Commission on Intellectual Property Rights

CONFERENCE

"HOW INTELLECTUAL PROPERTY RIGHTS COULD WORK BETTER FOR DEVELOPING COUNTRIES AND POOR PEOPLE"

TRANSCRIPT
Session 7: Research Tools, Gene Patenting and Public-Private Partnerships

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THE ROYAL SOCIETY
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SESSION 7: Research Tools, Gene Patenting and Public-Private Partnerships

Gill Samuels: Chair, IPR Commissioner

We have four distinguished speakers this afternoon. The first speaker is Professor Sir John Sulston a very distinguished scientist here in the UK who made substantive contributions to the UK effort on sequencing the human genome. John has recently retired from the Directorship of the Sanger Centre at Cambridge. I know that from past encounters with John we can all look forward to a controversial presentation.

John Sulston: Sanger Centre

My justification for being here at all today is my experience with the human genome over the last few years. As a result I became involved with the battle to get the sequence of the human genome in the public domain, which was not straightforward, as you have read in the newspapers. In so doing, I found myself discovering things about our society that I personally hadn't realised, although I had led a very sheltered existence in my Cambridge ivory tower up until then. The social implications of what has gone on with the human genome project seem to be quite significant. As a result of that, Georgina Ferry and I wrote a book about it all called "The Common Thread" which I am showing to you because this is a more complete account of what I have to say today. As I see it, the human genome sequence and the IP around it provided a special case of what I see now as a confusion, which goes on between invention and discovery in IP Protection. The human gene is a discovery and the gene itself, the bit in grey (shows slide), is beyond patent or IP protection of any kind. As a result of the international sequencing effort it went into the public domain. It is thanks to the release of prior art of sequence, which is now obvious, that means that the sequence of the human itself is beyond patenting. That is not for want of trying on the part of others. Consider the little trails of discovery coming out of the gene. That is supposed to be in time and space and mental activity. The trails going into diagnosis are short. That is the stage we are at with human genetics right now. As soon as we have the sequence, and we have collected some variants in it in the population and compared them with people's medical conditions, we have a great ability to diagnose their prospects medically. Much further along the line and only just beginning are the long difficult trails leading to therapy, for example, and which may on the way uncover additional functions of the gene. Well, of course, the point is that the way patent law is being applied at the moment is that having the first diagnosis, for example, is giving people in practice, and in an increasing number of cases, rights to the entire gene. Instead of just having protection for their own invention, they have protection for any uses of the gene whatever. And in a case that is long running and is now hitting Europe, I need look no further that the RCA Genes and Myriad Corporation. They are trying to prevent anybody doing any other diagnostics and they have patents that they believe control the use of those genes. In business terms, this is fair game, it is not illegal, and the US Patent Office has condoned it. So what is the problem? The problem is very simple, it is extremely counter to the principles of our society to allow monopoly to be developed. You can't invent around a discovery, you can't invent around a

human gene, you can only invent competitively around somebody's use of it. I think that the way patents have been allowed to become so broad that they create monopoly of all uses is absolutely counter to progress, to good business and its counter to another matter, which is extremely important to us today. There can be disparities in the spending on healthcare in excess of two orders of magnitude, probably three orders of magnitude, you see (shows slide) I have not taken by any means the poorest country, I have taken India which is a good mixed society. If someone ring fences the gene and starts to charge fees for the use in diagnosis, a fee which makes it totally acceptable in the richer societies is completely prohibitive in poor societies. So we have a real practical problem of prevention of delivery of a medical good to the patients who need it. It doesn't have to be limited to patenting. You can achieve the same results by proprietary databases and by restricting access. Some say this is very simplistic talking that one must have a ring fence around the gene to motivate discovery and allow it, well I think that is nonsense. I think the more competition the better. We are also told that you need to ring fence the gene to raise money. There are two problems with that. I think it is well documented now that the cost of actually researching and developing a drug is greatly exaggerated, but of course it is still very substantial. Just as important is the fact that profit motive does not help us in delivering cures for diseases that affect mainly poorer countries because they are unprofitable. That is really irrelevant and far more important that we are restricting research by allowing the sort of broad patenting. In practice what needs to be done, in my opinion, is to narrow the patents to the actual application which is at hand and which the patentee has some ability to cope with immediately. They have to get on with it. I think we have to renegotiate the TRIPS Agreement, which is enforcing an inequitable patent law in this grossly imbalanced world wealth situation and I think we need to balance legal representation so that countries are fairly represented and are not steamrollered by large teams of lawyers from richer countries. We need not only to think about discoveries and research, but we need to spread infrastructure and technology throughout the world. It is no good having PPPs, good as they may be, if all their operation is in the richer countries. You have got to spread technology; otherwise you will not produce a sustainable development of the situation. This is not intended to be in any way controversial or antagonistic, but I do think we cannot use corporate responsibility as a way forward in this. The job of companies is to make money. If they are not profitable and don't make as much money as they can they wont survive, so you have to have regulations, there has to be a democratic process on top of the profit motive which will lead us to these good effects. I would pray to the Commission that its job is to create a better world and if it can take some steps in that direction I will thank it very much indeed.

