organisations might allocate additional research funding to a team or teams who have been successful in commercialisation.

2.12 Before 2002, the Department's incentive scheme for rewarding inventors among its staff consisted of an award related to the benefit accruing to the government from an invention's use or commercial exploitation, for example 30 per cent of receipts up to £10,000 and one per cent of receipts over £500,000. However, the scheme had never been applied in practice, and hence no payments to inventors have been made. The Department explained that the small returns from commercialisation, after deducting expenses, would not leave sufficient income to allow awards to be paid.

2.13 The Biotechnology and Biological Sciences Research Council's incentive scheme is applicable at all its sponsored research contractors, including Roslin and the Silsoe Research Institute. Inventions are reviewed by a panel at each institute, comprising the Director, a senior scientist not involved in the invention's exploitation, and a nominee of a trade union. Awards can be made to teams of scientists involved in commercial successes on the basis set out in **Figure 8**. Other incentives include exceptional performance awards (as part of performance related pay), personal bonuses and individual merit promotion.

2.14 Scientists we spoke to had mixed opinions on incentive schemes. Most considered incentive schemes to be motivating and worthwhile if properly applied, giving recognition to the scientists' work. It could be demotivating if scientists generated considerable commercial income for the establishment but did not receive any financial reward.

**8 The level of awards payable on the Biotechnology and Biological Sciences Research Council's incentive scheme**

| Income from commercialisation (based on gross and net receipts) | Proportion of receipts to staff involved | Proportion of receipts to the Institute |
|---|---|---|
| **Gross receipts** | | |
| First £1,000 | 100% | Nil |
| £1,000 to £50,000 | 20% | 80% |
| **Net receipts** | | |
| £50,000 to £500,000 | 20% | 80% |
| Over £500,000 | 5% | 95% |

2.15 There were, however, potential conflicts of interest, such as scientists becoming more interested in commercial ventures at the expense of their other responsibilities. Similarly incentives could be divisive if not carefully applied, for example, if only one or two scientists out of a team were rewarded, even if they were the key members, when a larger team had also made a contribution to the success of a project.

2.16 For those bodies directly sponsored by the Department, it has asked its research contractors to identify their own needs with a view to adopting staff incentive schemes to suit their particular circumstances. The first pay-out to staff under one of these schemes is anticipated in late 2002. Our report on *'Delivering Commercialisation of Public Sector Research'* found that commercialisation specialists such as the business experts employed by research establishments also need incentives. This approach was adopted in the sale of the technology that led to Dolly the Sheep, discussed in Part 4 of this report.

## Giving research contractors the freedom to exploit

2.17 The legal and administrative status of research contractors, including research institutes, executive agencies, and non-departmental public bodies, may affect the level of autonomy and, consequently, the level of commercial freedom to exploit research.

### The status of the contractor has a bearing on its financial freedom

2.18 Two of the **research institutes** we examined, Roslin and Silsoe, are companies limited by guarantee (without share capital) and registered charities, sponsored by the Biotechnology and Biological Sciences Research Council. In principle, the institutes have the freedom to set up joint ventures and spin-out companies as they wish, although the Council has an oversight role and its approval for such enterprises is required. Roslin has set up several spin-out companies in which it has equity stakes and from which it can retain a share of any income.

2.19 The **non-departmental public body** we examined, Horticulture Research International, is also a company limited by guarantee (without share capital) and a registered charity. It is sponsored by the Department. The body had experienced difficulties in becoming more commercially orientated because of its constitution. For example, Horticulture Research International does not own its assets and its borrowings count against the Department's Departmental Expenditure Limit. Horticulture Research International consider that this is a significant constraint because in effect any additional expenditure proposals by the body have to be assessed by the Department against the Department's other spending priorities rather than the potential benefit to Horticulture Research International alone.

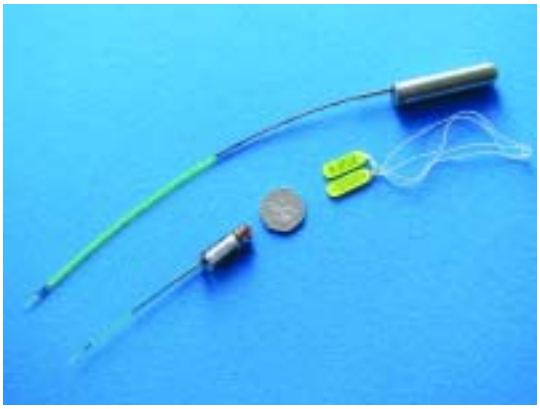
2.20 However, the Department believe that Horticulture Research International's ability to exploit its science has not been hindered by these factors. A request from Horticulture Research International to the Department to borrow money would not be turned down automatically and exploitation of its science would not necessarily depend on using its assets as financial security. Non-departmental public bodies such as Horticulture Research International are subject to five-yearly reviews which evaluate their performance and organisational arrangements. Such a review, currently ongoing, will consider the scope for giving more commercial freedoms.

2.21 For the **Department's executive agencies**, financial constraints have arisen because they have not normally been able to carry forward any money underspent on programmes (for example, on capital equipment) from one year to the next. Agencies have had to surrender any surpluses to the Department at the end of each year. Under the government's Wider Markets Initiative, agencies will have the flexibility and freedom to retain receipts from commercial exploitation of assets for non-core purposes, such as irreducible spare capacity from equipment, land and buildings but also from assets such as databases, skills and intellectual property.

2.22 From 2003-04 end-year flexibility will be available to executive agencies, consistent with the Department's Departmental Expenditure Limit.

2.23 Staff at the Centre for Environment, Fisheries and Aquaculture Science considered that the Department had a "hands on" approach to proposals for commercialisation. Consulting the Department and gaining their approval for proposals meant that business could be lost, and hence there was a disincentive to approach the Department. **Figure 9** shows the conflicts which can arise between a sponsored research body and the Department in taking forward commercialisation proposals.

**9 Data Storage tags: a case study**



*Photograph courtesy of Centre for Environment, Fisheries and Aquaculture Science.*

*Electronic data storage tags designed for monitoring fish behaviour in the open sea. The yellow tags inform fishermen that the fish contains a tag. CEFAS*

The Centre for Environment, Fisheries and Aquaculture Science developed a series of electronic tags capable of storing data, which could be attached to fish to enable scientists to study fish behaviour. The Centre licensed these 'Data Storage Tags' to Lotek Wireless Inc, a Canadian company at the forefront of the wildlife telemetry market. Following developments in the Treasury's policy on selling government services to wider markets, the Centre saw an opportunity to generate sustainable income for its specialist electronic engineering unit, gain access to complementary skills in production engineering and quality assurance through a joint venture with a commercial partner. This would enable them to develop a new range of smaller, more accurate, long-life devices.

A deal was progressed with Lotek Wireless from early 1998, but negotiations were not concluded until July 2001. The novelty of the deal, which was to be the first overseas joint venture with a private sector company, contributed to the delay. The Department (the Ministry at the time) also had a number of concerns including its own legal and financial liability, the tax position, the commercial risk of poor performance and the need for the National Audit Office to have access to audit the deal. During negotiations the structure of the original deal was revised so that rather than royalty income the Centre would obtain a minority equity share in Lotek, which the Department considered increased the riskiness of the deal.

The Centre thought the Department was too risk averse and not supportive of the proposed deal, while the Department considered that the Centre had not identified and addressed all the risks involved. The Centre eventually prepared a document listing all the risks and the steps taken to address these risks. Had this risk-based approach been adopted sooner the deal may have progressed more quickly.

2.24 The publication of the Baker report was seen to have encouraged a more pragmatic stance towards commercialisation within the Department. The Central Science Laboratory, for example, told us that Departmental staff responsible for intellectual property issues were now more encouraging, looking at the merits of each case.

## The Department currently owns the intellectual property derived from its research but plans to allow contractors to own it in the future

2.25 Baker recommended that intellectual property rights should lie with those carrying out, and not those financing, the research. Traditionally, the Department owned or part owned almost all the intellectual property derived from its funded research, except in the special case of LINK grants as described in paragraph 1.14. Research contractors viewed the Department's ownership of intellectual property, and rights and benefits of exploitation as a disincentive to commercialisation. The Department has, in line with Baker principles, decided to transfer ownership of intellectual property to contractors except where there are valid reasons not to do so (for example where the research results relate to development of regulations or where there is a need to disseminate information widely, quickly). Contractors will make their own decision on the need and most appropriate method to protect and exploit their intellectual property.

2.26 Although the status of executive agencies - legally indivisible from the Minister - precludes them from owning intellectual property in their own names, all agencies have delegated authority from the Department to identify, protect and exploit intellectual property and, within Treasury rules, to derive benefit from income generated. The Department continues to be involved in aspects of intellectual property management, for example: monitoring contractor performance; a step-in provision where an establishment fails to take reasonable measures to exploit intellectual property; and provision of advice in cases where there are challenges to intellectual property or legal issues to resolve.

## Management of intellectual property does lie with contractors and can be expensive

2.27 The Committee of Public Accounts, in its report *The Management of Intellectual Property in the Ministry of Agriculture, Fisheries and Food (HC 237, 1994-95)* examined the work of the Ministry's Intellectual Property Liaison Unit. This Unit, now disbanded, had earned £65,000 from exploitation, in a period in which the Unit's costs had been some £465,000. Following an internal review the Department devolved the management of intellectual property to research contractors to encourage them to take the lead in the identification and exploitation of such research. For example, contractors have been allowed to retain 90 per cent of royalty receipts, with the Department receiving the remaining 10 per cent. Responsibility for the costs of protection and exploitation have also been passed by the Department to the contractor.

2.28 **Figure 10** summarises the Department's guidance on the division between the contractor's and the Department's responsibilities:

**10 Division of responsibilities for intellectual property**

**The contractor's responsibility is to**

- identify any intellectual property and notify the Department of its nature;
- decide whether to protect exploitable intellectual property which arises from the research contract;
- decide how best to protect the intellectual property;
- pay for that protection;
- identify markets and licensee(s) for exploiting the intellectual property; and
- ensure that the Department is informed of developments at all stages.

**The Department's responsibility is to**

- determine whether there are valid and compelling reasons for the Department to retain ownership of any intellectual property;
- monitor, through annual and ad hoc reports, exploitation activities (where ownership of intellectual property is vested with the contractor); and
- ensure the Department receives its share of any royalty income.

2.29 In managing and exploiting intellectual property research contractors face a number of challenges:

- Pre-seed finance, usually to demonstrate the commercial feasibility of prototype products or processes, is required to support work beyond the initial research stage to develop the idea sufficiently to attract financial support from business investors or venture capitalists.
- Resources are needed to administer knowledge transfer activities including advice and expertise to help identify commercial opportunities and patenting costs for example.
- Establishing and maintaining intellectual property rights is expensive. Silsoe Research Institute estimated, for example, that to file and maintain an international patent for the first five years could cost £30,000, and over the lifetime some £250,000. If legal costs and other costs arise to defend the patent against challenges or infringements, the cost of litigation could be at least another £100,000, or as much as £1 million in the Roslin Institute's experience.

2.30 Whilst research programmes may identify ideas with commercial potential the costs of further research and additional funds to demonstrate their commercial viability, for example to develop a prototype of the product, can be significant. Our consultants suggest that as an example, developing commercial feasibility in the life sciences sector typically will cost between £50,000 and £250,000 to get it to a stage at which it can attract private funding for development. The Central Science Laboratory estimated that to take an idea from proof of concept to prototype product stage could cost more than £500,000. Contractors have to fund this from their own resources or find private sector partners. The lack of funding for development may mean that ideas with commercial potential are not progressed. A robotic mushroom harvester invented at Silsoe Research Institute is a good example **(Figure 11)**.

**11 Silsoe Research Institute's robotic mushroom harvester**

Mushrooms are the United Kingdom's single most valuable horticultural crop, worth £300 million a year. Each mushroom must be picked by hand. After investing nearly £1 million Silsoe Research Institute developed an automatic robotic mushroom harvester which identifies and picks ripe mushrooms in a manner that does not damage or contaminate their neighbours. The feasibility of the system has been proven and a pilot system has been tested.

