HOUSE OF LORDS

Revised transcript of evidence taken before

The Select Committee on Science and Technology

Inquiry on

THE RELATIONSHIP BETWEEN EU MEMBERSHIP AND THE EFFECTIVENESS OF SCIENCE, RESEARCH AND INNOVATION IN THE UK

Evidence Session No. 7 *Heard in Public* *Questions 69 - 76*

TUESDAY 26 JANUARY 2016

10.40 am

Witnesses: Dr David Hughes and Mr Steve Bates

USE OF THE TRANSCRIPT

This is a corrected transcript of evidence taken in public and webcast on www.parliamentlive.tv.

Members present

Earl of Selborne (Chairman)
Lord Cameron of Dillington
Lord Fox
Lord Hennessy of Nympsfield
Lord Hunt of Chesterton
Lord Maxton
Baroness Morgan of Huyton
Baroness Neville-Jones
Lord Peston
Viscount Ridley

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Examination of Witnesses

Dr David Hughes, Global Head of Technology Scouting, Syngenta, **Mr Steve Bates,** Chief Executive Officer, BioIndustry Association

Q69 The Chairman: On behalf of the Committee, I welcome Dr Hughes and Mr Bates. We are grateful to you for helping us in our inquiry. We are being broadcast, so I am going to ask if you would like formally to introduce yourselves for the record. If you would like to make any opening statement as you do so, please feel free to do so. Dr Hughes, would you like to start?

Dr David Hughes: My name is David Hughes. I have 20 years' experience in agricultural research and development for Syngenta and her legacy companies. I have been based at the Jealott's Hill research station in Berkshire all that time. It is our biggest single individual research station globally. It is focused on crop protection research. I have had a number of roles in that time, all of them very much scientific and technical. I very much regard myself as a practising scientist. About six years ago I became interested in collaborative innovation, and my current role is Global Head of Technology Scouting. That essentially means I run a network of scientists around the world whose job it is to go out and develop relationships with key players in the outside world, academics and other companies, with a view to setting up collaborative research projects, ultimately aimed at accelerating the development of new technologies for use by farmers.

Mr Steve Bates: My name is Steve Bates and, if I can, I will make an opening statement. Thank you for inviting me to give evidence to your inquiry. As the chief executive of the BioIndustry Association, the UK trade association for innovative bioscience enterprises, I am proud to represent today over 300 companies in a sector responsible for over 90% of the biotechnology-derived medicines currently in clinical development in the UK. Our sector is at the forefront of innovative scientific developments targeting areas of unmet medical need, and this leads to better patient outcomes, development of a knowledge-based economy and economic growth. Many of our members are small pre-revenue companies; some are multinational pharmaceutical companies.

Over a generation, regulators and legislators have built up an integrated EU regulatory environment for biosciences. It is corner-stoned in the UK, here in London in fact, and has significant UK input. The European Medicines Agency, their regulator, is at Canary Wharf. The EU is at present building an integrated unitary patent system, which will be corner-stoned here in the UK, with the life science decision-making part of the Unified Patent Court in London. The UK bioscience cluster leads Europe and is growing, and one facet of that is linked to our relationship being within the European Union, the single biggest market for pharmaceuticals. In innovative life science the UK influences and strengthens the EU. In the last few decades the UK has truly developed as a location of choice for global companies to build and grow their life science businesses in Europe. Just last week, to give you some context, Andrew Witty, the chief executive of GSK, said, "Europe has gone from having 27 fragmented, independent, not-talking-to-each-other regulatory authorities in the healthcare space to one, and that's a big deal."

From our perspective, if the UK were to leave the EU, this long-term integration would need to be unpicked. It would affect legislation, patient access to medicine, the European leadership role of the MHRA—the UK regulator—and our intellectual property and patents ecosystem. Any change to the current arrangement would lead to disruption, expense, and a time lag in setting up a new system, and we believe that uncertainty would pose significant risks to the UK's attractiveness for inward investment.

Crucially, what businesses lack is the information they need to undertake a fact-based cost-benefit analysis of what any alternative would look like. The bioscience sector needs long-term stability for long-term investment. It can easily take a decade to develop a drug. We want the UK Government to objectively set out the logistics and costing scenarios of the implications of the UK leaving the EU and how they would be dealt with, and we have called on the Government to set up a plan on any expected disruption to UK life science. This should look particularly at how the European Medicines Agency and the Unified Patent Court might have to leave London, how medicines would be approved and regulated, and the likely impact on investment.

I look forward to the opportunity of being here and expanding on these issues today.

Q70 The Chairman: Thank you, Mr Bates, and we will move on now to the questions which we would like to put to you. Could I start by noting that the evidence we have had shows that, as a country, the United Kingdom does rather well out of European Union-funded research but, when you mine into the figures, it looks as if it is the universities which are doing well but not the business sector, which is, after all, a larger share of the research in this country. I wonder if you can account for the fact that United Kingdom large business participation seems to be rather low compared to some of our competitor countries, and why SMEs appear to be doing rather better—albeit, again, not brilliantly—compared to competitor countries?