Gill Samuels

Moving on the Professor Joseph Straus to cover some of the legal aspects of these issues. Professor Straus is Professor at Law at the University of Munich and Director of the Max Planck Institute for Foreign and International Patent Copyright and Competition Law. He has a distinguished career and has consulted with a number of organisations, including OECD, WIPO, UNCTAD, The European Commission, The World Bank etc.

Joseph Straus: Max Planck Institute

I want to talk today about is a different view on whether a DNA sequence or gene is a discovery or an invention. What is the deplored TRIPS situation, deplored by Sir John, what is the manoeuvring space under the TRIPS Agreement and also to try to be a little bit in the real world without being a shareholder, inventor or a practicing lawyer. Genes, as you have heard, are discoveries but, of course, we have to bear in mind that genes on the one hand are biochemical substances because they are ordered sequences of nuclear types located on a particular chromosome. On the other hand, this is maybe something special, they have very valuable information and, therefore, they can be used in different way. Under the case law of developed countries, the disclosure of a gene sequence cannot be patented as such, because it is a discovery that cannot be patented. However, it is an established practice of all, lets say, patent offices and also court case law in the US, Europe, Japan etc that also a DNA sequence can be viewed as an invention if it is a disclosure combined with teaching how to produce that sequence, which means how to isolate it from the human or plant or other bodies and how to use it. In other words, if you indicate the how to isolate it and what the function of that product is, then we are dealing, traditionally speaking, with an invention. However, the question what is patentable does not really mean that the product as such, even if combined with this information, should always be viewed a something patentable. The question in my view, and this is shared by some people in the meantime, is where is the invention? Is the invention only the teaching of how to produce and to use that sequence or is it only linked to the new use of that sequence? The invention should meet all the patentability criteria and if the discovery, or lets say finding of the sequence as such, is a trivial matter and the only inventive step lays with the use then, in my opinion, the use should be included into the claim and that would automatically narrow the scope of protection, not leading to the monopoly or the exclusive right mentioned by Sir John. However, we will always also have cases where, despite all the recent developments in science and technology, the identifying of the open reading frame may be something linked to the inventive step. It is quite clear that under the TRIPS Agreement all inventions in all fields of technology have to be patented and there is no possibility of discrimination. On the other hand, the TRIPS Agreement allows a number of exclusions. First, those which are necessary to prevent commercial exploitation and would violate human, plant or animal health and environment. However, this possibility of exclusion is linked to the proviso that commercialisation of such inventions may not be allowed in a particular country. Further exclusions are possible to, diagnostics, therapeutic and surgical matters for the treatment of humans or animals are at stake but also plants and animals as well as essential biological processes may be excluded under this particular TRIPS provision. Mandatory eligibility for patent protection must be micro organisms in general, non-biological and microbiological processes which leads under certain conditions also to the situation where even plants and animals as direct products of a process have to be patented. With regard to manoeuvring space, one should always try to change international conventions, which is a very cumbersome and very ambitious goal. Try to use all the possibilities which exist under the specific treaty and under the TRIPS Agreement there is no doubt that the research exemption covering research for further improvement and developments, also clinical trials of all kinds if you take into the account the US or Japan situation, case law or statutory law and irrespective of

the fact that those results will be used for commercial purposes. It is also possible to cover, at least for the academic area, the use of these inventions as research tools. Compulsory and dependency compulsory licenses are available. They are also available for plant breeders. The best example is the European Biotech Directive, which provides for such a possibility. Also, saying that that would directly affect farmers is not a correct statement. If you take the European Biotech Directive we have A Farmers' Privilege under that directive which is shaped exactly the same way as under the Plant Breeders' Rights scheme. What is expected from patents from my understanding and of the entire DNA technology? Providing incentives for local R&D activities, securing optimal use of local genetic resources as far as available, including fair share of proceeds from their exploitation, attracting foreign investment in such local activities, satisfying special local needs for drugs, nutrition, plant and animal breeding which may be due to soil or climate conditions and one should not disregard the fact that each country should try to be part of the global market which means securing participation in that global market. I am absolutely sure that the lessons from the past where there was no protection, where copying was allowed, for instance India or Latin America, plant breeding, etc. nobody took the possible advantages of that. What is needed is a balanced system exploring the full range of available exceptions under the TRIPS Agreement and adapted to local needs. Excluding any kind of live material or substances already existing as provided in Article 6 of the decision 344 of the Indian Pact is doubtful under the TRIPS Agreement. But disregard TRIPS. I really don't believe that this is a recipe for success, neither for indigenous local activities nor to attracting foreign investment. Access and benefit sharing legislation under the CBD should really take into account the interests of host countries in mid and long-term, which means having realistic barriers and requirements. Benefit sharing means not only royalties but also building up local R&D resources, including manpower and, as a lawyer, nothing whatever irrespective of what Sir John has said, negotiate the best possible contracts, engage the best lawyers and try to educate not only scientists but also lawyers in the country.