Having established the basic technologies needed to make automatic mushroom harvesting feasible, Silsoe Research Institute needed a private sector partner to commercialise the robot. In 1995 the Institute entered into an agreement with a small company to manufacture the product using their technology. A pilot harvester was completed in 1997 and demonstrations were held for British and international firms. Although the trials went well, private sector companies were unwilling to commit to a system that was unproven in the commercial world. Further funding of £250,000 was required to develop the pilot system into a commercial product but the private firms were unwilling to make such an investment prior to firm orders. No company has been willing to meet the funding gap between a successful laboratory system and a commercial operation. Silsoe Research Institute estimates that the potential commercial income could be some £100,000 a year in due course, if a commercial product were successfully launched.

*Photograph courtesy of Silsoe Research Institute.*

## The Department could do more to assist research contractors obtain the resources and financial support they require to commercialise their intellectual property

2.31 The Department has encouraged its research contractors to attend seminars on commercialisation of intellectual property presented by the Department of Trade and Industry and Partnerships UK. Partnerships UK has also provided direct assistance to contractors. However, although research contractors are now able to retain 90 per cent of any commercial receipts to help sustain further commercialisation activity and fund extra scientific research, they may still lack funding on a scale necessary to exploit intellectual property, particularly 'pre-seed' funding.

2.32 The Natural Environment Research Council, a Department of Trade and Industry research council, has established and set up a small innovation fund of £500,000 over two years (renewable) to provide pre-seed funding, and the Office of Science and Technology held a £10 million competition in 2001, the Public Sector Research Exploitation Fund competition, to build the commercial capabilities of eligible bodies. The competition enabled public sector research establishments to bid for seed funding to support commercialisation of research and to develop their capacity to exploit their science and technology. The Biotechnology and Biological Sciences Research Council for example submitted a bid for £4 million on behalf of the institutes and agencies of the Council, the Department and the Scottish Executive Environment and Rural Affairs Department. The bid, however, was unsuccessful.

2.33 Whilst the Department may not be in a position to fund development of an idea to market, it could ensure contractors are aware of how to identify other sources of finance. For example, Regional Development Agencies are working closely with universities, and research establishments can apply for University Challenge funding as part of a university bid if they have an existing relationship with the University. Four of the Biotechnology and Biological Sciences Research Council's institutes are members of a University Challenge consortia and the Roslin Institute gained access to funding in collaboration with Edinburgh University.

# Part 3

# Managing the risks of commercialisation

3.1 In this Part we examine how the Department's research contractors were:

- selecting which ideas to protect and to exploit; and
- managing risks when making deals.

## Selecting the intellectual property with commercial potential

3.2 Unless research contractors can identify intellectual property with the greatest commercial potential good ideas may be overlooked and resources may be wasted pursuing ideas with limited chances of success. There are generally three key stages in selection - identification; assessment; and preparation of a strategy **(Figure 12)**. We examined how our sample contractors approached these stages.

### Contractors, usually their scientists, tended to identify ideas with commercial potential

3.3 Contractors relied primarily upon scientific staff to identify commercial opportunities from within their individual areas of research. Scientists were regarded as having the best understanding of the science involved, the collaboration required to take ideas forward and an awareness of which private sector firms might be interested in partnership deals.

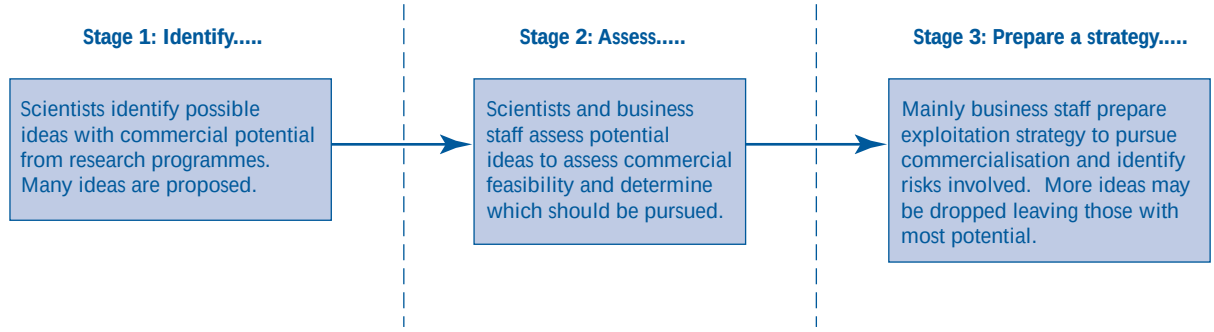
3.4 Systematic reviews of science activities were useful. The Central Science Laboratory, for example, had used business managers and scientists together to review all its science streams, to focus resources on the protection and exploitation of the ideas most likely to be commercially successful. Ideas identified include a new range of plant disease detection kits and a decision support system associated with pesticides management and control. The Laboratory had also joined a Department of Trade and Industry Biotechnology Exploitation Platform, which will fund an audit of their intellectual property to look for synergies in the field of biotechnology between local universities, health authorities and private companies in the Yorkshire area.

3.5 Research contractors recognised that they have to actively manage their portfolios and seek potential commercial partnerships. For example, the Roslin Institute provides information on the Internet about its science programmes, indicating where it is seeking partners for commercialisation projects.

### Ideas with commercial potential tended to be assessed by business staff

3.6 The experience and expertise of business staff was key in making an assessment of which ideas had greatest commercial potential and which might be quickly dropped. How ideas were assessed, and the speed with which the processes were carried out varied between establishments. Business managers could become a

**12 Key stages of selecting intellectual property with commercial potential**



"bottleneck" in the assessment process because of time constraints. **Figure 13** is an example of some of the criteria used to address ideas. Results of the assessment process were rarely documented although contractors were aware of the need to make the processes more transparent.

**13 Key questions for assessing the strength of commercial ideas**

- Who funded the research that led to the idea? Who will own the idea (intellectual property or other asset)?
- Is the idea protected? Can it be protected?
- If the idea cannot be protected, is there any value in commercialising it? Is it possible to be first to market?
- What are the benefits of commercialising? For example, is the idea innovative or is it better or cheaper than existing market products?
- What alternatives exist to the idea? Who are the competitors? What do they know about the idea?
- What is accessible market size? How will it be accessed? Are there barriers to entry?
- What is the value of the idea and to whom?
- What level of development / investment is required?
- Is the value greater than investment? Will the sponsor department agree?

*Source: The former Defence Evaluation Research Agency*

### Silsoe Research Institute work with British Technology Group to assess commercial potential

3.7 The Silsoe Research Institute worked in close partnership with British Technology Group (see below) to assess their portfolio of patents. The Group applies a risk model to ideas, involving an assessment of the technical feasibility of an invention, whether to protect the idea and if so how, and the invention's commercial potential. If the Group considers that an idea is worth exploiting it arranges for patenting and protection, seeks private partners, and becomes responsible for negotiating any commercial deal.

**The British Technology Group** helps many public sector institutions to develop and transfer to industry commercially promising technology resulting from their work. The Group licenses technology internationally and shares the income received with the source.

3.8 Silsoe Research Institute considered that the arrangement with the Group had worked well. Ideas had been reviewed by experienced people and those taken forward were well supported. However, there was a risk that scientists did not get sufficiently involved with business customers, with the result that opportunities to gain an insight into commercial activity were lost.

3.9 In 2000 the British Technology Group notified Silsoe Research Institute that their criteria for managing portfolios was changing, and that they would only proceed with ideas with potential to produce revenue of more than £250,000 a year. It was likely that many of Silsoe Research Institute's ideas would be too low in potential value to meet that criterion. In response to this challenge, the Silsoe Research Institute had, with support from the Technology Transfer Partnership, developed a new strategy for commercialisation coupled with an in-house training programme in commercial awareness. As a result, three new potential products had been identified and are being further developed. In addition, Silsoe Research Institute has identified a number of external sources for the provision of expert legal and patent advice.

### Exploitation or business strategies could be proposed more widely

3.10 Once an idea has been assessed the research contractor has to decide whether to take it forward to the exploitation phase. Baker advocated a culture that encourages research establishments to take decisions which provide the possibility of significant benefits but explicitly take account of the risk of failure. Research contractors therefore need to demonstrate to their sponsor departments, and any private sector partners, a robust approach to the pursuit of commercial opportunities and active management of inherent risks.

3.11 Our five research contractors did not generally prepare exploitation strategies or business plans setting out project risks and how they were to be managed. It was difficult to judge therefore whether risks had been identified and fully assessed, and whether appropriate decisions had been made at the right time. Well thought-through business cases are particularly important for larger or riskier activities, and especially for joint ventures and spin-out companies. Partnerships UK regards exploitation strategies and business plans as very important documents. A checklist of good practice for exploitation strategies based on the former Defence Evaluation and Research Agency's guidelines is shown in **Figure 14** opposite.

## Managing the risks when making deals

3.12 Financial and non-financial risks exist in commercialisation. These include:

- selecting the right type of deal and partner;
- obtaining appropriate expertise to get the best deal; and
- managing conflicts of interest.

## Selecting the right type of deal and partner

### Licence agreements are the most common

3.13 The most common deals available to contractors are licence agreements, joint ventures and spin-out companies **(Figure 15)**, of which licence agreements with private sector companies were most frequently used by the Department's contractors **(Figure 16)**.

**14 Checklist for a research contractor's exploitation strategy**

**Identify the risks of the deal**

- financial - assess liabilities and impact on use of resources for exploitation of other projects;
- political - consider the stakeholder interests and implications;
- legal - ensure relevant laws including European Union and international laws are adhered to;
- conflicts of interest - determine how they will be managed;
- ownership and protection of the intellectual property - ensure the implications of transferring ownership are worked through.

**Financial considerations**

- investment and returns;
- business performance;
- sensitivity analysis for various options.

**Selecting the most appropriate type of deal**

- establish the type of deal that would meet development objectives and optimise commercial returns. This might be licensing, or a joint venture, or spin-out company.

**Selecting the right partner**

- define the criteria for potential partners, such as complementary science and investment requirements;
- carry out due diligence of potential partners;
- plan exit provisions if the deal proves unsatisfactory.

**Structuring of the deal**

- ascertain the likely returns for the establishment in terms of royalties and equity;
- decide responsibilities for protecting the intellectual property.

*Source: The former Defence Evaluation Research Agency*

**15 Main types of commercial deal involving intellectual property**

| Type of deal | Description |
|---|---|
| *Licensing intellectual property* | Contractors can license the use or exploitation of a piece of intellectual property that they own in return for a share in a future income stream. |
| *Joint venture* | A private sector company will provide funding to develop the research and will seek to exploit commercial opportunities. Often used when a marketable product has been identified but the contractor does not have the resources or capability to manufacture or market the research. |
| *Spin-out company* | A new company is set up to exploit commercial potential of the research. Private sector investors provide funding and/or commercial expertise and in return receive a share of the commercial income. They give public bodies the means to raise private finance to develop the research into a marketable product. The deals often provide the contractor with an equity stake in the new company. |

**16 Licence agreements and joint ventures at five research contractors to date**

| | Number of licence agreements operating | Number of Joint ventures | |
|---|---|---|---|
| | | Joint ventures (equity) | Spin out companies |
| Central Science Laboratory | 8 | - | 2 |
| Centre for Environment, Fisheries and Aquaculture Science | 5 | 3 | - |
| Horticulture Research International | 100[1] | - | 3 |
| Roslin Institute | 6 | - | 2 |
| Silsoe Research Institute | 15 | - | - |
| **Total** | **134** | **3** | **7** |

**NOTES**

1. *An approximation. Numerous plant varieties trialling and other licences.*

3.14 The nature of research carried out may determine the most appropriate type of deal. For example, Silsoe Research Institute and Horticulture Research International had sought partnerships with private companies to develop and manufacture, on a commercial scale, prototype models, and to provide access to a market for the product. In another instance, CEFAS Technology Ltd (CTL) is a wholly-owned company that was established on guidance from the Treasury to handle the financial interactions with Lotek Wireless Inc., the Canadian company who are licensed to commercialise the Centre for Environment, Fisheries and Aquaculture Science's Data Storage Tags technology (Figure 9). So far, CTL has not undertaken any trading, beyond an initial sale of intellectual property to Lotek and a matching purchase of equity. However, it has the potential to be used more widely as a vehicle to facilitate commercialisation, and the Centre is likely to do this before long. CTL is not a "spin-out company" in the usual sense; formally it is a public corporation. Licence agreements have been the favoured vehicle for exploitation, mainly because they involve low levels of maintenance of rights and of funding by the public sector. Private companies invest in the development of the intellectual property to establish a market product and pay the research establishment a percentage of income received on sales of the product. Examples of successful licensing deals include the exploitation of technology to improve the productivity of leeks set up by Horticulture Research International **(Figure 17)**.