Dr David Hughes: I am not surprised to hear the statistics that you are citing there. I can speak only from Syngenta's point of view, of course, but Horizon 2020 as a funding mechanism is not particularly good from our point of view. Speaking from a big corporate point of view, there are better mechanisms, through schemes like the research councils and Innovate UK, that are far superior to Horizon 2020, so I am not at all surprised that big companies in the UK would prefer to use those mechanisms over and above Horizon 2020. Of course, big companies based in Europe do not necessarily have access to funding schemes

of the same type. So I am not at all surprised; if you have such good funding schemes available, why would you resort to Horizon 2020?

The Chairman: Would you like to comment, Mr Bates?

Mr Steve Bates: I think this is all about access to finance and the different types of finance you can choose. All money comes with strings; the question is, which strings do you want to take with that money? Money is not only available from public sector support. Large companies in our sector may have the resources to avoid the hassle of onerous forms of money that come from the public sector. We held a round table on Horizon 2020 in the House and people were concerned about the burdensome process. However, SMEs perhaps are not as lucky with opportunities to get money; getting money for early-stage medical research is particularly risky and they do struggle to attract private investment, therefore Horizon 2020 is seen by many members as a useful component in a plethora of funding schemes.

There are a couple which I think work particularly well, and people do like the partnership working that you get with this. If I can just cite New Drugs 4 Bad Bugs, part of the Innovative Medicines Initiative, that is a good one, where you have companies in seven partnerships working on antimicrobial resistance, where it would be much harder to get investment. So I think it is to do with the attractiveness of the scheme and whether it works for you.

Lord Hennessy of Nympsfield: Dr Hughes, I was very struck by that paragraph in your evidence about the problems with Horizon 2020, which you have alluded to already. Could you give us the order of magnitude of difficulty of getting money from that source compared to a British research council? Also, if we stay in, and we were to respectfully suggest that there needs to be a little more reform than the ones the Prime Minister has come back with, and Horizon 2020, in a burst of open-mindedness, said to you, "How could we improve our ways?" what would you say to them?

Dr David Hughes: In terms of the order of magnitude, I would say approximately one. It is significantly more difficult to get money out of Europe but it is not impossible.

Lord Fox: Ten times worse!

Dr David Hughes: Yes, significantly worse.

Baroness Morgan of Huyton: When you say worse, do you mean it is more complicated or we do not get the money? I am sorry to interrupt, but from what you were saying earlier, it seemed to me to suggest that a lot of companies did not bother to try to get the money. Are you saying they try and they do not get it, or the complication just puts them off?

Dr David Hughes: A little bit of both. We have strict rules of engagement defined by our legal team, which say, "Okay, if you have a potential opportunity that could be funded through Horizon 2020, it has to tick all these boxes." The objections to Horizon 2020 alluded to already were the hassle and bureaucracy of doing it; there is a big overhead in terms of what you need to do in order to get money. But it is more than that from our point of view. There are significant issues around the intellectual property aspects in terms of what intellectual property rights we have to give other people, if that is relevant to the project, and what intellectual property rights are associated with the results of the projects that are actually done, also unacceptable from our point of view. It is not as if it is impossible to overcome these but, if you have other means of supporting these same projects, it is much easier to do so. For instance, from the research councils and Innovate UK, it is between the

partners, who are free to negotiate what those intellectual property rights are, and that works very well indeed for us. For Horizon 2020, they are more or less defined and beyond where our red lines would normally be.

The Chairman: I am not sure I entirely follow all that because, presumably, the intellectual property rights issues are the same for other countries as they are for this country. Are you saying that, given that that will be equal inconvenience for both countries, it is simply the hassle and overheads which is the relevant factor?

Dr David Hughes: Yes. It comes down to a cost-benefit analysis: so if the costs associated with putting these agreements in place exceed the benefits that we perceive in terms of getting that funding out of the European Union.

Lord Hennessy of Nympsfield: It is inherent to having 28 countries involved. How would you reform Horizon 2020, or is it beyond reform?

Dr David Hughes: My impression is that Horizon 2020 was not really designed with big companies in mind. I think it was designed to encourage collaboration, primarily in the private sector, with small and medium-sized enterprises. You can tell that by what is missing in some of these boilerplate agreements; there are certain things to do with corporate structure, which is very important for big companies, which do not appear in these boilerplate-type contracts. Again, that is beyond our red lines. We would not necessarily be allowed to share results from a project that has been driven from the UK. I would not be able to share those results with other researchers in different countries, for instance, because they are working for different affiliated companies and that structure is not catered for in these standard agreements. That is never usually a bone of contention but the fact is that clause has never been included in the contracts that we are being asked to sign. Again, the lawyers would have to get involved and renegotiate what should be a boilerplate-type agreement, and that is just time and expense.

Lord Fox: So are we wrong to worry about big business not going to Horizon 2020, in that, as you say, you do not think it is designed for big business? Should we not be concerned about that or should we continue to worry?

Dr David Hughes: In our view, the processes in place via the research councils and Innovate UK are much better. We do 25% of our collaborative research in the UK, which is a remarkable statistic for a global company. We think the UK is a fantastic place in which to do collaborative research, and these support structures are a very important component of that.

Viscount Ridley: Can I just press a little bit further on this point? You also said of Horizon 2020 in your written evidence that "the questions being asked are very narrow, too focused and consequently fail to look at the bigger picture and address the fundamental issues". What do you mean by that? Are you referring to the loss of agrochemicals in Europe or the GM problem or something like that? What is the fundamental, big-picture thing that Horizon 2020 is missing?