Gill Samuels

This morning there were several references to public private partnerships and I am pleased to introduce to you Dr Roy Widdus who has made an extensive study of PPPs. He is the project manager at the Initiative for Public Private Partnerships for Health in the Global Forum for Health Research in Geneva.

Roy Widdus: Initiative for PPPs for Health in the Global Forum for Health Research

By the definition that our group uses, Public Private Partnerships for Health are somewhat experimental ways of combining the different resources of public governmental and private sectors whether the private sector be for profit or not for profit. They combine these resources in complementary new ways to tackle problems that have remained intractable when subjected to separate action. I will only deal with one group of PPPs, which is for product development. I think that PPPs, as you will see from the categorisation, are active in other areas and can contribute to reducing health in equities. Where they are appropriate, done properly

and sustainable I think PPPs can be win win for both public health and for business, but I do not think they are a panacea. I certainly do not think that the creation of PPPs in any way removes the responsibility of governments in both rich and poor countries to ensure that health systems are in place. The term “developing countries” is used often. It does constitute probably 90% of the global population. That it constitutes a huge economic spectrum from the failed states, which essentially have no economy to low income countries as The World Bank calls them, low middle income countries, upper middle income countries, economies in transition. Additionally, the largest poor countries have sizeable rich population and the richest countries have sizeable poor populations. So the issue of access to medicines goes across all of these. There are a number of institutions that fund research and development that have a shared social goal, which is equal access to the fruits of research and development for those disadvantaged by poverty. Public agencies in the richest countries and in the lower middle-income countries philanthropy PPPs. Many of these groups share similar goals and they face somewhat similar but not identical issues in the management of IP. Product Development Public Private Partnerships operate in a part of the research and development delivery continuum in which the public sector has very limited skills. If you look at this continuum as research development application for marketing approval, manufacturing and utilisation, the public sector is almost completely deficient in skills, true product development and manufacturing. What Product Development PPPs attempt to do is bring together the skills of the public and private sectors towards the social goal of having products for neglected diseases, and for the other PPPs that are concerned with their delivery, getting them to the people that need them. For this reason, because of the way they operate, many of the Product Development Partnerships tend to call themselves virtual not for profit pharmaceutical companies. They tend to operate on a shoestring and you would be surprised at the small size of some of them. When one looks at where PPPs exist, you can see a whole range of categories in which different PPPs exist. There are a couple of PPPs that are particularly looking at generating basic knowledge around the Genomes SNP Consortium. One of the interesting things happening there is that they are protecting the IP so it will be available for wide use and so that its exploitation cannot be cornered by other groups. The group I am going to deal with is the category of Public Private Partnerships that are interested in developing products. There are PPPs focusing on drugs, vaccines, diagnostics, contraceptives, device and equipment and I suspect if we do a little more digging there will be ones that deal with effective control agents to drugs, medicines for malaria, the Global Alliance for TB Drug Development, activities for leichmoniasis and conpenosoniasis drugs. The Mechdisan Donation from Merck actually began as a public private collaboration in the research area for vaccines and the best-known one is the International AIDS Vaccine Initiative. There is a Malaria Vaccine Initiative at PATH, the Hookworm Vaccine Initiative with the Saban Institute, a Leichmoniasis Vaccine Initiative with a Not-for Profit called IDRI, one for meningitis and there is a proposal out there for one for lassa fever and many more. There are good examples in all of these areas. One of the things that they are often doing is designing the products that they are working on for use in resource poor settings. Many different ways in these PPPs can create an operating base (shows slide) depending on where the solid line, is you have a different set of controls over the operations. The goal of Product Development PPPs essentially can be summarised as the development and, to the extent that they can influence it, the accessibility of products for which there is