3.15 In selecting a private sector partner research contractors may be reluctant to widen their search beyond existing contacts. Contractors tended to approach potential partners who were known to be expert in the relevant field and with whom they knew they could do business. Relatively little competition was applied, although this may reflect the small number of commercial firms prepared to invest in agriculture. And in some cases open competition may risk damaging the value of the intellectual property by revealing too much information. In other cases time is critical and there is a short window before other scientists develop a similar technology. If partners are sought by competition then that window may be lost. Research contractors should be able to demonstrate that they have identified the best partners.

## The number of joint ventures and spin-outs that have been set up is relatively small but likely to grow

3.16 In recent years joint ventures and spin-out companies have been the preferred vehicle for commercialising intellectual property. Our sample contractors had set up a total of three joint ventures and seven spin-out companies. Factors constraining use of joint ventures and spin-out companies have included:

- the relatively small number of private companies prepared to invest in the agriculture sector;
- the funding gap and financial restrictions; and
- prior to 2000 the bar on direct participation by serving government scientists in the commercial exploitation of research, and in particular on receiving equity or share options. The Civil Service Management Code was changed in July 2000 to enable government scientists to participate in the commercialisation of their research.

### 17 Licence agreement to exploit male sterile leek material

Natural pollination of plants - by wind or insects - can lead to in-breeding in vegetables. For leeks this causes wide variations in quality and a failure to reach supermarket quality in 50 per cent of cases. Scientists at Horticulture Research International recognised the commercial potential of developing a variety of male sterile leek from which it was possible to produce commercial quantities of hybrid leek seed (i.e. that do not produce pollen). They sought a partner to produce, market, and distribute commercial quantities of hybrid leek seed. In 1993, after a competitive process, they negotiated a licence agreement with a Dutch company, under which they received £50,000 immediately and the right to royalties over a six-year period. Since 1993 gross receipts shared with the Department have been over £430,000. The original licence agreement ended in December 1999. A new agreement has been negotiated, allowing Horticulture Research International to licence the technology to more than one party, and a further £55,000 income has been generated so far.

*Photograph courtesy of Horticulture Research International.*

3.17 **Figure 18** sets out the companies set up by the Roslin Institute between 1987 (the first) and 1999. In 1987 PPL Therapeutics plc was set up to exploit transgenic technology, specialising in the production of human proteins and peptides for therapeutic and nutritional use. Roslin did not receive any equity in the company on set up, as government policy at the time precluded public sector research establishments from holding equity. Instead Roslin entered into a royalty-bearing licence (for which Roslin received just £7,000) and received research funding.

**18 Spin-out companies set up by the Roslin Institute**

**PPL Therapeutics plc** was set up in 1987 to develop and commercialise the technology that allowed the production of human proteins in the milk of sheep and cattle. PPL employs 200 staff and has a market capitalisation of £63 million (2001).

**Rosgen Ltd** was a specialised animal genotyping company established in 1997 with funding from venture capital, the Holstein Friesian Society of Great Britain and Ireland, two animal breeding companies and private investors. It offered a range of DNA-based tests including parentage testing for cattle and dogs, and disease resistance testing in sheep and pigs. The Roslin Institute is a minority shareholder (approximately five per cent). Rosgen went into voluntary liquidation in January 2001.

**Roslin Nutrition Ltd** was created as a wholly owned subsidiary of the Roslin Institute in March 1997. It provides a high quality feed compounding and feed evaluation service and employs 12 staff and had a turnover of £750,000 per annum. It was sold in February 2002 for £50,000 to a company formed by the previous management of Roslin Nutrition.

**Roslin Bio-Med** was set up in April 1998 by the Roslin Institute and the venture capitalists, the 3i Group, to develop the nuclear transfer technology that had led to Dolly the sheep. The 3i Group invested £6 million of funding to develop the technology. The Roslin Institute and 3i Group both held 42 per cent of the equity in Roslin Bio-Med. Geron Bio-Med was formed in May 1999 when the Geron Corporation of California bought Roslin Bio-Med.

3.18 In June 1996 PPL Therapeutics was successfully floated on the London Stock Exchange at an initial valuation of £110 million. The Roslin Institute estimate that had it held equity it would have benefited from a share of the flotation proceeds of up to about £10 million.

3.19 By contrast, in 1999 Roslin negotiated a deal with a private company, the Geron Corporation, in which it did acquire an equity stake in the acquirer. In this deal, for example, Roslin negotiated an equity shareholding in Geron Bio-Med, worth £3.2 million at the time of the deal, and £12.5 million worth of research funding. The scientists involved also took equity. Part 4 examines this deal in more detail.

3.20 Despite the funding gap and other constraints the Department's executive agencies have also begun to set up joint ventures in which they have an equity share. For example, in March 2000 the Centre for Environment, Fisheries and Aquaculture Science set up its first joint venture with the private sector to develop "SmartBuoys," **(Figure 19)** and another with Ultrabite Limited to manufacture a fish bait based on pheromones for use by sportsmen and commercial fishermen.

## Successful commercialisation requires appropriate expertise

3.21 Appropriate business expertise in patenting, finance, and negotiation of deals, is needed from the stage of evaluating ideas and developing a business strategy to the stage of making deals. The Department has been concerned that research contractors might lack the expertise to manage commercial deals and assess the risks involved; and that it would ultimately have to bear the costs of failure by the contractor despite having no "hands on" management responsibility for a project. As a result, prior to the Baker report, the Department had tended towards caution in its approach to joint ventures and spin-out companies.

**19 Joint venture to commercialise "SmartBuoys"**

For several years the Centre has been developing devices that can be mounted on buoys to record a range of marine-related chemical and physical measurements over long periods at sea. It is a novel approach that may replace some of the monitoring that is currently being undertaken by research ships, which can be expensive and hazardous. The Centre formed a partnership with WS Ocean Systems Limited (WS) to develop the technology. The Centre will provide the science and engineering expertise while WS provide the commercial skills in design, manufacture, and operational support. WS set up a new company - Eco-Sense - to develop the business opportunities for the "smart buoy" technology. Initially, the Centre and WS agreed to split profits from sales of products. The joint venture developed, however, and the Centre became a 49 per cent shareholder in Eco-Sense in return for rights in unregistered intellectual property and know-how. The Centre will receive a proportion of the profits according to its equity share.

*Photograph courtesy of Centre for Environment, Fisheries and Aquaculture Science.*

**20 Access to expertise at five research contractors**

| Establishment | How many employees involved in commercialisation do you have? (number of full time equivalents) | Is external expertise required to set up joint ventures and spin-out companies? Patent agent | Legal | Due Diligence | Negotiating skills |
|---|---|---|---|---|---|
| Central Science Laboratory | 8 | Yes | Yes | Yes | Yes |
| Centre for Environmental Fisheries and Aquaculture Science | 8 | No | Yes | No | No |
| Horticulture Research International | 13 | Yes | Yes | Yes | No |
| Roslin Institute | 1 | Yes | Yes | Yes | Yes |
| Silsoe Research Institute | 3 | Yes | Yes | Yes | Yes |

3.22 Research contractors have appointed support staff or business teams with commercial expertise. Teams varied in size for example, from three people at Silsoe Research Institute - reflecting the greater role of the British Technology Group described above - to 13 staff at Horticulture Research International. The size of business teams was determined by the number of staff needed to exploit the organisation's commercial potential, mainly commercial services such as consultancy advice or project work.

3.23 Most of our sample research contractors would have to seek patent protection, financial, legal and due diligence advice, and the skills to negotiate deals to set up joint ventures or spin-out companies **(Figure 20)**. For example, the Centre for Environment, Fisheries and Aquaculture Science felt that in negotiating deals, in particular for joint ventures and spin-out companies, it specifically required legal advice. It would have liked access to call-off contracts with legal firms and financial advisors (on due diligence procedures, and valuation of intellectual property, for example). Although the Centre had access to in-house patent expertise, the international prosecutions of any patent application would always be carried out by an external agent. The external advice required was often highly specialist and it would not generally be cost-effective for research contractors to employ staff with specialist skills on a permanent basis.

3.24 Where the Department is the owner of intellectual property (i.e. where ownership has not passed to the contractor in line with the Baker Report) research contractors may seek the Department's advice on drafting licence agreements and the defence of intellectual property rights. Although the Department has no in-house experience or expertise defending patents, in appropriate cases it will seek external advice. Partnerships UK was set up by the Government to act as a source of assistance, combining private sector expertise with a public sector mission in order to bridge the gap between public and private sectors. Partnerships UK has provided advice to several research establishments including those sponsored by the Department, such as the Central Science Laboratory and the Centre for Environmental Fisheries and Aquaculture Science, on how to exploit their technology, laying down systems for identifying intellectual property, preparing business plans, and supporting due diligence in spin-out company set ups. It can also provide equity finance in public sector spin-outs.

## Conflicts of interest are being managed

3.25 In order to avoid possible conflicts of interest, resource contractors advising government or fulfilling a regulatory role must be impartial. The scope for conflicts of interest may increase, however, as commercialisation gathers pace. For example, commercial partners increasingly want research establishments and scientists to give priority to their work, creating a potential conflict for scientists in allocating time between commercial work and fulfilling the objectives of core research funded by the Department.

3.26 Our five contractors had taken, or were taking steps, to address this issue, including:

- Specifying time to be spent by scientists on commercial work in the contracts and other agreements with the private company.
- Establishing registers of interests in which all staff are required to declare details of any advisory positions or contracts.
- Limiting involvement in potential areas of commercialisation in order that the Department remains the primary customer.

3.27 Contractors acknowledged that procedures could be further improved and updated in the light of experience and the Office of Science and Technology's guidelines, produced in July 2000. The guidelines encourage research establishments to have clear procedures in place to prevent personal interests of individual scientists interfering with the proper expenditure of government monies, or from influencing, or appearing to influence, advice to government. Public sector research establishments are recommended to introduce procedures based on the following three principles:

- active disclosure of interests;
- a review of interests in terms of their materiality; and
- mechanisms to handle conflicts when they arise.

## Lessons on managing the risks of commercialisation could be learnt from both the private sector and other public sector research establishments

3.28 Figures 13 and 14 present key questions for assessing the strength of commercial ideas and for developing an exploitation strategy. To minimise the risks associated with the failure of a venture, exploitation strategies should also include exit plans. Our report on *'Delivering the Commercialisation of Public Sector Research'* found that formally considering the risks and opportunities before a project enters each successive stage of development helps safeguard value for money and the public interest. Trade-offs exist, for example, between taking rewards in equity or upfront income for research, and between outcomes. Where the public sector passes more of the risk to the private sector it must expect a lower return.

# Part 4

# Commercialisation of nuclear transfer technology

4.1 On 27 February 1997 scientists from the Roslin Institute published details of the birth of Dolly the sheep in the scientific journal, Nature. Dolly attracted worldwide media interest because she had been successfully cloned from an adult cell, using nuclear transfer techniques. The discovery opened up the potential in the longer term for new treatments for human diseases and other medical science applications. Background to the science and the creation of Dolly is given in Appendix 4.

4.2 Between April 1998 and May 1999 the development and exploitation of the nuclear transfer technology was transferred under licence to the private sector primarily as a result of two successive deals. This Part of the Report examines:

- The partnership deal between Roslin and the venture capitalists, 3i Group, to set up a new private company called Roslin Bio-Med; and
- The sale of Roslin Bio-Med to the Geron Corporation of the United States.

## Setting up the Roslin Bio-Med spin-out company

### Why was the nuclear transfer technology commercialised?

#### Government funds to develop the technology were not forthcoming

4.3 Early research into exploring the scope for identifying and disseminating genetic improvements in livestock for the benefit of the industry was funded over several years from a variety of sources. The earliest work was funded in the 1980s by the predecessor to the Biotechnology and Biological Sciences Research Council. Later funding came from the Department, the European Union and PPL Therapeutics (formerly Pharmaceutical Products Limited). Some £3 million was invested of which the Department provided about two thirds between 1991-92 and 1996-97. Roslin funded the major technology breakthroughs,[4] which eventually led to Dolly, out of its reserves. However, this was not a fully developed technology; further work was required to identify how the reprogramming of nuclei occurred, how the efficiency of the process could be improved, and if targeting of specific genes could be achieved.