Dr David Hughes: First of all, the way the funding structures are set up within Horizon 2020 is highly fragmented, so there are some big questions affecting agriculture in Europe right now which do not seem to fall within any of the categories that we can actually use. For example, the neonicotinoid in bees question remains scientifically open. We would suggest that the evidence we have to date suggests that there is no impact if these chemicals are

used as they are designed to be, yet there are no Horizon 2020 opportunities to actually investigate that on a significant scale. The really appealing thing about Horizon 2020 is the amount of funding that is available, so you could in theory say, "Okay, we are going to spend a lot of money to actually get a definitive answer to this question" but that opportunity has been missed.

Mr Steve Bates: Perhaps I can give a perspective from the other side. You talked about whether Horizon 2020 tackled the big challenges, and I think an example where perhaps Horizon 2020 is tackling a big challenge is antimicrobial resistance, New Drugs 4 Bad Bugs. If you look at that, I would say there has been a development from the FP7 processes, the former processes, to the H2020 processes. They are not perfect but there has been an improvement. If you look at that, that is part of the Innovative Medicines Initiative, which is the largest public/private partnership in the world, which does have the engagement of global players in pharmaceuticals: GSK UK, European branches of AstraZeneca, Janssen, Sanofi-Aventis and others, with academic partners, SMEs and non-profit organisations, on the challenge of science, regulation, businesses around antibiotics. So there are some examples of things that are working as well as some that are not.

Viscount Ridley: Is it fair to say that Horizon 2020 is working better in biomedicine than in the agro-industry area?

Mr Steve Bates: Probably.

Dr David Hughes: Probably.

The Chairman: You are agreed about that. Lord Peston.

Lord Peston: Could you clarify something for me? The business sector is not a set of charities, is it? Companies are in business to make money, and they do, particularly in our country; the pharmaceutical companies are rather good at it. Do you accept that the taxpayers, who provide some of the money we are talking about, are entitled to some benefit as well? Can you let me know how they get a benefit, other than the pride that we financed whatever drug it was that saved so many lives? What is your position on how we recompense taxpayers, not just in our country but throughout Europe generally?

Mr Steve Bates: The major benefit to taxpayers or society of the development of new pharmaceuticals is the actual development of the product to tackle a disease or an unmet medical need. It is the translation of the science into something that turns into practical benefit. Without some support, many of the small and medium-sized enterprises in fact are pre-revenue companies, so you are right that the global pharmas do make money, but pre-revenue companies are putting at risk significant amounts of venture capital, perhaps capital from other sources, to make the difficult steps from the breakthrough in the laboratory into something that can make a practical difference. That endeavour is not always a journey that private money will go on alone. Having the support of money from the state, as we see in the USA, as we see in Japan, as we see in Europe or in the UK, is an important component in getting that translation to happen.

Lord Peston: Do you accept, on the intellectual property side, where a lot of secrecy is of importance, that one group that ought to be able to benefit from this is university researchers? They should not be told that "this is business secrets and we are not going to let you know what we know". What is your position on that? I had an example years ago of a PhD in pharmaceuticals where I was the external examiner and I discovered I was not

allowed to see the original data. I had a real ethical problem: did I reject the PhD because I could not see the data and so on, or did I award the PhD because it was a very good PhD? What is business's position on keeping things secret?

Mr Steve Bates: You are right that some intellectual property is held by universities, for instance through the work done by PhD students, and they then look to license that to a company for a royalty, and some of that money goes back to either a research council or a university. There are some good examples of new drugs, like Keytruda, which the Medical Research Council or MRC Technology will make a significant amount of recompense through to be able to reinvest. Similarly, if you look at a drug like Campath, an early monoclonal antibody, that also provides significant revenues back through the licensing deals they have done. So I think the intellectual property, where it sits, who owns it, is always a process of negotiation, and I would say a small percentage of something that goes to make a real difference in the world is better than a deal falling apart and something not being translated.

Dr David Hughes: I think I would echo that. We have seen a step change in philosophy over the last 10 years or so about how collaborative research is done. In the past it has been highly transactional: big companies got a lot of money. "We give you the money, you give us what you know and we will sell it, and thanks very much." Nowadays things are much more collaborative. We recognise the fact that collaborations are much more likely to succeed if the partners collaborating are much more open with each other and the benefits are shared. A collaboration which does not benefit all parties involved is very unlikely to succeed, and we have woken up to that now. Maybe it was not like that in the past but it is today.

Lord Maxton: Is not one of the better ways, however, that the university that has done the research then sets up its own company to carry out the financial benefits that come from it? Is that not the best way forward? That is happening in some universities in this country.

Dr David Hughes: It is one way. I would not say it is necessarily always the best. We are very open to that sort of interaction. It is in everybody's interests that technology is commercialised. Exactly how it is commercialised and how the value is shared is up for negotiation.

Q71 Lord Cameron of Dillington: Good morning. I would just like to ask Dr Hughes about Syngenta's written submission on the regulatory regime. You seem to start off by saying that because of the deficiencies of the EU regulatory regime, you think Britain would be better to come out and have its own regulatory regime after a period of time. One has to question whether being subject probably, if you have to trade in Europe, to two regulatory regimes is necessarily the best option. Then at the same you say, "Actually, no, on second thoughts, our position really is that it is best if Britain stays in the EU and uses its influence to change the EU regime, and then we would all be better." Is that a fair summary of what you are saying?