limited or no commercial incentive to conduct R&D. I tend to believe that patents are not a motivation for research and development. I think that revenues and the security of revenues are the real motivation for R&D. Even industry in lower middle-income countries tends to ignore diseases for which there are no potential revenues. It isn't as though we can look to the pharmaceutical industry in developing countries necessarily to put these products for neglected diseases at the top of their spectrum of priorities. The goal is a social goal but to achieve that goal PPPs have to manage IP. They may be given IP assets, they may need to access assets and particular technologies in order to achieve the goal. They make R&D investments that lead to IP. Some may be patentable others may be a package of very well documented information that can be used for an irregular application. They need to leverage both the IP they have and the investments they make for their social goal. There has been a shift over the last decade in the way in which people who have a public interest in the health area have been managing their interactions with commercial entities. Typically they didn't bother much with managing IP, they were not very explicit in their agreements if they gave out a research grant. They said that they wanted a reasonable price for the purchase by the public sector, not defining which countries they wanted that price for, not trying to nail down milestones to get there. Needing social goals under the old paradigm often meant leaving the decisions to industry. Many times those decisions worked out favourably, many more times I think they didn't because of lack of diligence by the people that were funding R&D from the public sector or the philanthropy side. There is a new paradigm coming up, much more intensive management by these PPPs of their IP assets. They want to leverage their own investments and they are specifying expectations of industry. There are fundamentally two things that PPPs want to achieve. One is that if commercial interest in a product falters, they want to be able to continue to develop it for the markets and for the diseases that they are interested in. This may mean segmenting markets, it may mean discussing the indications for which the PPP can continue the development. As you get further down the pipeline, partnerships are interested in achieving a low-priced sustainable supply of a product. I mention sustainable because the lowest price is not necessarily sustainable. If you make the market unattractive people may eventually leave it, even if they are generic producers, if there isn't any profit there whatsoever. We have commissioned a study bringing together, we hope, all of the expertise and experience in negotiating social goals within contracting agreements. The assumption that all of these public private partnerships are making is that they want to use the existing system. I have not heard from any of them a desire to ignore the system and not protect what they are doing. I have not heard from any of them a desire for massive change in the system. Maybe they would like the transaction costs to be a bit lower, but they recognise that they have to use the system. Our goal is to finish this by the Summer 2002. There are three challenges for PD PPPs and other 'public interest' funders of R&D. There is essentially a lack of capacity in the public sector and in PPPs to manage IP in a really professional way. That is often coupled with an under valuation of that expertise so that people are really not willing to do it professionally. There is also relative paucity of examples that they can use as models for negotiating these social contracts. We are trying to pull that together. The third challenge is to make sure that if they develop products successfully someone is going to pay, whether they are produced in the private sector or whether they are produced in public sector manufacturing plants all of these products will have a price

and the willingness to pay in the global health system, at the moment, for products and their delivery is far below what it should be.

Gill Samuels

Thank you for that comprehensive overview of the PPPs. I think that your presentation illustrates some of the challenges. It also in part answers a question this morning about whether we should address medicines for neglected diseases or vaccines for neglected diseases. It is clear that both approaches are important. They are important because you cannot guarantee the success of any R&D programme that you start. The scientific and technical challenges are huge in many of these areas. It is not just whether the funding is available, not just whether IP can be sorted out, the scientific and technical challenges are huge and so I am pleased to welcome Greg Galloway who will take us through one of the very specific examples of these PPPs. Greg is a founder and President of Falco-Archer Inc, which is a consultancy specialising in working with companies and private research institutions to identify, manage and extract the value from IPs

Greg Galloway: Falco-Archer Inc.

Thank you for this opportunity to speak today. I am here representing two parties. One my company Falco-Archer, a consultancy in IP management and also one of our most favourite clients, The Programme for Appropriate Technology in Health and specifically one of their programmes, the Malaria Vaccine Initiative. **tape change ….** and what I am hoping is to convey what we have found in terms of IP issues as they impact on the development of vaccines for developing countries and also I hope to answer the question "help or hindrance" and I will answer this right now. The answer is neither, the answer is both and it is very much contextual and depends very much on the situation. I want to tell you a little bit about the Malaria Vaccine Initiative, also the importance and impact of patents to MVI as an enabler of product development in the vaccine arena and also to tell you specifically about some results of a patent assessment that we did on one malarial antigen, the antigen being that protein particle that tells your body to create an immune response to a disease and then offer up some recommendations for the Commission to consider.

The MVI's mission is here and I will let you read that. I just want to emphasise two points. One is to accelerate the development on malaria vaccines and ensure their availability and accessibility for the developing world. There are development issues that MVI face. First of all, there is a significant amount of malaria vaccine research, the R, but there has been historically very little industry involvement, the D. You can imagine why. Yet the fact of the matter is over three people per minute die, many of them children, from malaria. There is clearly a need for speed and the people involved in the project are very impatient. A couple of development aims. MVI uses an industrial development model. This is very much in line with what Roy Widdus was talking about, seeking to catalysed "D" or development by identifying the most promising candidate technologies, orchestrating resources and partners, providing funding in particular, in this case, for clinical trials, proof of concept testing in order to span the gap from research laboratory into full scale product development and