4.4 The Roslin Institute recognised that, with the prospect of human medical benefits, the technology had commercial potential. The technology was, however, very inefficient. Dolly's birth was the only one from 277 experiment attempts. Substantial further research was therefore required to get to the proof-of-principle stage, and any product might take up to 20 years to invent, develop, and reach the market. In the pharmaceutical industry, for example, the chances of success in the early stages of new developments are around one per cent. However, without a clear view of the potential products or outcome of this breakthrough, the Roslin Institute considered that further public sponsorship should be provided.

4.5 In 1996-97 the Department concluded that the potential for realising the original agriculture-related related aims of the research were remote because of the high cost of developing the technology, because most nuclear transfer technology applications were non-agricultural, and because bio-medical applications were more likely to provide the major opportunities for commercialisation. As non-agricultural applications were outside the objectives of the Department it concluded that the research had achieved its purpose and that any further work should be funded by others, such as the industries that would benefit. The Department informed Roslin that their cloning programme would not be extended beyond March 1997. The livestock industry was also approached but no sources of funding were identified. The Biotechnology and Biological Sciences Research Council also rejected a research grant application from Roslin for further nuclear transfer funding as the specific

4 *In 1995, the Institute funded a new experiment which produced the lambs Megan and Morag and proved that differentiated cell populations could be used as nuclear donors for the production of live offspring. This led to the filing of two nuclear technology patents on behalf of the Roslin Institute. In 1998, the Department sought co-ownership of those patents on the grounds that they had sponsored the general research area at Roslin. The Institute conceded this point in order to progress establishing a spin-out company (paragraph 4.18). Since the Baker report, ownership of patents normally lies with the research contractor, and the Council and the Department are now assigning their part ownership of the Dolly patents to the Roslin Institute, subject to the retention of certain residual rights.*

proposal was unsuccessful when judged alongside other applications in the competitive peer review process. However, the Council considered that additional core funds should be made available to Roslin to develop the Institute's capability in cellular and molecular biology relating to nuclear transfer and Roslin was awarded increases of £150,000 a year over four years. The Biotechnology and Biological Sciences Research Council also invested some £1.5 million over three years in a national effort, including Roslin, four universities and the Babraham Institute to improve the efficiency of cloning mice.

4.6 Given the importance of the scientific breakthrough that led to the birth of Dolly, the Department later agreed to provide Roslin with funding of £125,000 for 1997-98, half of their original commitment for that year, to continue the research. To keep together the scientific team responsible for the discovery this amount was supplemented by funds from the Institute's financial reserves. Without longer-term funding, however, the former Director of the Roslin Institute records that Roslin felt it had no alternative but to go to the private sector to raise funds to keep the United Kingdom's lead in this research. Without this, research into nuclear transfer technology would have stopped and the scientists might have been attracted into moving to countries such as the United States where funds might have been more readily available.

### Roslin wanted to maintain its lead in developing the technology

4.7 The potential for commercial and other returns from developing a breakthrough to produce new therapies or human health medicines has led to fiercely competitive research. Institutions worldwide have sought to develop their own cloning technology. Sheep cloning was the preserve of Roslin but there were, for example, moves to clone pigs, cattle, and mice in other countries such as Japan, USA and France. To achieve any significant commercial return from the technology it was important that Roslin maintained its position at the head of the field and retained the services of the majority of scientists involved in nuclear transfer, perhaps over a period of many years.

## How did Roslin commercialise the nuclear transfer technology?

### Roslin explored collaborative deals with the private sector

4.8 In recognition of its earlier collaboration with PPL Therapeutics on developing nuclear transfer Roslin licensed the nuclear transfer patents to PPL for the specialist fields of producing pharmaceutical proteins in the milk of farm livestock and rabbits. To develop the other, wider, potential application of the technology, and in the absence of government funding, Roslin explored potential collaboration with a private sector partner. A large number of small to medium sized biotechnology companies expressed interest, of which three were considered credible, all involving licence deals on the technology. The offers were not taken forward because:

- the financial terms were not considered sufficient. The highest offer was for Roslin to receive £200,000 of research contracts for three years and an additional £40,000 to start up the research; and
- the research would be carried out away from Roslin's laboratories and the Institute would lose the research, and perhaps its scientists.

4.9 The interest shown encouraged Roslin to consider creating its own spin-out company to exploit the technology. To achieve this objective Roslin decided to approach a venture capital company. Roslin's objective was to obtain £4 million of research funding over three years and up to 20 per cent equity in the spin-out company. In March 1997 Roslin approached the venture capital company, 3i Group, for advice on how to proceed with a spin-out. As one of the largest venture capital companies in the United Kingdom, 3i Group had experience in backing biotechnology enterprises, and immediately saw the benefit of being associated with Dolly and hence in setting up a new company.

### Roslin wanted equity in a spin-out company and appointed specialist advisers

4.10 Drawing on its previous experiences in creating spin-out companies to develop and exploit different technologies as described in Part 3, Roslin decided to acquire an equity holding in the new company and to secure a share of the long-term return if the company were successful. Roslin also sought to keep the science at the Roslin site. In negotiating a deal with 3i Group, Roslin engaged several experts:

- for legal advice: Wright, Johnston and MacKenzie, lawyers specialising in commercial and intellectual property matters and who had previously worked for Roslin;
- for financial advice: KPMG Corporate Finance; and
- for patent advice: Kilburn and Strode - European patent attorneys specialising in biotechnology and who had previously worked for Roslin, and LBT Services - consultants employed to evaluate the patent applications (but now no longer trading).

4.11 3i Group asked Roslin to prepare a business plan setting out the structure, finance, and scientific programme of the new company and its proposed approach to commercialising the nuclear transfer technology. In doing so, Roslin determined that it would be better to establish a company to concentrate on the bio-medical applications **(Figure 21)** which might have the greater potential in the long term. Agricultural applications were considered weaker, given the generally depressed state of the agriculture sector. It is interesting to note that none of the original proposed objectives relating to animal nuclear transfer technology have developed into commercial opportunities.

4.12 Developing a medical approach would require a substantial and unpredictable level of investment. The amount of investment offered by 3i Group was therefore based on an assessment of the amount of research funding required to develop the technology over a fixed period, in this case three years. It was also based on the idea that further funding, perhaps from a syndicate of investors, would be available after three years if the initial development work were successful and if certain conditions were met. 3i Group accepted Roslin's business plan and the deal was made.

**21 Commercial uses of the nuclear transfer technology**

- Xenotransplantation - using animal organs as the source of organs for transplantation into humans. The nuclear transfer technology in conjunction with gene targeting could be used to overcome some of the difficulties, such as rejection, involved in the process of organ transplantation.
- Pharmaceutical protein production, for example, engineering the antibody genes of pigs to make them more human-like or the production of humanised haemoglobin from genetically modified sheep or pigs for the synthetic blood market.
- The generation of genetically tailored animals which could be used to model various human diseases in order to evaluate new therapies.

## What were the terms of the deal?

4.13 On 7th April 1998 a private spin-out company, Roslin Bio-Med, was set up to operate at the Roslin site. 3i Group were to provide Roslin Bio-Med with £6 million of investment over a three-year period to develop the nuclear transfer technology[5]. As the sponsor of the Roslin Institute, the Biotechnology and Biological Sciences Research Council was required to authorise the deal, which it did in April 1998.

### Scientists and the Roslin Bio-Med management team would be based at Roslin and would own shares in the company

4.14 All nuclear transfer research was to be undertaken by Roslin's staff, Roslin providing the new company with use of its research facilities, including laboratory space. Professors Wilmut and Clark would continue to work for Roslin and would take up consultancy assignments with the new company, the initial terms of which specified that they would spend 75 and 60 per cent of their time respectively on the Roslin Bio-Med research programme. Professor Wilmut joined the board of Roslin Bio-Med as scientific director and Professor Clark attended board meetings as an observer.

4.15 Roslin and 3i Group each received 42 per cent of shares in the new company **(Figure 22)**. The balance of shares, 16 per cent, was set aside for Professors Wilmut and Clark and the management team of the new company.

4.16 It is standard private sector practice in dealing with public sector organisations to ensure the commitment of key staff through consultancy arrangements and share options in the new company. A condition of 3i Group's involvement was that the two scientists should buy shares in the new venture. From the investor's perspective, this provided an incentive for the scientists and acted as a means of exerting some control over their contributions to the company. The scientists purchased 12,000 and 8,000 shares respectively at £1 per share, which action was approved by the Biotechnology and Biological Sciences Research Council.

4.17 A further condition of 3i Group's investment was that they would appoint Roslin Bio-Med's key executives, namely the non-executive chairman, chief executive and a non-executive director, John Brown. Ian Kent was appointed as non-executive Chairman and Simon Best as Chief Executive Officer. Ian Biggs was appointed Chief Finance Officer of Roslin Bio-Med. All had experience in the biotechnology and agriculture industries. The 3i Group considered that in order to retain and reward staff of the calibre required, the management team should have equity in the new company, as indicated in Figure 22.

5 *In the event, 3i group invested £5.6 million by the time Roslin Bio-Med was sold to Geron, less than three years later.*

**22 Investment and distribution of shares in Roslin Bio-Med**

| Shareholder | Number of shares | | | Percentage of equity held in company (%) | Investment in Roslin Bio-Med (£) |
|---|---|---|---|---|---|
| | Issued | Options | Total | | |
| Roslin Institute | **172,000** | **-** | **172,000** | **42.0** | **-** |
| 3i Group | **172,000**[1] | **-** | **172,000** | **42.0** | **5,600,000** |
| **Scientists** | | | | | |
| Ian Wilmut | 12,000 | - | 12,000 | 2.9 | 12,000 |
| John Clark | 8,000 | - | 8,000 | 2.0 | 8,000 |
| **Management team** | | | | | |
| Simon Best | 10,000 | 10,000 | 20,000 | 4.9 | 80,000 |
| Ian Kent | 4,000 | 10,000 | 14,000 | 3.4 | 56,000 |
| Ian Biggs | - | 5,000 | 5,000 | 1.1 | 40,000 |
| **Non-executive Director** | | | | | |
| John Brown | 2,000 | 5,000 | 7,000 | 1.7 | 28,000 |
| Sub-total | **36,000** | **30,000** | **66,000** | **16.0** | **224,000** |
| **Total** | **380,000** | **30,000** | **410,000** | **100.0** | **5,824,000** |

**NOTE:**

1. 3i Group were also issued 630,637 shares without voting, income or capital rights.

### Patents to the technology were co-owned and Roslin was able to grant licences for use of the patents

4.18 To protect the use of the nuclear transfer technology in August 1995 Roslin had filed two international patent applications - called *Unactivated Oocytes* and *Cytoplast Recipients for Nuclear Transfer ('Magic')*; and *Quiescent Cell Population for Nuclear Transfer ('Quiescence')*. Pending the grant of patents, Roslin, the Biotechnology and Biological Sciences Research Council and the Department made a three-way co-ownership agreement whereby each party would own one third of the intellectual property. The co-ownership agreement delegated to Roslin the right to license the intellectual property for all applications relating to human health care.

4.19 Within the terms of the agreement, Roslin granted two licences in 1998 - one to PPL Therapeutics and one to Roslin Bio-Med. The licence granted to PPL was for their specialist interest in the use of milk derived from transgenic animals (paragraph 4.8). As a result of this licence Roslin has received at least £100,000 a year in licence fees. Of the two licences, the more significant, however, was granted to Roslin Bio-Med for all bio-medical applications except for those in the field granted to PPL Therapeutics. The licence gave Roslin Bio-Med a worldwide exclusive right to commercialise the nuclear transfer technology.

4.20 In line with Government policy, the co-ownership agreement strictly prohibited the use of the technology for human reproductive cloning or for any process designed to create a human being with the same nuclear genetic information as another human. The patents were granted to the parties of the co-ownership agreement in January 2000. The co-owners (Roslin, the Council, the Department) retain ultimate control over the legal use of the technology, and retain the right to terminate licences in the event of a breach of the use terms.