Dr David Hughes: Well, yes. It is more of a thought experiment really. You have heard from many people that harmonisation of the regulatory environment is very important, and we would certainly concur with that, though I think in our particular case the argument is more nuanced, because for agricultural technologies—at least, some of them—the regulatory systems that are defining those technologies in Europe are not fit for purpose. They are non-scientific, scientifically unjustifiable and dysfunctional. It is a bit of a mess, quite frankly. From our point of view, it is at least worth considering what the options might be, so if the UK were to be in a position where it could somehow define its own set of rules, there would

be benefits to that, clearly. Farmers are the obvious beneficiaries but also, by knock-on effects, British consumers would be too, innovators, UK PLC—they would all see benefits from that—but of course, on the flipside, there are significant costs, as you have outlined. For example, you would have to set up and run your own regulatory system and that would have significant costs. There would be the costs from our point of view of de-harmonising the regulatory system, which are very significant. There would be trade issues with Europe, as you outline, but the real key for us is that, if Britain went its own way in Europe, we would lose the most powerful, most influential, significant voice pushing for a rational, science-based regulatory system governing our technologies. If Britain went its own way, Europe would be in a pretty desperate situation, from our point of view. The chances of actually achieving a continent-wide, rational, functioning regulatory system for our technologies would be distant.

Viscount Ridley: Can I just follow up on that and perhaps encourage you to follow the courage of your own convictions here a little more? In our previous inquiry, on genetically modified insects, we heard, exactly as you said, that these regulations are not fit for purpose and that harmonisation has achieved harmonisation in the wrong direction, as it were; it has achieved harmonisation of a scientifically illiterate consensus, if you like. Therefore would it not be possible to imagine a world in which it might be better for Syngenta if Britain were in Europe, but it might be better for Britain if Britain were not in Europe?

Dr David Hughes: Yes, you could argue that, but of course, I am speaking from Syngenta's point of view. What we would like is a strong, predictable regulatory system which keeps farmers, consumers and the environment safe, and is harmonised across the whole trade bloc; that is our position.

Viscount Ridley: But you spoke of de-harmonisation. Is that not exactly the process by which we have tried to reform the genetically modified crops policy in Europe, to say it should be subsidiarity, it should be delegated to individual states? Is that not de-harmonisation?

Dr David Hughes: Again, that is scientifically unjustifiable because it is all based on non-scientific factors, is it not? We do not support that way forward, but that is what appears to be happening.

Baroness Neville-Jones: You alluded to but did not expand on this: you said there might be trade issues when you were talking about a different regulatory regime, say in a UK outside the EU. What is in your mind?

Dr David Hughes: I am a little bit out of my field, because I am a scientist, clearly, but I am following what is going on in terms of the TTIP negotiations, which is exactly the same kind of issues, and how difficult those negotiations have been. Following that thought experiment, if that is the way we decided to go, I would imagine that similar issues would arise with similar difficulties.

Baroness Neville-Jones: That is to say?

Dr David Hughes: That is to say that growing food under a different set of regulatory conditions may act as a trade barrier between food produced in the UK and consumers based on the continent.

Baroness Neville-Jones: That is the point I wanted to get to.

The Chairman: I note that we have provoked a thought experiment, perhaps a suitable role for a science and technology committee.

Q72 Lord Peston: My question follows on the previous question and on Lord Ridley's intervention. A priori, I am inclined to the view that, if you are in Europe, harmonisation is the right way to do things. A series—I have forgotten how many countries there are—of different harmonisations would just be a mess. It would be an intellectual mess and a practical mess. But Lord Ridley pointed out that if the harmonised system is itself nonsensical, you are in for a major catastrophe, so I am not clear how we get the right harmonised system, in your view.

Dr David Hughes: It is a very difficult question. I am not sure I have a good answer to that, other than to say that other parts of the world do seem to have more rational harmonised regulatory systems, but Europe has got itself into a mess where the regulatory system has become highly politicised, so the regulations being made do not make scientific sense any more. We have now gone so far down that path that it is difficult to see a straightforward way back but, from a rational point of view, that has to be the ultimate destination, has it not? We have ourselves a situation where we have a dysfunctional regulatory system, where technologies like GM crops, without actually being banned, have been taken out of the hands of farmers for 20 years, such is the dysfunctionality of the system that we have to operate in. That cannot be right. What is the solution? I do not know whether I have a good answer to that.

The Chairman: Perhaps Mr Bates would like to comment on the biopharmaceutical sector, as to whether you see the issues of harmonisation in the same way.

Mr Steve Bates: We see them very differently, I think. We would say that the overall balance of the benefits of regulatory harmonisation versus detrimental effects is positive. These are designed for patient benefit and, as an EU member with a seat at the table, we have had the scope to improve EU regulation. In fact, I would say that the challenge in recent years has been the interpretation of European Union legislation when it has come to the UK; that has been the actual challenge for the pharmaceutical sector rather than the other way round. The majority of UK legal frameworks governing medicines, clinical trials, marketing authorisation, licence to manufacture and pharmacovigilance is based on European Union legislation, and that is a harmonised benefit. The key purpose from our sector is that it is very attractive for the UK within Europe to be a place to place your European HQ for this sector. It is interesting that I am here representing over 300 companies based from the UK; Syngenta is based in Switzerland, and the majority of companies that do GM crop work are not based in Europe.