generally increasing the net present value of projects to tip the balance in favour of delivery. This organisation faces a number of complexities along this development pathway. First and foremost, technically there are a number of complexities, which must be faced. First of all the antigen or, as it turns out, combinations thereof. This slide illustrates the various lifecycle stages of malaria and surrounding that lifecycle stage are various antigens, which are known about today. If you are interested in catalysing the development of a malarial vaccine, you need to be not only familiar with this but you need to be prepared to throw your weight behind one or more of these antigens and, in fact, its key when I say more because the chances are a successful malarial vaccine will utilise more than just one of these antigens. I have highlighted MSP1 because that is our target for discussion today. In addition to complexities with respect to antigens and combinations thereof, there are additional complexities having to do with platform technologies, for example antigens, and also production technologies. All of the various different players also alluded to this, be it active missions, governmental agencies, most certainly industry, local contacts in particular those involved in clinical testing and their different missions and also locals. MVI has contacts with partners in every continent on the globe. Finally, the complexity of dealing with economics. As you can imagine, with all these different antigens, productions technologies etc, anybody who gets into this area is going to be required to take out multiple licenses. Whenever we have multiple licenses, then we have what is called “royalty stacking”, so this is a complexity where everybody wants 10% of net sales but you end up with 6 licenses. This is a problem. Then we have the complexities associated with IP, in particular patents. Patent coverage does, we have found, tend to be important to those involved or potentially involved in this process even if patents don’t extend into developing countries. I have a couple of suggestions as to why this is. One is that malaria, probably fortunately, may very well be a duel market product, in other words, a market in the developed as well as the developing countries. So IP, although we see it is primarily focused in the developed countries is still of interest to players considering developing a vaccine for developing applications. There are a couple of other reasons for this also. With all these different technological pieces it is highly likely that you may have production of an antigen or platform technology taking place in one location under certain IP and production of an antigen taking place in another location and a combination taking place in a different geographic location. So patent coverage in this particular project appears to be very important. MVI is an enabler, it is an investor, its risk as an investor is minimised and, in fact, outcomes may be improved if the value from the exclusionary facts of patents is identifiable and managed well and if supported products and technologies have reasonable freedom to practice. By that I mean MVI doesn’t want to make an investment in a malaria vaccine then two years down the road someone comes along and files an infringement claim. One of the ways that we deal with these complexities is by a process called patent mapping. In essence we want to establish the value of patents and the freedom to practice risk for any product or technology. We want to answer questions such as who owns IPRs in this area, when were they developed, where are they restricted to, what might the scope of claims be in the relationships between the different parties. As a case in point, MVI asked us to prepare a patent out for the particular MSP1 antigen because it does appear to be technically preferred, at least on a par with some other antigens, and very important to the overall success of this project. When we started looking at patents covering MSP1, the first thing we found was that there were about 34, this later became 39, patent families describing and claiming the antigen, processing

fragments, constructed DNA, production methods, delivery etc. all of this developing over about a 15 year period. We were really surprised to find this. Relatively speaking, this is a fairly large number, but it gets better. This was actually the first map (shows slide) that we generated which shows each of these 34 patent families and you will notice that the lines between them in many cases have a notation related with a question mark. We could not determine from the patent literature and from reviewing many of these patents whether or not they were in fact MSP1 and, if they were related to one another, how to actually categorise them. This is what anybody developing a malarial vaccine using MSP1 will see at first. Interestingly, we have patent families with conflicting claims, this is also known as double patenting we suspect, we have little IP heritage, in other words patents don't tend to site backwards and forwards to one another, they tend to exist only in isolation and there are a lot of qualitative questions about scope and enforceability. This is a very critical business related issue. A very large number of patents have become extinct which is unusual and yet at the same time a number of new landforms, new patents coming and also we noticed a great deal of diffuse nomenclature. There was very little use of the term MSP1, especially early on. This necessitated that we had to do things by sequence alignments in order to figure out whether or not various technologies were MSP1. We were also able to identify that there are foundational patent families and there are, in fact, categories for the others. (Shows slide) - We ended up with five foundational patent families, a whole collection of add-ons, which are to use Professor Sulston's figure or all of these other technologies emanating out from the centre. There were some production related technologies and then informational and then probably unrelated to MSP1. We have this map now, so now we can take any MSP1 related technology and overlay it on this and be able to determine very quickly where the relevant patent rights lie. Regarding key learnings, this kind of very highly complex patent landscape tends to dissuade companies, in particular cases where alternate antigens may exist. It also slows access to enabling technologies. It certainly adds cost and extends lead times. You can imagine the amount of time it would take to negotiate all these various licenses. There is also something of a "tragedy of the commons" corollary where we have everybody patenting in the MSP1 area without any knowledge of what anyone else is doing and what that does is tend to disrupt the landscape rather than create a comprehensive whole. Viewed as a whole, this is very specific to vaccine technologies and probably MSP1 in particular. A great deal of value is probably placed upon platform technologies and much less value placed upon antigens. A couple of key recommendations, which came out of this. We are hoping that these kinds of mapping projects can be completed and widely disseminated to enable development and keep the way clear. Informed patent applicants and entrants into the landscape need to know that these complexities exist so that they don't add to them. We are also very interested in the possibility of shared, dynamic knowledge bases. Here we might rely upon the expertise of organisations such as the European Patent Office. We suggest that public institutions who are using our money to create for the greater good have a unique duty to be informed about these landscapes to orchestrate a little bit better to manage and license wisely. For example, retaining field of use restrictions for developing countries. In some cases, organisation enablers like PATH may have to end up bearing the burden of these kinds of analyses.