## Was the deal with 3i Group fair and reasonable?

4.21 Roslin's deal was an appropriate basis on which to proceed taking account of:

- Roslin's equity stake of 42 per cent, equal to that of 3i Group, was much higher than spin-out deals in the public sector of a similar nature. In the higher education sector for example, universities have typically obtained between 10 and 20 per cent of equity in a spin-out company, although in more recent months the stakes held by universities have diminished, perhaps linked to the current financial climate for some investments. 3i Group considered that the science involved in creating Dolly was exceptional and warranted the Institute having a much larger stake.

- 3i Group's planned investment of £6 million was a relatively high amount for a venture capitalist to invest at such an early stage of scientific research. It was also £2 million higher than Roslin's early estimate for the research. Patents had not been granted, and all potential uses were speculative and not proven.
- In 1998, there was very little commercialisation by public sector research establishments by which the valuation of scientific and technological intellectual property could be judged.

4.22 In April 1998 Roslin's financial advisers on the deal, KPMG Corporate Finance, reported their overall conclusion that the financial terms of the deal with 3i Group were fair and reasonable so far as Roslin was concerned. KPMG noted, however, that the financial terms were not necessarily the best available in the market, as negotiations were only held with 3i Group. KPMG reported that this was particularly so given the publicity surrounding, and interest in, the technology, the abundance of funds in the private equity market at the time and the potential values that might be attributed to the technology by trade partners who could gain considerably through the licensing of the technology. In September 1997, some eight months before the deal with 3i Group was signed, KPMG had advised Roslin that there were a number of other venture capitalist companies in the United Kingdom that specialised in backing biotechnology companies with early stage funding and which had the financial ability to commercialise the nuclear transfer technology.

4.23 The former Director of the Roslin Institute considers that KPMG's advice of September 1997 to Roslin did not mean that Roslin should approach other funds - rather that there were other venture capitalists that it could approach if the deal with 3i Group fell through. Furthermore, the Roslin Institute considered that none of the funds suggested were realistic competitors either because the company had a conflict of interest, their biotechnology funds were closed, or the company had no track record in Roslin's field.

4.24 Roslin did not go to other funders because their preference was to work with one United Kingdom funder, preferably with a Scottish presence and with the financial resources to support their research programme. Roslin favoured 3i Group in Scotland because they were willing to support early stage science with a long lead-time from initial exploitation to market application. Roslin were also reluctant to disclose details of the technology to more parties than necessary, even if under confidentiality restrictions, and to enter into a competitive bidding process due to the time that this would take.

# The Sale of Roslin Bio-Med to the Geron Corporation

## What were Roslin Bio-Med's objectives?

4.25 Roslin Bio-Med was set up to develop, augment and exploit commercially the nuclear transfer intellectual property, with a strong focus on biomedical applications. 35 new staff were recruited which enabled the research to proceed apace. A new business plan was produced which broadened the focus of activity to include the production of human blood-substitutes as well as xenotransplantation (using animal organs for transplantation into humans), which were both judged to be attractive and viable commercial opportunities. Other biomedical applications were judged to be premature until further development of the technology. Efforts were initially focused on seeking collaborations and deals with companies in the field of xenotransplantation, blood-substitutes and human blood products.

## Why was Geron the preferred partner?

4.26 On 6th November 1998 the Geron Corporation (Geron), a biotechnology company based in California, announced a scientific breakthrough, which successfully derived human embryonic stem cells and maintained them in tissue culture. Geron employed about 150 staff in discovering, developing and commercialising therapeutic and diagnostic products to treat cancer and other chronic degenerative diseases, had a multi-million dollar turnover and net assets worth $64 million in 2000.

**Embryonic stem cells** are cells which have an unlimited ability to divide and the capability to turn into any and all types of cell and tissue in the body: skin, muscle, liver, brain cells and so on. Scientists believe they hold great promise as a universal source of replacement cells for transplantation and for use in pharmaceutical research and development. In addition Geron already had significant expertise in a technology called telomerase. **Telomerase** is a cellular enzyme which, when reactivated in normal cells, extends their healthy life span. Geron was the first to discover the critical molecular components of human telomerase.

4.27 Scientists at Roslin Bio-Med contacted Geron immediately to discover if their respective technologies were complementary and, if so, to seek collaboration. By January 1999 both organisations found that a partnership between them would greatly increase the potential for commercial exploitation through the development of medical treatments for a large range of human diseases. In December 1998 Roslin Bio-Med and Geron entered into detailed discussions to explore

the potential for collaboration in their research programmes. Initially both parties considered cross-licensing arrangements relating to each other's intellectual property. However, the acquisition of Roslin Bio-Med by Geron quickly became the preferred option of the Roslin Institute and the shareholders in both Roslin Bio-Med and Geron, as the new entity would be in a position to become the world leader in an important and fast-developing area of work. As a spin-out company with limited assets there was no question of Roslin Bio-Med acquiring Geron.

4.28 The then Chief Executive of Roslin Bio-Med, Simon Best, considered that without the deal with Geron there was little prospect of maximising the potential of the nuclear transfer technology. British companies did not have the complementary science and were not interested in developing the technology at a sufficiently satisfactory price. Companies in the United States had developed and secured intellectual property for allegedly alternative methods to clone animals and there was a real risk that Roslin's nuclear transfer technology would have become outdated and worthless. For example, in 1998, the largest pharmaceutical company in the market for nuclear transfer (xenotransplantation) licensed rival technology from a United States technology company. This was despite efforts by Roslin Bio-Med to secure a deal with the same pharmaceutical company.

## How was Roslin Bio-Med valued?

### The value of Roslin Bio-Med was determined by several factors

4.29 The value of Roslin Bio-Med was determined by the following:

- 3i Group's expressed aim to obtain a return of at least twice their original investment in Roslin Bio-Med. 3i Group originally agreed to invest £6 million in Roslin Bio-Med so they sought £12 million from the deal with Geron. As 3i Group owned 42 per cent of the shares in Roslin Bio-Med, this priced the whole company at about £28.6 million.
- A valuation carried out by financial advisers, J P Morgan, for Geron which valued the company at some $44 million (£29 million). The Chief Executive of Roslin Bio-Med assisted in the preparation of the valuation at the time Roslin Bio-Med and Geron were seeking a collaborative arrangement.

4.30 When Geron became the prospective purchaser of Roslin Bio-Med, however, there was no independent valuation on behalf of all shareholders of Roslin Bio-Med. The Chief Executive of Roslin Bio-Med was confident that Geron's assumptions were still based on the work he had participated in earlier, carried out by JP Morgan. The management board of Roslin Bio-Med accepted that the Morgan report was a fair reflection of the valuation of the company. The board saw no point in spending additional money, perhaps up to £500,000, on an independent valuation. In their view another valuation would have been of poorer quality because it would not have had access to the technical knowledge available to Geron and JP Morgan. 3i Group consider the arrangements ensured a fair deal and consider an independent review of the deal might have jeopodised completion.

4.31 On 3i's advice Roslin Bio-Med had appointed the investment banking firm, Bankers Trust (known as BT Alex Brown, taken over by Deutsche Bank in 1999, and no longer used as a trading name) to advise them on any deal with Geron. BT Alex Brown specialised in the investment banking of biotechnology stocks. They provided advice on negotiating strategy and tactics. Although they were not asked to value Roslin Bio-Med, John Brown, a non-executive director of Roslin Bio-Med at that time (paragraph 4.17), considers that knowledge of their involvement in the deal was a significant factor in maintaining the value of the deal.

## Valuation of intellectual property, particularly novel technology, is difficult

4.32 Our consultants, Morgan Harris Burrows, advise that there is no set model for the valuation of biotechnology intellectual property. In the United Kingdom, privatisation of public assets and spin-out companies formed by universities have provided some benchmarks but not sufficient base information for evaluating scientific and technological intellectual property. In the United States, the valuation of intellectual property using methods of estimating low probability income streams have been used and seen as a logical if imprecise means to assess the risks and rewards in the pharmaceutical, media and natural resource industries. These valuation techniques are not, however, generally used for valuing companies, such as Roslin Bio-Med.

4.33 An independent valuation, although difficult, could have provided assurance that the deal with Geron was a fair one. Equally important are independent assessments about the market in which a spin-out operates, who the buyers might be and why, and how much they might be willing to pay for it. With no benchmark against which to compare the proposed deal there is a danger that Roslin may have undersold its intellectual property. However, it is the view of the former Director of Roslin that any valuations would have been flawed since there was no commercial product envisaged and no clear route to exploitation.

## What was the deal between Roslin Bio-Med and Geron?

4.34 Our consultants, Morgan Harris Burrows, find that deals typically may take at least six months to conclude from the first declaration of interest. Following initial contact in November 1998, a deal with Geron was completed on 3rd May 1999 and announced on 4th May. Speed was essential since the field was moving so quickly. This negotiation seemed relatively short for a major licensing deal but the Roslin Institute had concluded other deals in less time. Roslin Bio-Med became a wholly-owned subsidiary of Geron, renamed Geron Bio-Med Limited. The deal between Roslin Bio-Med and Geron was complex and comprised several elements:

- shareholders in Roslin Bio-Med exchanged their shares for Geron stock worth nearly £17 million;
- a research agreement between Geron and Roslin worth £12.5 million, with potential for royalty payments in the future;
- a new licence agreement between Roslin and Geron; and
- research benefits to the Department.

Each of these elements is examined below.

### Shareholders in Roslin Bio-Med exchanged their shares for Geron stock worth nearly £17 million

4.35 The shareholders in Roslin Bio-Med exchanged their shares for 2.1 million shares of Geron stock worth £16.8 million at the time of the deal **(Figure 23)**. Some 59 per cent of the shares were allocated to the 3i Group and the Institute received 19 per cent. The remainder of the shares were divided between the members of the Roslin Bio-Med management team.

4.36 The Roslin Bio-Med management team and the two scientists exchanged 66,000 Roslin Bio-Med shares (16 per cent of the company shares) costing £224,000 (Figure 22) for 460,000 Geron shares (22 per cent of the Geron shares on offer) worth £3.68 million at the time of the deal. Professors Wilmut's and Clark's share dealings were approved by the Biotechnology and Biological Sciences Research Council, as required by the Council's guidelines. To tie them into the deal, the two scientists were required to carry out the Geron directed research at the Institute on the basis of a consultancy agreement.

4.37 Roslin accepted a lower proportion of shares in Geron (19 per cent) compared to the proportion that it had held in Roslin Bio-Med (42 per cent). Instead of receiving its quota of shares in Geron, Roslin chose to receive cash funding from Geron for scientific research (see below, paragraph 4.40). Roslin saw advantage in accepting the certainty of cash funding over the unpredictability of the market in technology stocks.

4.38 Apart from 3i Group all shareholders had about 60 per cent of their shares placed in escrow for one year in case Geron had any claim against the shareholders for breaching the terms of the deal. Geron shares were also subject to a "dribble out" clause in the contract which allowed the sale of up to 35,000 shares every three months after the one-year period had passed, to prevent all shares being sold at once. Keeping shares in escrow is normal business activity and dribble out clauses are common practice in the United States. 3i Group, in accordance with their usual business practice, refused to have its proportion of shares "locked in" for one year or to be constrained by the dribble out clauses.

**23 Distribution of Geron shares and research funding**

| Shareholder | Number of shares | Value of shares at 4 May 1999 (£ million) | Research funding (£ million) | Proportion of equity (%) |
|---|---|---|---|---|
| **3i Group** | **1,240,000** | **9.92** | - | **59.0** |
| **Roslin Institute** | **400,000** | **3.20** | **12.5** | **19.0** |
| **Roslin Bio-Med management team and scientists** | **460,000** | **3.68** | - | **22.0** |
| Of which: Simon Best (Chief Executive Officer) | 149,800 | 1.26 | | 7.2 |
| Ian Kent (Chairman) | 99,800 | 0.79 | | 4.8 |
| Professor Ian Wilmut (scientist) | 82,800 | 0.66 | | 3.9 |
| Professor John Clark (scientist) | 52,500 | 0.42 | | 2.5 |
| Dr John Brown (Non-Executive Director ) | 44,300 | 0.35 | | 2.1 |
| Ian Biggs (Chief Finance Officer) | 30,800 | 0.25 | | 1.5 |
| **Total** | **2,100,000** | **16.80** | **12.5** | **100** |

Value of Geron shares at time of Roslin Bio-Med takeover was approximately $12 or about £8 per share.