Lord Peston: Just one other point of clarification. Supposing we cannot reform the harmonised system, would it then happen, if we all went our own separate ways, that any company exporting to another country in Europe would be subject to their regulatory system? They would have to convince the country they are exporting to rather than us, where it was all right. They are going to say, "Well, it doesn't suit us." To go back to my a priori argument, if we really did have a free-for-all, that would also be a total disaster, would it not?

Dr David Hughes: It would be a mess, yes, absolutely.

Lord Peston: There are two possible messes. Are you optimistic that somewhere between the two we can find the right way?

Dr David Hughes: That an outbreak of sanity prevails? Am I optimistic? No, frankly, I am not; I cannot see it happening, but it has to be the ultimate destination.

Lord Hennessy of Nympsfield: I am very struck, Dr Hughes, by the case you have been building over the last three or four answers you have given that the UK is a bringer of rationality to the benighted. It is a modern version of our civilising mission, a last imperial pang. I may well share it; it is just that you have been building this very big case. What is it about the other 28 that leads them to not follow the evidence in the way we do in our cold, damp isles off the mainland of Europe? What is it that is so special about us, and why are those other poor souls, as Frankie Howerd would say, so benighted so continually?

Dr David Hughes: I do not know, to be honest, but that is the case. This Government and previous Governments have been very supportive about applying rational, science-based principles to regulation, and that has been extraordinarily welcome. We do not see that same political will in other countries in Europe; the situation is more politicised there. They seem to be more willing to make poor decisions based on political judgments rather than scientific judgments.

Baroness Morgan of Huyton: Is it not the effect of having a PR system with lots of Greens? Is it not as basic as that really, that they have not been represented in our Government particularly?

Lord Hunt of Chesterton: The fact is you came up with the first remarks about being anti-scientific, for those people obviously all across Europe, the Greens and so on, who are very concerned about, essentially, the degradation of agriculture. You go to America and have all these marvellous things you like but the food is terrible; it is disgusting to eat an American tomato, and that is the point. As you said at the beginning, you do not understand the question of the bees and the plants. There are a lot of unknown scientific questions and, while these are unknown, the people in Europe who like tomatoes, and farmers and so on, are not persuaded by what you call the rational, scientific approach. Surely a bit more humility on that point of view would be appropriate. You have been, if I may say so, almost arrogant in the way you say scientists know and these benighted people do not. That is rubbish.

Dr David Hughes: I can give you some examples of some of the things we have to deal with. We are seeing an increase in hazard-based regulation as opposed to risk-based regulation, which is wrong. Safety correlates with risk; it does not correlate with hazard, yet we are now seeing increasingly hazard-based regulation coming in. We are seeing an assumption in some cases that things which are natural are assumed to be safe; things which are synthetic are assumed to be harmful, and that is nonsensical, and, if anything, it should be the other way around, should it not? If you list all the most heinously toxic and carcinogenic substances known to science, almost all of them are natural.

We are seeing regulation on process rather than product, so we end up in the situation where identical products potentially would be regulated in very different ways according to the way they were produced—the genetics of a seed, for example. There is nothing wrong with precautionary approaches to regulation but the way it is applied in Europe makes it

literally philosophically flawed and hopelessly open to abuse. So there is a lot wrong with the regulatory systems that we see in Europe.

Viscount Ridley: Just to congratulate Dr Hughes on that excellent little speech and to answer Lord Hennessy by saying that Scottish enlightenment is the answer to his question. I wanted very quickly to press Mr Bates on one point. You said that on the whole the various directives have been helpful in terms of your industry. What about the clinical trials directive? We have heard on other occasions that it has been really problematic for many parts of your industry.

Mr Steve Bates: The EU Clinical Trials Directive was not a step forward but the significant challenge with that was the interpretation of it into UK law. The EU Clinical Trial Regulation that is now going through, with significant input from the UK, we believe will improve things and make things speedier, simpler and more straightforward. If you look at some of the latest things coming from the European Medicines Agency, such as the PRIME scheme, or the ability of patients to get speedier access, we believe that that will be a positive step forward.

Lord Fox: I am sorry to prolong this issue but it is really the flipside of Lord Hennessy's question. Clearly, the scars on your back seem largely to be due to the genetically modified argument that has been going on around regulation. If regulatory competence was transported back to Westminster, what evidence do you have to suggest that the great rationality that was discussed on my left would prevail were Westminster under the same sort of pressure, political, social and otherwise, whether it is rational or irrational, depending on your viewpoint? Westminster has the privilege of being rational because it is not the competent authority. Once it became the competent authority, would it then revert to some of the same arguments that we find in Europe?

Dr David Hughes: I guess that would always be possible, though the arguments for science-based regulation in order to keep people and the environment safe are compelling, in my view. Whether the politicians would be able to resist the inevitable pressures that would come to bear is another question. I cannot really speculate.

Lord Fox: But it is not a given that our rationality, as you call it, would suddenly transform the regulatory horizon were it transported back to Westminster.

Dr David Hughes: I guess that is true.

The Chairman: I am going to move on to Baroness Neville-Jones.