Gill Samuels

The afternoon's presentations clearly illustrate that there are also challenges at the discovery end of the business, when you want to deliver new agents, which are clinically useful, particularly for infectious diseases.

Milton Lore: University of London

I was wondering if there was any need, at this point in time, to flag up to the Commission the possibilities that various schools thought have raised in the past about protection of biotech material using copyright where gene sequences could be treated as either literary or artistic work and whether this has any implications for the use of biotech material by poor people or people in developing countries with regard to applications in health and agriculture.

Helena Paul: No Patents on Life Coalition

I wanted to flag up the business of Human Genome Sciences and the gene, which is called CCR5, the receptor. The company, Human Genome Sciences, obtained a patent on this without actually describing the future use which was then discovered to be an AIDS receptor, an AIDS virus entry point, and HGS then said that they had received a patent on the AIDS virus entry point and their stock rose enormously. The fact was that the scientists who found and isolated the protein and then isolated the gene lost out completely on this and obviously there are huge implications for the cost of future drugs. Human Genome Sciences dominates this whole area and the scientists have basically worked for the company without actually working for the company.

Sandeep Shah: SSL International plc

Regarding the calls for reducing patent life to less than 20 years, I think we heard a suggestion that it should go down to 10 years. That is a bit naïve if you take into account that many patents are actually filed at a pre clinical stage and when one considers the three major diseases effecting human kind, TB, malaria and HIV many of the clinical studies are beginning to take at least 5 to 7 years to complete. If you take into account the formulation work and modifications etc that need to go on and the regulatory process itself, you will find that ten years will elapse automatically from most patent filings before you can actually get in commercial value.

Joseph Straus

Regarding gene patenting, I would say the Commission or the practice should consider this possibility because by attaching the attention to what is the invention, that could be reached without any statutory changes. If the patent offices and the courts would accept that, for instance, in Germany judges see it quite the same way, then the Commission could consider that but whether to say anything specific on that I'm not sure. The second question was about copyright and whether this would help developing countries. I'm sure you are aware that there have been a number of attempts to advertise the possibility to have copyright protection on DNA sequences.

So far this has never been really convincing for a quite relatively simple reason that patents don't really provide for a blocking right even if they are linked only to a use, but also the so-called independent inventors of such use would be blocked by a patent and those who are investing in R&D and this is the difference with the copyright community, although they claim that they do the same but there is a considerable difference between the two. I don't believe that that would be a solution and especially would not attract local R&D activities. The problem is that the critics of the patents in this area they have the CCR5 example and, of course, in the area of diagnostics the BRCA 1 and 2. In the case of CCR5, in my opinion, if it was really difficult and the information put at the disposal of the scientific community was really very valuable, then even dependency would have to be accepted because otherwise those second two inventors who found out that this is a receptor in the HIV area wouldn't have that information. In my opinion, if it had been trivial then, of course, that would be an unrelated use and shouldn't be covered by that patent. Depending on the state of the art, you may not have black and white answers.

Hannah Kettler: Institute for Global Health

I would like to comment on the PPP initiative**.** Roy Widdus pointed out that they are an experiment, they are new and not the final solution. I just want to emphasise to the people who are participating in them now and need to make a sustainable commitment that just their mere existence doesn't mean the problem is solved. Funding is essential and if these don't succeed, and at the moment there are a mere 3 or 4 products per PPP which isn't anything when you think we had none before, but its not a complete pipeline when you think that success rates are 25% of products that make it into humans and most of these products are still in the pre clinical stage. So I think continued work on both fund development and exploration of different ways to engage industry and the other partners in these PPPs and other initiatives are essential and patients is needed, not just impatience.