4.39 The Biotechnology and Biological Sciences Research Council imposed conditions on how Roslin could dispose of its Geron shares and initially the Council prevented Roslin from selling its shares at under $30 a share, later revised at the request of Roslin to under $25 a share. A total of 59,450 shares were sold mostly at between $30-35, realising $1.74 million (£1.16 million).

### A research agreement was agreed between Roslin, Geron and Roslin Bio-Med

4.40 In addition to the Geron shares, Roslin received £12.5 million[6] in research funding from Geron over a six year period from 1999-2005. Of this, £10 million was to be directed by Geron towards developing nuclear transfer technology, and £2.5 million was to be used by Roslin as they wished. Roslin invested in animal genome research which was seen as a key area of future research by the Institute and one where private companies were keen to invest.

4.41 Any new intellectual property arising from the nuclear transfer programme is co-owned by Roslin and Geron. If Geron sell any products arising from the research, Roslin will earn a royalty stream set at the rate of either one half per cent or one per cent, of net sales income, the rate depending on the ultimate use of the products developed. Any intellectual property arising from the genome research is owned wholly by Roslin.

### A licence was agreed between Roslin, Geron and Roslin Bio-Med

4.42 Roslin granted a new research and licence agreement to Geron for a period of six years. It gave Geron exclusive world-wide rights to exploit the nuclear transfer technology for all applications, (excepting PPL Therapeutics' interests - paragraph 4.19). It expressly forbade human reproductive cloning, and placed controls on using the licence for unforeseen purposes without prior written permission of Roslin. After six years, the agreement remains in force on a country by country basis for at least ten years in the European Economic area and at least twenty years outside that area, depending on when the patents expire.

4.43 The licence provided that Geron and Roslin would become the joint owners of all intellectual property arising from future research except that arising from a pigs project relating to xenotransplantation. The rights to this research would belong solely to Geron. Geron requested that the Biotechnology and Biological Sciences Research Council and the Department, as co-owners of the nuclear transfer patents, consent to the granting of the new licence to Geron. This they did. The exclusive licence gives Geron a free hand in the granting of sub-licences which neither the Roslin Institute, the Council, nor the Department can challenge. Geron were buying unproven intellectual property and did not wish to be fettered in their commercial freedom, for example through constraints on their ability to award sub-licences.

### The Department received benefits from the deal

4.44 As part owners of the intellectual property, the Department was entitled to benefits from the deal. The Department declined to take shares in Geron because of the complexities involved in a government department holding shares in a private company. Instead the Department agreed to accept £120,000 worth of research of its own choosing to be carried out by Roslin over a two year period. This was based on the value of shares the Department would have received if it had accepted them. In addition, the Department would have 3.3 per cent[7] of the royalties, estimated to be no more than £5,000 a year in 15 years time. Roslin agreed to bear the cost of managing and protecting the patents. The Department's aim was to secure a reasonable return without exposing itself to the risks of the market or of the technology collapsing.

## What were the roles of the Biotechnology and Biological Sciences Research Council and the Department?

### The Council and the Department were kept partially informed

4.45 Under the Biotechnology and Biological Sciences Research Council's conditions of funding, the Director of the Roslin Institute required prior approval from the Chief Executive of the Council before setting up a subsidiary or spin-out company and before making a commitment to any major commercial development. The Department's interest in the deal was not as great as that of the Council, since the Department was not a shareholder in Roslin Bio-Med. However, as joint owners of the patents, the Council and the Department also had to be kept fully informed about licensing agreements. Negotiations about collaboration between Geron and Roslin Bio-Med started in December 1998 and about a sale of Roslin Bio-Med in earnest from mid January 1999. The Council and the Department were not made fully aware of the detail of the proposed deal, such as share ownership and the licence agreements, until February 1999.

*6 Since the research funding was spread over a number of years the equivalent value of the total funding in 1999 would be some £10.842 million (that is the Net Present Value assuming the Treasury discount rate of 6%).*

*7 Under the Department's arrangements for retention of royalty receipts the contractor is allowed to retain 90 per cent, with the Department receiving the remaining 10 per cent. As the Department is a one-third owner of the intellectual property, 10 percent of one third is 3.3 per cent.*

4.46 The Council regard the discovery as unique. However, the former Director of Roslin, considered that there was a need to secure the deal quickly or it could have been lost. The nuclear transfer technology was at an early stage of development with the patent filed but not yet granted. Competitor companies and other institutions in the United States and elsewhere were filing comparable cloning patents. With each day that passed the value of Roslin's nuclear transfer patents was being devalued. Discussions with staff at the Council and the Department could have led to delays and jeopardised the deal. The Council and the Department could have been directly involved in detailed negotiations if they had wished but they chose not to.

### There was an intervention in the deal negotiations by the Chief Executive of the Biotechnology and Biological Sciences Research Council

4.47 During initial discussions with the Director of the Roslin Institute, the Chief Executive of the Biotechnology and Biological Sciences Research Council who had 15 years commercial and research experience in the pharmaceutical industry, and for 20 years previously had acted as consultant to the industry, advised that the Institute should seek to retain an equity stake in Geron shares equivalent to about half the 42 per cent held in Roslin Bio-Med. In April 1999 when the apportionment of Geron shares became apparent, the Chief Executive of the Biotechnology and Biological Sciences Research Council intervened in the deal negotiations. The terms of the deal at that stage would have given Roslin 134,000 Geron shares (6.4 per cent of the equity on offer) but the Chief Executive considered that this share was too low relative to the other shareholders. The then Director was successful in increasing the offer from 134,000 to 250,000 shares (11.9 percent) but the then Chief Executive felt this was still insufficient. He asked for Roslin's stake in Geron to be increased to 400,000 shares (19 per cent). During earlier negotiations Geron had said that they were not prepared to increase the number of shares on offer, and hence the management team agreed to reduce their stake by 150,000 shares in favour of Roslin. We found no evidence that at this stage Geron were formally asked to consider increasing the overall number of shares on offer, the participants' views being that this was non negotiable.

4.48 The intervention by the then Chief Executive of the Research Council achieved an increase in equity for Roslin of 266,000 shares valued at the time at $3.2 million (£2.1 million) without any reduction in the £12.5 million research funding. Members of the Roslin Bio-Med management team considered that the intervention came close to losing the deal. While the team might be regarded as having a potential conflict of interest on account of shareholdings, its members were willing to forego a significant proportion of their personal equity in order for the deal to proceed.

## Was the deal with Geron fair and reasonable?

### Movement in Geron's share price indicate that the deal was fair

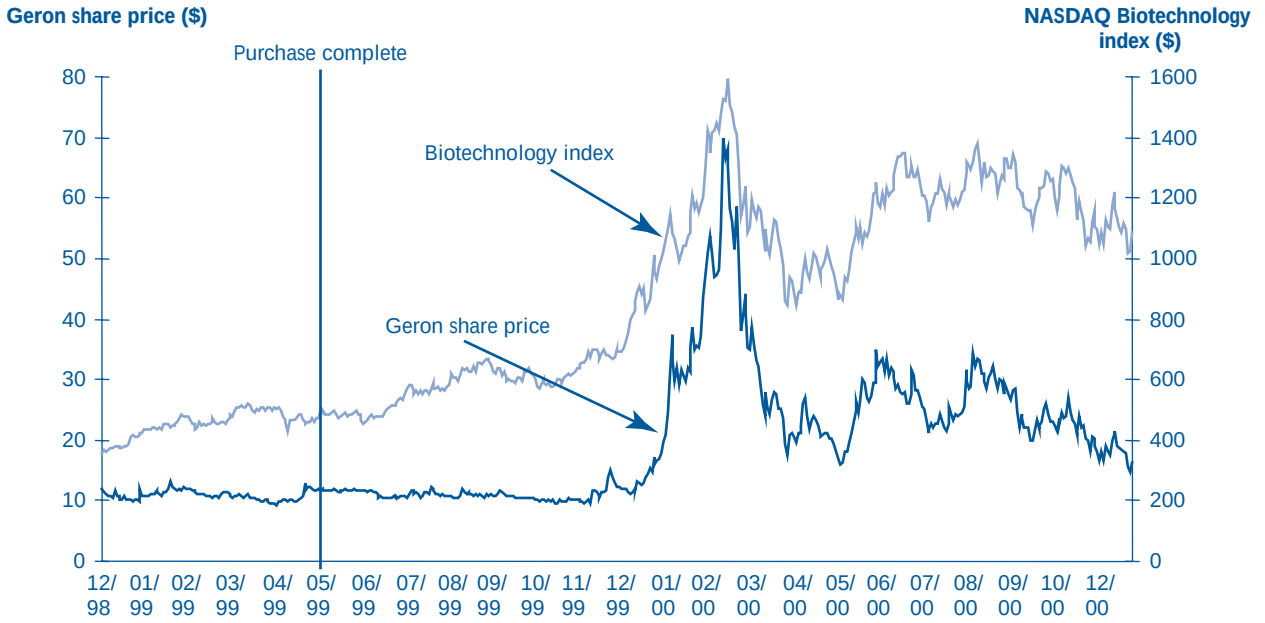
4.49 **Figure 24** shows Geron's share price between December 1998 and December 2000 and compares it with the trend in average biotechnology shares (as measured by the National Association of Securities Dealers Automated Quotations ("NASDAQ" Biotechnology Index). Immediately before and after the purchase of Roslin Bio-Med in May 1999 there was little movement in Geron's share price suggesting that in the US market's view the deal was fair. Subsequent movements in Geron's share price, for example in February and March 2000 when the share price increased significantly and then fell back, also generally reflected the Biotechnology Index.

4.50 As a requirement of the United States Securities and Exchange Commission any take-overs are subject to an opinion on the fairness of the deal by a financial company. In this case, J P Morgan Securities Inc advised the Geron Board of Directors about the acquisition of Roslin Bio-Med. In their opinion the purchase of Roslin Bio-Med was fair from Geron's financial point of view.

### Potential conflicts of interest were managed and good practice reinforced

4.51 There were potential conflicts of interest arising from the deal but they were managed. Roslin's negotiators (the then Director, Grahame Bulfield and the Company Secretary) did not gain financially from the deals, and the scientists who did gain were not involved in negotiations. Even so the Biotechnology and Biological Sciences Research Council later strengthened its rules regarding shareholdings and private interests. From March 2000 the Council required all employees, including those at Roslin, to note any outside interests, such as shareholdings, consultancy work, or informal links to the private sector. The register is used to ensure that external activities do not impact on any negotiations or interactions with third parties in which staff may be involved.

**24 Movements in Geron Corporation's share price and the Biotechnology Index: December 1998 to December 2000**




*Source: NASDAQ*

## The partners considered that terms of the deal were reasonable for Roslin

4.52 The benefits gained from the deal were:

- A United Kingdom research institute, Roslin, received £12.5 million in research funding over a six year period.
- Shareholders in Roslin Bio-Med received shares in Geron worth nearly £17 million in 1998.
- Nuclear transfer research would be carried out by Roslin staff on the Roslin site in Scotland. The key scientists involved in carrying the research forward remained in the United Kingdom and Roslin is currently at the forefront of embryonic stem cell technology.
- Any new intellectual property arising from the nuclear transfer programme would be co-owned by Roslin and Geron. Roslin would be entitled to royalty payments in the event of successful exploitation of the technology.
- The Department received £120,000 worth of research of its own choosing at Roslin.

4.53 The management team of Roslin Bio-Med; 3i Group; the Roslin Institute, and Geron, all consider that they had each achieved an acceptable outcome from the deal. The deal was also welcomed by the Biotechnology and Biological Sciences Research Council, as the involvement of the Roslin Institute in future nuclear transfer activities had been protected and enhanced. At the stage at which the deal was being negotiated, the patents applied for by the Institute had not been granted, and no-one could therefore have been certain that the technique was significantly unique to warrant patents.

## Expert advice was not sought on aspects of the deal

4.54 Roslin did not seek expert advice on the financial benefits and costs of the arrangement to commute shares in Geron for funded research. Although £12.5 million of research funding for Roslin was a positive outcome of the deal, Roslin might have secured a better deal overall if they had accepted the same shareholding as 3i Group (worth £9.2 million) as Geron might well have still funded the scientific research at Roslin. It is not clear that Geron would have wished to put this work elsewhere, rather than at Roslin and with Professors Wilmut and Clark in particular.