Q73 Baroness Neville-Jones: I have one last question on the effects of the regulatory regime in Europe. Could you comment on the following? It has been claimed to us that the regulatory regime has actually had a negative effect; that is to say, a reduction in commercial R&D in Europe, deriving from the nature of the regulatory regime. I sense that you may not be united in this; it may differ according to the regulatory regime, but I am interested to know whether you agree with that as a factual assessment of what has happened, i.e. there has been a decline, and what view you have as to its causes and how it could be reversed.

Mr Steve Bates: On this point, I would like to clarify that this is not a point in evidence that the BIA made, and our sense is that this point was made in relation to GM crops, because if you look at what the BIA sees, this point is not representative of the medical bioscience industry. In partnership with Ernst & Young we have published data on the UK and European

biomedical research R&D business activity for the last few years, and the data shows that in terms of financing the UK leads Europe, and that Europe as a whole is also improving in terms of our sector. Europe experienced its best ever financing year, with total innovation capital raised of £3.9 billion, up 77% from 2013.

Baroness Neville-Jones: Are you arguing that the effect is actually positive?

Mr Steve Bates: I certainly do not think that we are seeing commercial R&D declining as a consequence of the regulatory environment. I think there are other factors to do with the business cycle and the fact that we are coming out of the banking crisis, which may be more significant than the regulatory environment, but I think what you are seeing is that the regulatory environment is not a barrier. The UK has raised almost a third of the innovation capital that is available in Europe, and perhaps the reason why the UK has the position to rival some of the big US biotech clusters is because of or despite our membership of the EU. So I think that is where we are at.

Dr David Hughes: From our point of view, I think I would differentiate one word in the question: commercial R&D in Europe, I do not think, from our point of view, has declined. We lost a big slug of people in 2004, when we shifted our GM crop research from the UK to the United States but the number of scientists that we now employ in the UK and in Europe is pretty much as it was before. What has declined though is the proportion of R&D that is aimed at developing products for use in Europe. That has declined significantly. I can tell you that anecdotally from conversations that I have been involved with in our R&D organisation. We see chemicals coming forward, for instance, which look very promising. Then the realisation is made that it would be a great product for use in northern European wheat and you can just see the energy drain out of the people involved, because you know that the hurdles in terms of commercialising such a substance are very, very difficult.

Baroness Neville-Jones: Does that mean that product development and exploitation goes elsewhere, outside Europe? You may develop the science here but the commercial exploitation goes elsewhere?

Dr David Hughes: If the European market would be the key driver, the commercial driver for a particular research project, and we realise that the hurdles are so tough, it is likely that we would focus on different research projects, aimed at developing products for use by farmers elsewhere. I have a report here which says that the proportion of global R&D aimed at crop protection for farmers in Europe went from over 30% in the early 1990s to 6% or 7% in 2013, when the report came out. So we have seen a catastrophic collapse in the amount of investment for developing technologies for use in Europe. The problem is, though, these technologies have a very long lead time; it takes 10 to 12 years sometimes to get these technologies from the bench to the market, so the fact is that people have not really noticed yet. Because the investment stopped happening back here, we have not seen the lack of products coming to the marketplace, but we will. We can see this as a big gap in terms of new products coming forward and, of course, when that gap actually hits and farmers start struggling, it will be 10 or 12 years before we can start filling that gap again. It is a very serious situation.

Baroness Neville-Jones: As regards the future, if a company, a commercial organisation, assessed that a given product was unlikely to pass the regulatory hurdles for use in Europe, would it then simply not pursue that bit of science?

Dr David Hughes: That is right.

Baroness Neville-Jones: Are such decisions being taken?

Dr David Hughes: Yes. Consider the neonicotinoids, for instance. Neonicotinoids have been banned in Europe. They are one of the most effective and safe forms of insect control chemistry that has ever been invented, and if that is now the benchmark, you have to be safer and more effective than that, no chemistry has yet been invented. If that is the height of the bar, if you like, and it is just so difficult to jump that bar, why would you bother if there were lower hurdles in big commercial markets elsewhere?

The Chairman: Could I just follow this up? Clearly, the concern that Syngenta has about the European market arises from a regulatory background in which there is much more concern in Europe about agricultural leakages into soil, air and water than there are perhaps in other countries. Does it follow from that that you might expect new technologies which are less leaky, which are more precise and better targeted, to start in Europe rather than elsewhere?

Dr David Hughes: Yes, I think there is a very good chance that that will happen, if we look for alternative technologies, but some of those alternative technologies exist. At the moment though I think it is fair to say, in terms of cost-effectiveness from the farmers' point of view, they cannot compete with the best chemistry that is currently available. Farmers would be looking at a step down in terms of efficacies, costs and profitability in order to adopt those technologies, but if those technologies are not available, then farmers will have no choice.

The Chairman: I am simply making the point—and I had better declare an interest as a farmer here—that society has a right to look at the external costs that agriculture is imposing, and if there are indeed leakages into soil, air and water from agriculture, then it is not unreasonable for the regulation to take this into account in trying to capture these external costs. Of course, that will not be the case in other parts of the world where people do not live alongside their agricultural production in the same way as we do in Europe.