Ruchi Tripathi: ActionAid

I was happy to hear a little bit about the difference between discovery and innovation but I am still confused, especially if the mere act of isolation of a gene could be classified as an inventions. I would like your comment on that. This session was looking at both agriculture and drugs and looking at gene patenting for agricultural purposes in addition to pharmaceuticals. The whole agricultural aspect was a bit missing and I would like more comments on that, especially as the TRIPS Agreement says that all developing countries, all WTO member states must patent micro organisms and microbiological processes and Professor Straus mentioned biotech plants and animals and what would the implications of that be for developing countries because we already see litigations and farmers in North America being sued. Once bio safety guidelines are in place in many developing countries we will see biotech patents. It would be useful to know the implications of that for developing countries. The biotech firms and the pharmaceutical companies who often are the same but in the pharmaceutical field in the sessions before we heard that they would like the generic drug companies to get prior informed consent before copying the drugs. When you take the biotech firms they often copy from the farmers and

developing country governments have been talking about prior informed consent and disclosure for a long time and they disconnect between the two, whereas the drug companies copy and drug companies do not want generic companies to copy, they want prior informed consent. Biotech companies don't do the same.

Christopher May: University of the West of England

A brief comment on Professor Straus' paper. I found most of it interesting and useful but was struck by this slightly surreal nature of his final conclusion. The US Patent and Trademark Office has great difficulty in retaining highly skilled and clever lawyers because they are quickly poached by those companies that are seeking to negotiate patents and, in fact, the USPTO has a great problem in litigation because of that. If they cannot maintain a group of good and skilful lawyers what possible chance have the poorest states got in maintaining those lawyers, being that they cannot even offer them the wages that the rather badly funded USPTO can offer them. It seems to me that any settlement that is required to litigate its way to a solution is not really a very good idea. We really need to be looking at the political issues of resettling what needs to be done.

Joseph Straus

The American example is not a good example. I emphasised that under the TRIPS Agreement farmers' privilege is allowed, therefore it is not a necessity to follow the US law. In the second question about plants and animals, I shouldn't be misunderstood. It is quite clear, only as direct products of patentable processes, not in general. There is no obligation under the TRIPS Agreement, but if there is a process and you are using it and plants and animal are, this is not an essentially biological process. Now the question about the USPTO, of course, it is a very difficult issue. Less financially wealthy companies of scientists from time to time discover some good lawyer and can solve the problem. The other problem, if you change the system you have to be sure the system would work and it is essential that you don't kill the goose that is laying the eggs. You have to ensure that the innovation is in place, because without that innovation there is no point talking about compulsory licensing etc. This is, maybe, a bigger problem than to finding a good lawyer.

Helen Wallace: GeneWatch UK

What is going to happen when we start looking at needing to use several different genes or obtaining information about different genes in producing new treatments, as it is almost certainly going to be the case in developing new vaccines for things like HIV or to tackle complex diseases like heart disease and cancer, the biggest killers. It seems to me that will exacerbate the problems of getting stuck with multiple licenses and patents. The other issue is companies getting stuck at the diagnostic patenting stage and further innovation can be stifled. That has another implication for inequalities of health around the world. We are already seeing some companies talking about essentially expanding the drug market to the healthy ill, those people with the wrong genes with the genetic predisposition to illness and it seems to me

that is going to exacerbated the discrepancies where your market is actually becoming healthy people in rich countries even before it becomes ill people in poor ones. My question is how are we really going to encourage investment in health products that actually reach poor people. That question that has come up all day and it seems to me that we are slightly side stepping it by simply discussing TRIPS and perhaps not looking at other mechanisms in enough detail to see how we can make that happen.

Salem Mezhoud: United Nations Association

Professor Straus' injunction to train more lawyers and the remark made by Daniel Alexander that there are many lawyers in the panel and in this room. It reminded of a certain passage in Henry IV or V regarding lawyers. I shall refrain from quoting it because there is a lack of safety in numbers, so I wont push my luck. As a human rights practitioner, when I hear or see the word "rights" lights start flashing, so I was very happy when I heard Sisule Musungu bring a certain focus to the discussion by mentioning the Universal Declaration of Human Rights and mentioning the agreement between the US and UK, for instance, rejecting economic, social and cultural rights as human rights. Fortunately, we've gone a long way from that and we are in the third generation and we are talking about collective endeavours to create the conditions for the enjoyment of human rights. That includes the right to development and, therefore, the rights to education and health etc. I will come back to my question later.

John Sulston

Regarding the question about multiple gene patents, of course, you understand I gave the mildest form of my own philosophy, which did allow some patenting, and I absolutely see the point. In the workshop, we were hearing the horror story of trying to get golden rice through the whole business. There is a reverse thing, the narrowing of patents can lead to tangled landscapes. I feel that having multiple narrow patents is probably safer than having one big one in one pair of hands that can negotiate for anything it wants. I feel that if we do push down the root of discoveries being free of all this and really being pushed down there then we shall avoid the problem to a very large extent. What will be happening then is that we shall be negotiating the dreaded process patents that nobody wants if they are in the business of trying to secure intellectual real estate, but where the thing should end up because it really comes back to my point. Invention more or less equals process patents, it is how to do things, not an exclusive and not a monopoly that you have. I agree with the comment and feel it is an added region for trying to push international law towards not allowing discovery at all as a reason for protection.