4.55 Roslin accepted research funding instead of additional equity in Geron because:

- It helped to establish and maintain Roslin as an internationally renowned centre of scientific research, and the United Kingdom benefited from £12.5 million of inward investment from the United States.
- The funds enabled the Institute to expand its nuclear transfer and genomics research programmes, retain the services of nuclear transfer scientists, and recruit additional high quality scientists.
- In a highly volatile market such as biotechnology (borne out to some degree by the movement in share prices shown in Figure 24 and by the figures in the paragraph below) the value of any equity held by Roslin would be uncertain. The research funds were guaranteed and made up for funds being lost from other sources.

4.56 The Roslin Institute considers that the conditions imposed by the Biotechnology and Biological Sciences Research Council on the sale of the Institute's Geron shares (paragraph 4.39) were onerous and that the policy of opting for fixed price research has been more beneficial in the long run than taking the full value in equity. As a consequence of the Council's action to prevent Roslin selling Geron shares at the times of its choosing, the Institute estimates that it has foregone some revenue, mainly because the price of Geron shares, (along with other biotechnology stocks) has fallen dramatically - down to $4 a share in early November 2002. When they were purchased Geron shares were worth $12 a share and rose to nearly $70 a share at their peak. However, partial disposal of shares did realise over £1 million (paragraph 4.39) and the intervention of the Council's Chief Executive in the negotiations with Geron substantially increased the number and value of shares held by the Institute by a number which at the time were valued at £2.1 million. (paragraph 4.48).

## Share ownership was distributed among a number of parties

4.57 The Biotechnology and Biological Sciences Research Council was concerned that the proportion of shares owned by the four members of the Roslin Bio-Med management team and the two scientists was high relative to that owned by Roslin. In the deal with Geron, six people shared 22 per cent of the total shares on offer, compared with 3i Group which took 59 per cent of the shares and Roslin which took 19 per cent.

4.58 At the time of the deal individuals' shares in Geron were worth £3.68 million. Each individual had invested their own money at the outset at their own risk. These sums comprised some £20,000 by the two scientists and £204,000 by the management team (Figure 22). The value of the shares at the time of the deal was therefore 16 times the amount originally invested. The scientists and management team were fundamental to the commercialisation of the technology and the deals with 3i Group and Geron would not have gone ahead without them.

4.59 Comparisons with the other investors, the public sector (mainly Roslin and the Department) and 3i Group, are not so straight forward because the periods in which they were investing varied. In addition the Department and Roslin received a combination of Geron shares and cash for research over several years. Apart from the general underpinning core funding provided to Roslin by the Biotechnology and Biological Sciences Research Council, in crude terms the Department, the Council and Roslin had over time invested up to £3 million in the Dolly technology and in return received some five times that amount by way of shares and cash. Over a one year period 3i Group received £9.9 million worth of shares, 1.65 times their intended investment of £6 million.

4.60 Partnerships UK consider that the proportion of shares held by the management team was higher than average, but in each deal the shareholding is different and reflects the particular management structure of the company and the structure of the deal. The distribution of shares in the Geron/Roslin Bio-Med deal was consistent with good practice. The management team committed personal money to buying shares at the establishment of the company and they were later rewarded for their commitment.

### Roslin's negotiating strategy was insufficiently clear at the outset of making the deal

4.61 The Director of the Roslin Institute was delegated to negotiate the deal with Geron on behalf of the Roslin Institute within a procedural framework laid down by the Biotechnology and Biological Sciences Research Council. However, it became apparent during negotiations that there were differences of emphasis between the Director of the Institute and the Chief Executive of the Council as to which negotiation strategy to adopt. The Director wanted to maximise the amount of cash available for research while the Chief Executive wanted Roslin to maximise the overall return by a balance of research and equity, whilst also being mindful of the potential conflicts of interest of some parties. The differences in strategy were exemplified by the intervention of the Chief Executive of the Council to increase Roslin's shareholding during the deal negotiations with Geron. However, the outcome was mutually acceptable as the gains in equity were not at the loss of research income.

4.62 In January 2000 the Council consulted its institutes and updated its conditions of grant to expand its guidance on commercial deals. The characteristics of a significant commercial development, about which the Institute is required to consult the Council's Chief Executive at an early stage, have now been defined as:

- sale of equity or intellectual property valued at £250,000 or more;
- licensing of intellectual property likely to give a royalty return of £250,000 a year or more;
- third party research contracts of a value of £1 million or more; and
- novel developments that may raise new policy issues.

## Developments since the deal with Geron

4.63 Since the deal with Geron the following developments have taken place:

- The focus of the research directed by Geron in Roslin (£10 million) changed from nuclear transfer (xenotransplantation) to stem cell biology, especially on producing and using human embryo stem cells, using Geron's patented technology. Only a small amount of nuclear transfer research on farm animals continued to be undertaken. The research funds directed by Roslin (£ 2.5 million) are used in the field of animal genome research. Geron is not carrying out any of its own research into nuclear transfer.
- changes in share price described above in paragraph 4.56.
- Geron signed several non-exclusive option agreements with other biotechnology companies that involve the nuclear transfer technology. The former Director of Roslin doubts whether any significant revenues will come from these agreements but in any event no revenues will be due to Roslin.
- Dolly is now six years old. She has had three lots of live lambs (six lambs in all). She is relatively healthy although suffers from some arthritis in one of her legs, which is unlikely to improve, despite medication. This sort of condition is not unknown in sheep of her age. On her death, Dolly will be preserved and sent to the Royal Museum of Scotland in Edinburgh for possible display.
- The two scientists, Ian Wilmut and John Clark, continue to work at the Roslin Institute.

The Roslin Institute

*Photograph courtesy of the Roslin Institute.*

# Appendix 1 Study Methodology

## One: General examination of the Department[8] and its research contractors' response to the challenges of commercialisation

We used the following main methods:

- Interviews with key personnel at the Department and within research establishments
- Review of policy objectives and strategies across the Department
- Site visits to funded research establishments working for the Department to identify local initiatives
- A review of case examples of innovations taken forward for commercialisation
- Comparison with other public and private sector research establishments
- Advice from consultants Morgan Harris Burrows

### Interviews with key personnel at the Department

We interviewed key staff involved in management of intellectual property and the commercialisation process, including staff from the Department's Chief Scientists Group, the Agency Ownership Unit, Finance and Legal divisions.

### Examination at research contractors' establishments

We visited a cross-section of the research contractors funded by the Department: two of its executive agencies - the Centre for Environment, Fisheries and Aquaculture Science and the Central Science Laboratory; one non-departmental public body, Horticulture Research International; and two research institutes - Roslin Institute and Silsoe Research Institute. The two research institutes are sponsored by the Biotechnology and Biological Sciences Research Council.

At each establishment we:

- Interviewed key people, including the head of the organisation; business development staff and senior scientists.
- Reviewed the procedures for identifying and exploiting intellectual property.
- Examined documents and files relating to the intellectual property being commercialised and trends in income and expenditure from commercialisation.
- Examined case files relating to pieces of research which had been identified for commercialisation.

We used our interviews with commercial directors to gather the following information:

- procedures in place to identify and evaluate research with commercial potential;
- the contractor's past record of commercial projects;
- the commercial expertise available in-house and externally;
- the level of awareness of staff to intellectual property issues and training offered to them;
- the application of financial incentive schemes operating;
- the main barriers to commercial exploitation in their establishment; and
- how establishments were tackling potential conflicts of interest.

### Focus groups

At each of the five research contractors we examined, we carried out discussions with scientists on:

- level of awareness of commercialisation and intellectual property management;
- attitudes towards commercialisation;
- views on incentive schemes;
- how their establishment could improve its commercial prospects.

8 *Work prior to June 2001 would have examined the activities of the Ministry of Agriculture, Fisheries and Food, although as elsewhere in this report, we refer to the Department.*

## Discussions with other public and private sector research establishments

We interviewed staff from other public and private sector organisations including ADAS Consulting Ltd; a research organisation formerly in the public sector under the Department (or Ministry's) sponsorship but now privatised; the Defence and Evaluation Research Agency; the University of Southampton's Centre for Enterprise and Innovation. and venture capitalists, 3i Group. We were also able to draw on work carried out by colleagues in the National Audit Office study of the Delivering the Commercialisation of Public Sector Science.

## Two: Nuclear transfer technology

Our main evidence came from an examination of papers and files relating to the deals at the Roslin Institute, the Biotechnology and Biological Sciences Research Council and the Department for Environment, Food and Rural Affairs (or its predecessor, the Ministry) and interviews with key parties involved in the deals.

The key documents included:

- Papers belonging to the Roslin Institute, the Council and the Department
- Papers belonging to Roslin Bio-Med.
- Documentation leading to the purchase of Roslin Bio-Med by the Geron Corporation.

## Interviews with the key parties included:

- Staff at the Roslin Institute and Biotechnology and Biological Sciences Research Council.
- Staff of the Department's Chief Scientist's Group.
- David Greenwood, Chief Financial Officer of the Geron Corporation.
- Staff of Geron Bio-Med.
- Ken McCracken of Wright, Johnston and McKenzie, lawyers to the Roslin Institute
- 3i Group plc.

Professor Ray Baker, who as Chief Executive of the Biotechnology and Biological Sciences Research Council until December 2001 was consulted on the final draft of the report, as was Professor Grahame Bulfield, Director of the Roslin Institute until October 2002.

We examined the NASDAQ Biotechnology Index share price movements of the Geron Corporation before and after the deal to take over Roslin Bio-Med.

## Consultants Advice

We also employed management consultants, Morgan Harris Burrows (MHB), to provide specialist comment and advice on the arrangements to commercialise the nuclear transfer technology developed at the Roslin Institute and to make suggestions for good practice. The consultants included Andrew Stamp a partner in MHB with experience of the establishment and development of science-based companies; Bill Smith of Inchgower Development Ltd, a specialist on the identification, protection, licensing, technology transfer, business development and commercialisation of Intellectual Property (IP); Dr Ed Dart, CBE who has extensive experience in research and development, and has worked extensively with the United Kingdom Research Councils and is currently chairman of Plant Biosciences Ltd; Alan Richardson, a visiting lecturer at Cranfield University School of Management with a background in corporate finance; and Jim Sinclair, CBE, an MHB partner, formerly with the Scottish Office.

# Appendix 2 Treasury Minute response to a report by the Committee of Public Accounts

## The Treasury Minute response on the Management of Intellectual Property in the Ministry of Agriculture, Fisheries and Food 1994-95

### The performance of the Intellectual Property Liaison Unit

PAC conclusion (i): We note that the Unit exists primarily to assist in transferring the technology arising from the Ministry's research programme to industry. However, although the Ministry have some 1,500 pieces of current research work, the Unit has transferred only ten items of intellectual property to industry since its creation in 1989.

*The Ministry of Agriculture, Fisheries and Food (the Ministry) notes the Committee's comments. However, there is no direct correlation between the total number of research projects funded by the Ministry, and the number of items of fully commercially exploitable intellectual property transferred since 1989. The Ministry's research programme is diverse in nature and purpose, supporting the Ministry's aims which encompass protection of the public, enhancement of the rural and marine environment, and protection of farm animals, as well as improvement of the economic performance of the agriculture, fishing and food industries. Effective technology transfer in pursuit of this aim does not depend on the maximisation of revenue through the identification of patentable intellectual property, which has therefore never been a key objective Only a very few projects will lend themselves to full commercial exploitation through the patenting and licensing system. In terms of expenditure on R & D, about 20 per cent of the total research spend within the Ministry is in support of technology and none of that is near market. It is within this area that the small number of suitable projects would be identified More generally, a variety of other mechanisms exist which are designed to transfer the results of research projects to industry (where appropriate), for example, publication, trademarks, copyright etc.*

PAC conclusion (ii): We note that, to the end of 1993-94, the Ministry earned £65,000 from the exploitation of their intellectual property. While we accept that research and its exploitation are long-term businesses, this looks to be a distinctly modest achievement particularly when set against the Unit's costs of £466,000 over the same period. We are concerned too that in at least one case the Ministry had not ensured that sums due to them had actually been paid.