Dr David Hughes: True, though you have to make sure that the regulation is proportionate. For instance, the groundwater issue that you were alluding to: the limit for any single chemical in groundwater is 0.1 parts per billion. That is a number it is very difficult to relate to but you just need to understand how low that number is. If you drank a litre of water contaminated with a chemical at that limit, one litre of water per day for the whole of your life from birth to the age of 80, your total exposure would be under 3 mg—your lifetime exposure. That limit is incredibly low, yet you have to ask what sort of consequences would actually entail if it was one part per billion, 10 times greater. Would that really be environmentally significant?

Baroness Morgan of Huyton: Is it not fair to say that your business—I do not mean your particular business but your businesses, your sector—failed from the beginning to be part of a sensible dialogue with the public? We saw it in the UK, let alone the rest of Europe, for a long time. It is not as if per se the EU regulatory regime is stopping any new technology developing. It appears to me from what I hear from both of you that, in your particular sector, it is from a historic failure at the beginning to have the correct dialogue with the public.

Dr David Hughes: Yes. I need to be a little careful what I say here, because my company was not the only company involved at the time

Baroness Morgan of Huyton: No, exactly. I am not talking about your company; I am talking about the companies which perhaps lost it for you.

Dr David Hughes: Quite. You would understand that maybe I should not comment too much on that particular question.

Q74 Lord Fox: A sigh of relief from everybody that this question does not involve the regulatory environment. It is people. Dr Hughes, in your evidence you cited the importance of free movement of people. I really want to probe that a bit and put it into context but also to set it into the context of European employment versus employment of people from outside of Europe in your European work; in other words, the balance of importance between those two groups of scientists and intellectual contributors.

Dr David Hughes: Looking at global megatrends in science at the moment, there are two big overarching megatrends. The first one is convergence, which is the blurring of scientific boundaries. The second is internationalisation. International collaboration and the physical movement of people to different locations around the world is now the norm; it is a very important trend, so anything which went against or hindered this free movement of people would seem to be a detrimental thing in terms of global science. In terms of how important employment of European nationals is, I got some statistics from our human resources people yesterday. Of the people employed at Jealott's Hill—there are about 750 scientists there—10% are non-UK EU nationals, and 5% are from further afield. So a significant proportion of our workforce is non-UK nationals.

Lord Fox: Another global trend is, of course, collaborative working without necessarily being in the same place. Do we need people to actually have to move and travel in order to contribute to your groups of researchers?

Dr David Hughes: I think you do. What you say is quite right but there is nothing like meeting people face to face to develop relationships. I mentioned earlier on the shift from a highly transactional way of collaborating to a more relationship-based way of collaborating. Nothing builds relationships like actually working with people and meeting them face to face. You can Skype or teleconference or whatever, and we do, but meeting people face to face is important.

Mr Steve Bates: Our sector is talent-based and is highly dependent on highly skilled employees at every step of the R&D and commercialisation pathway. We are a global sector. I echo the points about the different skills needed to make it successful. A lot of talent is home-grown from the UK science base, but business needs access to the best talent in the world, particularly from Europe, and any impediment to the freedom of movement of skilled employees in the EU inhibits the dynamism and success of bioscience in the UK.

Lord Maxton: We have been talking all the time about the UK but, to be honest, I come from a part of the country where, say, agriculture is not under the control of the UK. In Scotland it is the Scottish Parliament and the Scottish Executive, and they have said that they are going to ban GM crops totally in Scotland. How do you deal with that particular problem?

Dr David Hughes: You need to ask what that declaration actually meant in reality, because it is not as if any GM crops have ever been developed that could actually be used in Scotland. There is none on the horizon and nobody in their right mind would actually work on developing that.

Lord Maxton: What about fracking then?

Dr David Hughes: Okay. That is a little bit out of my area of specialisation, I am afraid.

Lord Hunt of Chesterton: Can I just comment? You have again used the word "science" in this very specific way but surely one of the points about both of your areas of expertise is that the science has to be applied in the cultural context. Surely that is one of the reasons why you have to have people from other countries, other cultures, working together. Even in weather forecasting this is very important, and how you interpret weather in different countries is part of what you have to do in a research lab. Is that not an important argument for why you have to have mobility?

Dr David Hughes: Absolutely. Quite right.

Lord Hunt of Chesterton: Science is not something you can do aculturally.

Dr David Hughes: That is right. We have over 100 R&D sites around the world. We have probably 10 big sites with 100-plus scientists working at them, everywhere from China, India, the United States, Europe, and we have to work together as integrated teams. The cultural compatibility between the scientists who are actually doing the work is a very important factor.

The Chairman: You referred earlier to the European Union presence within this country. Would you like to comment on the freedom of movement aspect of that?

Mr Steve Bates: I suppose if you look at the European Medicines Agency, which is staffed from people across the European Union, that is based here, that is providing jobs, and there is a number of service businesses that help support that through the people who do the regulatory dossiers, the people who do the intellectual property, which is part of the mix you get in London as a result of that. Those businesses depend on and need talent from across Europe and support jobs from across Europe. The flipside of this is, if the UK were to be a less attractive place for global businesses—we do not hear much these days about what was described as the UK "brain drain" back in the day—the US is still there as a very attractive proposition for scientists from the UK; Boston, Massachusetts, the Bay area are very attractive prospects and, rather than attracting in, we may see the flipside of this, which is people going out as used to be the problem.