Greg Galloway

We know based on experience that whenever you have these landscapes with multiple patents that you will inherently run into various complexities. It is worth keeping in mind that sometimes, surprisingly, it is not the big original patents that

truly have the most value, sometimes it is the smaller, more recent patents that commercially have more value. So I am a bit hesitant if we talk about simply limiting the breadth of patents. I think maybe its more constructive to try to do things to keep the landscape as clear as possible for development to occur and be a bit cautious about blanket initiatives like that,

Roy Widdus

Many of the diseases that PPPs are tackling are still unpredictable science and very difficult science and often-expensive science. Malaria, TB and HIV vaccines will all have to be proven not in animal models but in clinical trials in humans and this tends to be expensive. It is very difficult to predict which patents will have commercial value or will be controlling. I have done previous studies of the patent map of acellular pertussis vaccines of which there are three or four different products. There are literally thousands of patents on different things but there are only three or four that are controlling or commercially valuable and there is some cross licensing of these and there are even some public domain products with acellular vaccines. To respond to Chris May's question about human resources, there are a number of activities being planned at the moment to try and improve the access of developing country governments' institutions and those working in the public interest to IP management resources. Finally in response to the question on how do we increase public investment in R&D for diseases that are prevalent amongst the poor. It is a general misperception that there are literally thousands of diseases that only occur in poor populations. The vast majority of diseases and health conditions in the world that we need medications for occur predominantly in both the rich and the poor. The difference between the rich and the poor at the moment relates to infectious diseases and for a vast majority of premature deaths there are products that already exist that could be put to more use. There is an issue of getting out what we have and getting it used properly. Then there is a manageable problem of developing products for maybe 100 or so diseases that occur uniquely in developing country populations. We can either incentivise the existing system that is capable of developing products by making sure that for these diseases there will be some return on investment, and facilitate the process by then applying that expertise to product development for those neglected diseases, which I think is the most efficient way or we can try to replicate in the public sector with enormous investments and no certainty of success the type of experience and expertise that exists now in the private sector. The most intelligent use of resources is to facilitate the application of the current expertise in the private sector to those diseases by making sure that there is some commercial incentive there in the end. I think if you want to replicate institutions that spend hundreds of millions of dollars every year on R&D and you want to create a whole set of that expertise through public sector investment when that expertise exists and is willing to apply itself if its even minimally motivated if you want to go the public sector only route you are going to be making a bad investment.

Joseph Straus

I usually justify my presentation by saying in front of scientists that sooner or later they come to see the lawyers and, therefore, I think it would not solve the problem if

you follow the advice from the UK. I would like to emphasise that whatever has been said about the royalty stacking and the multiplicity of patents and the things you have found around the malaria antigen, it is quite clear that there is a dissemination of knowledge by disclosure in patents and also in the case of the golden rice, they wouldn't be able to do it without all the information they obtain from others. To say this is a moral claim we have to do it, the others also have a moral claim because they delivered the information, which they needed in order to succeed. This has to be taken into account. There is not only ethics for one party or the other. The ethics are with everyone and that should not be overlooked. The second point is also in the area of patents. The timeframe should be taken into account. What was invented yesterday is not invented today. It takes 4 years for the first billion, 1 year for the second billion then 10% per month of your sequences. That makes clear that many things will not be patented tomorrow as it was in the past. The last remark is in the context public/private. Who is the public? I am the public. I am financing the research in Germany you are financing the research in the UK. To make the claim internationally that this has to be disseminated to everybody. It is a courageous claim. And take the mono cloners, this is a nasty example in this country, but it is an example of losing hundreds of millions of pounds or dollars, and was financed by the British taxpayer, not the Americans, not the South Americans, not the Indians.

John Sulston

There is one thing we have missed out. I should say we don't disagree that much, I think we do have the same aims. The question is how. One thing we have skipped over, especially the TRIPS Agreement, is the question of lawyers and how important they are, unfortunately. What has gone wrong with TRIPS is not the lack of safeguards but the ability to implement the safeguards by having balanced legal representation. This has come up several times in various forms. The USPTO, for example, was mentioned as not having sufficient access to lawyers, so I think it is fine to have lawyers but they do have to balance on both sides because they are good debaters and the more they are paid the better they are. You have to make sure that everybody has plenty of them.

Gill Samuels

On that flag for lawyers from a scientist I will end Session 7 and thank the excellent panel.