*The Ministry notes the Committee's concerns However, the Ministry would reiterate that the purpose of its research is not the generation of revenue for government but the generation of useful results in furtherance of the Ministry's policy aims. The Ministry accepts, however, that in one case it had not ensured that the royalties due had been paid. A strengthened management system is now in place A new licence administration screen has been incorporated into the database which provides a full history of each licence, details of when income statements are due and when received, and similarly details of when payments are due and when these are received. This facilitates management of the licences and provides the necessary prompts for action Coupled with a requirement in every new licence for each licensee to provide an annual statement of costs, sales and revenue, this also enables royalty income to be monitored.*

PAC conclusion (iii): We appreciate that the exploitation of the Ministry's research involves, by its very nature, a considerable degree of uncertainty. Nevertheless we are concerned that the Unit's income projections were so wide of the mark. Reasonable accuracy on such matters is fundamental to sound planning and management. We look to the Ministry to make more accurate estimates in the future.

*The Ministry accepts the Committee's concerns and recommendations. From now on, income forecasts will be based on critical and thorough analysis informed by a number of factors: experience with the performance of existing licences as a guide to possible future performance; annual progress reports from licensees; and business projections where these are judged to be well-informed and realistic.*

PAC conclusion (iv): We consider it unsatisfactory that the Ministry's Intellectual Property Liaison Unit was unaware of so many cases where the Ministry's research contractors had stated that intellectual property had been identified. In some cases the contractor had already patented or licensed the intellectual property. We urge the Ministry to ensure that they have sufficient information in their new database to make them fully aware of emerging intellectual property. This is particularly important given that they are forecasting a major increase in income from the exploitation of research work.

*The Ministry accepts the Committee's comments. Mechanisms to identify intellectual property as early as possible in the life of each R & D project have been strengthened through changes to the project initiation and monitoring processes, including the flagging of potential and actual intellectual property on the database as it arises.*

*Recent restructuring of the Chief Scientist's Group within the Ministry has streamlined lines of communication, facilitating a uniform reporting process.*

PAC conclusion (v): We are concerned at the Unit's failure to relate initial and subsequent patenting decisions to commercial prospects; and at the failure to record the decisions taken. Such omissions may mean that patent protection, and its cost, may in some cases be unnecessary; or, conversely, not be arranged when to do so would protect the Ministry's position should third parties wish to publish the results of the work.

*The Ministry notes and accepts the Committee's concerns. The Ministry has modified its database to provide an automatic mark forward system which flags up the need to take patenting decisions, providing sufficient lead time for any necessary data to be collected and interpreted. This provides a regular and systematic approach to reviews which was absent in the past. The Ministry is now recording all patenting decisions, and supporting those decisions with full documentary evidence on the registered file. The Ministry will continue to review critically the criteria for these decisions, with assistance from an expert external source.*

PAC conclusion (vi): We are concerned, too, that the Ministry have paid little attention to the need to protect their interests in development agreements negotiated by contractors with third parties. It would not be unreasonable to expect that some may give rise to intellectual property which may turn out to be commercially successful.

*The Ministry accepts the Committee's comments. The Ministry has taken steps to ensure that any sub-contracting carried out by the contractor must be under the same terms and conditions as the main contract between the Minister and the contractor, and that contractors must not instigate developments which might affect the Ministry's intellectual property rights without first gaining the Ministry's agreement. This applies equally in the Ministry's agencies where the original problem lay. The Ministry has written to the Chief Executives of each agency requiring them to ensure that the Ministry officials responsible for intellectual property management are consulted in all cases. More generally, a requirement to supply information to enable the Ministry to monitor the success of exploitation will be built into any new licence agreement. New licence agreements with contractors will also have termination clauses.*

## The future management of intellectual property

PAC conclusion (vii): We note that the Ministry's policy review is considering the future of the Unit and a range of options for transferring the management of intellectual property to bodies outside the Ministry. We expect the Ministry to take early action on this review: to have full regard to the mediocre performance of the Unit to date and its apparent lack of concern at such mediocre performance until shortly before our hearing; and to address the conclusions contained in this report.

*The Ministry notes the Committee's recommendations and has reviewed its policy. New arrangements have been introduced to ensure closer attention to determining what should be done and then monitoring and ensuring effective progress, but not necessarily relying on the Ministry's own staff to arrange legal protection for the Ministry's intellectual property or to undertake exploitation activities themselves. The Ministry will avail itself of appropriate expertise from whatever source so as to obtain best value for money.*

PAC conclusion (viii): We note the Treasury's evidence that government accounting arrangements currently require that the Ministry's income from the commercial exploitation of their intellectual property be surrendered to the Consolidated Fund, and their acknowledgement that these arrangements do not provide any positive incentive for the Ministry to exploit intellectual property in the interests of the taxpayer. We are glad to note that the Ministry will consider this issue as part of their policy review.

*The Ministry has addressed the issue, but considers that the requirement to surrender income from the commercial exploitation of its intellectual property does not significantly affect its approach to the management of intellectual property. As has been stated, the Ministry's R & D is funded in support of a variety of policy aims in the public interest rather than in order to generate income for government. The existing Treasury rules reflect government accounting arrangements which flow directly from national account classifications and extend across government departments. The Ministry has concluded that it would not be appropriate to seek an exemption from these arrangements in the present case.*

# Appendix 3 The National Audit Office's report on "Delivering the Commercialisation of Public Sector Science"

## The 2001-02 recommendations from the report (HC580 2001-02) were:

### For the Department, the Office of Science and Technology, and Research Councils:

- Review performance indicators including recognition of the diversity of research and hence of the performance indicators required.

### For the Research Councils:

- Research Councils should hold annual operational review, dealing with commercialisation, with all Research Establishments.
- Research Councils should establish guidelines on an exceptional basis, for Research Establishments to take advice on conflicts of interest and to consider forming an independent science advisory board to advise them on novel cases.
- Research Councils should define major deals, or what would constitute novel deals, for oversight purposes, including guidelines for taking expert advice.

### For Research Establishments:

- Chief Executives (in the case of the Medical Research Council the head of Medical Research Technology) should review the scale of the commercial opportunity annually and submit a plan for their establishment explaining any major constraints.
- Research Establishments should review and set minimum levels of training in commercialisation.
- Scientific staff and research appraisals should give 'kudos' for effective participation in commercial exploitation, including timely patent applications.
- Research Establishments should budget time, down to research team leader level, for market assessment of the commercial opportunities of research projects.
- Each Research Council should review its budget for 'proof of principle' funding, i.e. funding work to demonstrate the commercial promise of an initial scientific discovery.
- Research Establishments should analyse the potential of their intellectual property in a systematic way.

# Appendix 4 Background to the nuclear transfer technology which led to Dolly

## What is cloning?

1 Cloning may be defined as the production of a number of cells from a single cell of an individual to produce another genetically identical individual. This can be achieved in two ways - embryo splitting and nuclear transfer. Identical twins arise when an embryo splits in two and are naturally occurring clones. In the laboratory embryo splitting can almost double the number of animals born but the processes involved are expensive and time-consuming. Splitting is routinely used commercially but has limited potential for further improvement. Nuclear transfer - the approach which led to Dolly - involves the transfer of a nucleus of one cell to a cell taken from another animal or embryo. In contrast to cell splitting, embryo multiplication by nuclear transfer has the potential to produce very large numbers of embryos.

2 Cloning by nuclear transfer is not new. It was reported in 1962 in frogs and has been used widely in amphibians to study their early development. By the mid 1980's several research groups from around the world had produced cloned sheep and cattle by transferring nuclei direct from the early embryos of live animals. However, the practical usefulness of this research was limited as the experiments had not succeeded in producing adult animals from adult cells. Scientists wanted to be able to genetically modify cells before transferring them into animals.

3 The major breakthrough in nuclear transfer technology came in 1995 when Dr. Keith Campbell, Dr Ian Wilmut and colleagues at the Roslin Institute produced live lambs - "Megan" and "Morag" - by nuclear transfer from early embryos that had been grown for several months in culture in a laboratory. By being able to work with cells in a laboratory scientists could genetically modify the embryos in a precise manner.

## Why was Dolly a major scientific breakthrough?

### Cells could be reprogrammed

4 Before Dolly, scientists believed that once a cell was 'committed' to being skin, bone, or an organ it could not be reprogrammed to be something else. Roslin scientists disproved that theory by creating Dolly. An experiment at Roslin demonstrated the ability to reproduce the whole genetic identity of an animal from a single cell. Scientists took an udder cell from a living ewe and, by using an electric current, fused it with an egg cell whose own nucleus had been removed. The udder cell's nucleus programmed the new fused cell to become a sheep embryo rather than an udder cell. Implanted into a surrogate mother, the embryo became Dolly, born in late 1996, and revealed in February 1997. Dolly the sheep was the first time that any mammal had been successfully cloned from an adult cell.

## The potential benefits could be huge and are likely to be medical

5 One of the aims of the initial cloning research was to develop improvements in conventional animal breeding by identifying desirable traits in cows and sheep and using the cloning techniques to speed up the dissemination of these characteristics through the national herd or flock. This would lead to benefits for the farmer by producing animals less susceptible to disease or improving animal fertility and growth. The technique could also contribute to the continuation of rare breeds and endangered species.

6 The nuclear transfer technology has implications for cell biology, embryology, gene therapy, organ transplantation, pharmacology and agriculture. The most significant potential benefits of the nuclear transfer technology are expected in the field of human medical science. The technology has the potential to play a key part in developing new treatments to reverse the effects of diseases such as cancer.

7 However, the most immediate application of the nuclear transfer technology is likely to be in the pharmaceutical industry. The technology has the potential to improve the efficiency of production of livestock that include genes from other species (called transgenic livestock). PPL Therapeutics (formerly Pharmaceutical Products



Limited), for example, are injecting human genes into sheep embryos to make the milk of the adults medically useful to humans.

8 In the longer term, it is conceivable that scientists will learn how to re-programme adult cells and use this knowledge to develop ways of regenerating damaged tissue such as heart cells.

## Where was Dolly created?

9 The Roslin Institute, located at Roslin near Edinburgh, is an international centre for research on farm animals and it has more than 300 staff, visiting scientists, and PhD students. Its aim is to be a leading centre for animal biotechnology and to carry out research on animal welfare to inform government policy and to address public concern in this area. Roslin has extensive expertise in quantitative genetics, genome analysis, and animal physiology and behaviour.

10 The Roslin Institute is sponsored by the Biotechnology and Biological Sciences Research Council from whom it receives an annual grant of some £2 million. The Council is a non-departmental body principally funded through the Science budget by the Department of Trade and Industry via the Office of Science and Technology. Staff at the Institute are employees of the Council. The Director of the Institute is responsible to the Chief Executive of the Council for the scientific leadership and management of the Institute.

11 The Institute also receives funding from the Department, the Scottish Office, the European Union, competitive funding from the Council and other public and private organisations. Every year the Institute receives annual research funding, from all sources, of some £12 million. The constitution and status of the Institute as a Scottish charity prevents it from carrying out any trading activity or making a profit.

12 Much of the research which led to Dolly was undertaken in collaboration with the private company, PPL Therapeutics. In 1987 PPL Therapeutics had been set up as a 'spin out' company of Roslin to commercialise the production of therapeutic human proteins in the milk of transgenic livestock. It has its headquarters and main laboratories at the Roslin site.

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|---|---|
| April 1991 - March 1997 | The Department (formally the Ministry) funds research into nuclear transfer techniques - to assess scope for improved breeding techniques in the livestock industry. |
| August 1995 | Birth of Megan and Morag - cloned sheep produced by nuclear transfer from differentiated culture cell populations established from early embryos |
| August 1995 | Roslin Institute files two patent applications for the nuclear transfer technology |
| 27 February 1997 | Publication of paper in Nature - nuclear transfer using adult cells leads to the birth of Dolly - the animal cloned from an adult cell |
| February 1997 | Ministry/Department confirm that funding for cloning research will not be extended |
| March 1997 | Roslin Institute considers offers from private sector to exploit the technology |
| May 1997 | Roslin Institute approach the 3i Group with a proposal to fund the technology |
| 26 March 1998 | Patent Co-ownership Agreement between the Roslin Institute, the Minister of Agriculture, Fisheries and Food and the Biotechnology and Biological Sciences Research Council |
| 7 April 1998 | Roslin Institute set up a spin-out company, Roslin Bio-Med, with the 3I Group |
| 6 November 1998 | Geron Corporation announce that human embryo stem cells produced |
| 4 May 1999 | Roslin Bio-Med taken over by the Geron Corporation |
| 21 January 2000 | Nuclear transfer patents granted to the Roslin Institute, the Department and the Biotechnology and Biological Sciences Research Council |
| August 2001 | Nuclear transfer patent granted in the United States. |