Q75 Lord Hunt of Chesterton: We understand Syngenta is headquartered in Switzerland, and we have heard lots of very negative remarks by Swiss colleagues about what has happened to them with them leaving the EU. Nevertheless, are there advantages for companies to be in the European Economic Area, just outside Europe, and how has Syngenta's move been affected by EU sanctions imposed on Switzerland?

Dr David Hughes: This is quite a complicated question, because I am actually employed by a British company; I work for Syngenta Ltd, which is a wholly owned subsidiary of Syngenta parent company, which happens to be headquartered in Switzerland. Discussing this question among my colleagues, we came to the conclusion that it makes very little difference where our parent company is actually headquartered; it makes little operational difference, quite frankly. It is a bit of an unsatisfactory answer perhaps but it does not really matter where the headquarters are in terms of what we do in science and technology.

Lord Maxton: Is your company divided in that way because it is headquartered in Switzerland?

Dr David Hughes: No, it is not. Dividing up big, multinational corporations into smaller subsidiary organisations, often nationally focused, is quite a common thing to do. It is a very complex, byzantine, corporate structure we have, which means that when we do deals in the UK, collaborations in the UK, it is the British company actually signing the contract with partner organisations and the research councils, not a Swiss company, so in actual fact it really does not make any significant difference.

Lord Peston: I missed one point. Surely, where your headquarters are has major effects on your tax rate?

Dr David Hughes: I guess so.

Lord Peston: There is the current catastrophe over Google. If Google were situated in London, it would be paying several orders of magnitude more in tax than it does in Dublin. That is important.

Dr David Hughes: From a tax point of view, yes. I am talking from a science and technology point of view.

Lord Peston: You are talking from a science and technology point of view, and only that.

Dr David Hughes: Yes, that is the angle I am taking.

Lord Hunt of Chesterton: It is a wider question. We have a lot of companies in Britain that are owned overseas, and in many of these cases you could say the R&D strategy is defined outside. The UK has clever labs and people doing clever things, but actually, like Honda, for example, all the big decisions are taken in Japan. In the case of Syngenta, you have some clever people in Bracknell and wherever it is, but is in fact the strategy of Syngenta all defined in Switzerland?

Dr David Hughes: It is by people who are located in Switzerland but they could just as easily be located in London or Beijing or New York.

Lord Hunt of Chesterton: But the fact is therefore the strategy, the big strategic decisions, are being made outside the UK, wherever the headquarters of companies are.

Dr David Hughes: That is right, by the leadership.

Lord Hunt of Chesterton: You think that is okay, do you? If all the companies in Britain were in that way, it means we are just service providers of science and technology for strategic goals defined outside the UK.

Dr David Hughes: The important thing is the people who are making those decisions, not their physical location. I do not think that makes very much difference in any kind of practical sense.

Lord Hunt of Chesterton: Well, it is a point of view.

The Chairman: Can I move on to intellectual property rights? Lord Hunt again.

Q76 Lord Hunt of Chesterton: How will the UK's EU membership impact on the intellectual property and patent landscape in the UK? There has been some progress in the EU about patents.

Mr Steve Bates: May I say something?

Lord Hunt of Chesterton: Please do, Mr Bates.

Mr Steve Bates: Intellectual property is the life blood of our industry, and the new European unitary patent and Unified Patent Court aim to facilitate more consistent decisions in patent litigation across Europe and to reduce the costs for patentees by limiting litigation to a single forum, and that is the same whether you are a university or a company or whoever owns the rights. The signatories to the UPC agreement and participating EU member states will benefit from this, and the central division that deals with chemical and pharmaceutical patents is to be based in London. It is in progress at the moment. From our perspective, it is beneficial for the UK life science industry and illustrative of the UK's position as a global leader in life science that we have the key organisations based here. We are very concerned. We want the Government to set out clearly what the implications would be of a Brexit for the life science industry, and the logistics of how any changes for the UPC, like leaving London, a political likelihood, would be managed. That is really our take on this one. I think the UK Intellectual Property Office has a strong international reputation. Its five-year strategy, launched last week, includes a commitment to joining and shaping this EU-wide patent system, and it intends to take the lead and use our influence in Europe for this, which we think is a very good thing.

Lord Hunt of Chesterton: Can I just understand? Does that mean we have reached the stage at which you can just take out one patent for the whole of Europe, or do you still have to take out 28 patents?

Mr Steve Bates: We are in the process of developing a unitary patent. If you went to the patent court today, you would probably take out something that is nearer the former than the latter. You would probably take out patents only in the major six or seven rather than the 28. We are going to a system where you have one.

Dr David Hughes: I think I would agree with that. Again, from a practical point of view, the UK is a signatory of the European Patent Convention, which is independent of the European Union, so other signatories include Switzerland and Norway. That is driving the convenience of applying for patents across Europe at the moment, and that is independent of the UK's membership of the EU or not. We are looking very closely at the unitary patent and how that might be used. There are pros and cons but we are generally supportive, and it may well be a very useful tool for us to use in the future, but it seems independent of whether Britain belongs to the EU.

The Chairman: Thank you very much. Looking round the Committee, I think we have exhausted our questions to you. We are most grateful for the very patient way you have responded to our inquiries. There will, of course, be a transcript sent to you for any minor corrections that you feel would get the record absolutely accurate. On behalf of the Committee, I thank you both for a very informative morning. Thank you very much.