

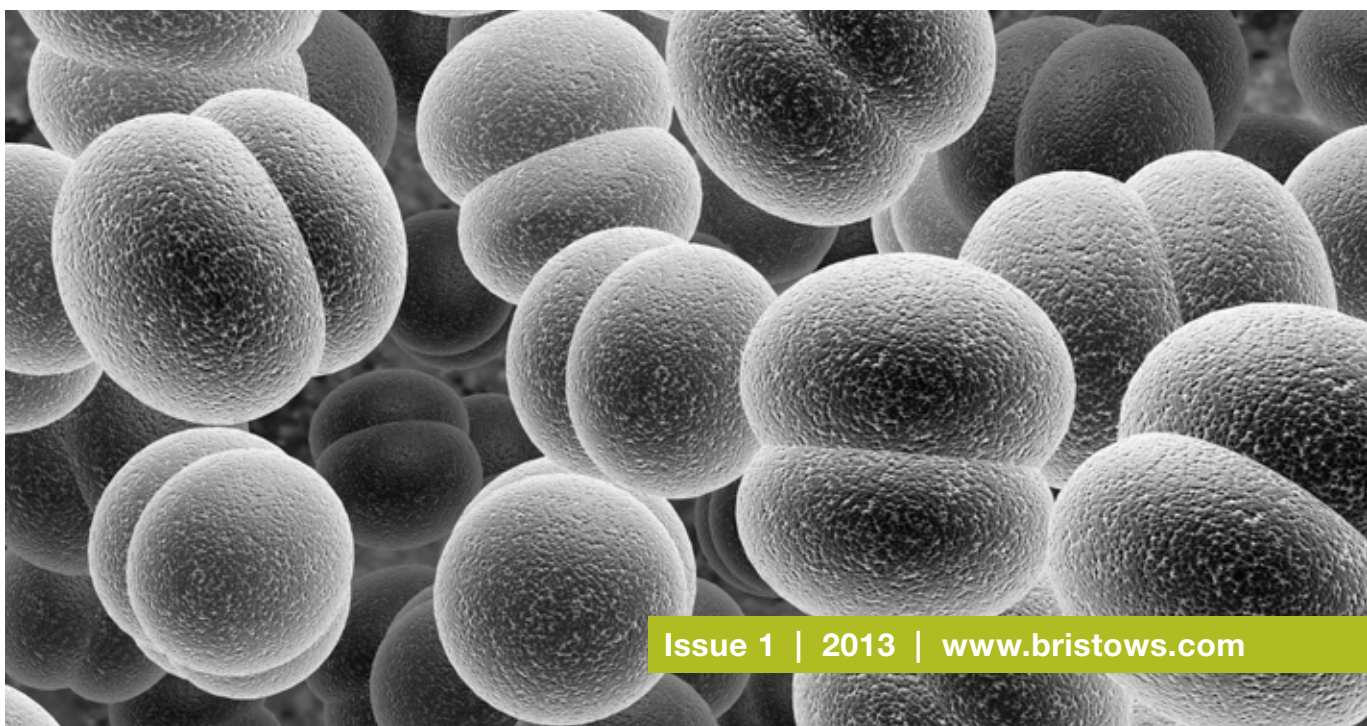
BIOTEC



REVIEW

BRISTOWS

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Introduction



Dr Robert Burrows
Partner
Bristows LLP

Robert is a Partner in Bristows' Intellectual Property Department. He has considerable experience of advising on patent litigation matters in the UK, particularly for clients within the life sciences sector.

A number of the cases he has managed in recent years have required the coordination of parallel proceedings in multiple jurisdictions within Europe and elsewhere in the world in order to ensure that consistent and optimal arguments have been deployed in all jurisdictions. The national and international cases with which he has been involved have required, *inter alia*, preparation for and attendance at preliminary injunction and main action proceedings in numerous countries within Europe and attendance at inspections of pharmaceutical manufacturing processes in India and Japan.

In addition to his litigation experience, Robert regularly assists clients with freedom to operate advice. Robert has a PhD in molecular genetics and has worked for a company specialising in DNA sequencing products.

Welcome to Bristows' first ever Biotech Review, a new publication designed to provide you with an update on what we consider to be some of the key developments in this area in recent times. From antibodies and the patentability of human genes to the transparency of data in clinical trials, we take a look at the issues critical to those in the biotech industry. As you will see, we have divided up the articles in this review by legal practice area. In contrast with a lawyer's love for detail, we have also attempted to keep the articles as concise as possible. Should you therefore like to receive more information on any of the topics discussed, or any other points of interest to you, please do not hesitate to contact us. Any other feedback you have on the publication would also be appreciated very much.

As well as thanking you for taking the time to read this Review, I would also like to thank all those who have contributed to its production, including the contributions from two of our clients: Brian Horsburgh of Blue Yonder Group, and Dianna DeVore of Ariosa Diagnostics who was kind enough to participate in the Q&A piece featured at the end of the Review.

For those wishing to learn more about the Unified Patent Court and the impact it could have on your business, please note that, in addition to our main website at www.bristows.com, we also have a separate site at www.bristowsupc.com which is dedicated to the UPC. Amongst other features, the site contains copies of, and commentary on, the relevant legislation, latest news and a helpful Q&A section.

Patent litigation

Our patent litigation practice

The majority of Bristows' IP lawyers have scientific and technology backgrounds, including physics, chemistry, biotechnology, electronics, engineering and material sciences. We actively recruit trainees who are First Class, and even PhD level, scientists from leading research institutions. This means that whatever the technology on which a client has built its business, Bristows will have someone with relevant background and experience.

Changes to patent infringement exemption for clinical trials



Liz Cohen
Partner
Bristows LLP

In its response to a recent consultation, the UK government has accepted that s.60(5) Patents Act 1977 should be changed to exempt from infringement:

- activities in preparing or running clinical or field trials involving any medicinal product (i.e. not only a generic) for the purpose of obtaining regulatory approval in any country; and
- activities involved in health technology assessments, e.g. data to support assessment by the National Institute for Health and Clinical Excellence.

The Patents Act 1977 currently exempts

from infringement acts done for experimental purposes (s.60(5)(b)) and clinical trials and other activities required for regulatory approval of generic drugs as set out in EU Directives (section 60(5)(i)). These are commonly known as the research (or experimental use) exemption and the "EU" Bolar exemption respectively.

Clinical/field trials will not be an act of infringement following change to Patents Act.

The narrow scope and lack of clarity of these exemptions has been an issue for some time and previous consultations, as well as the recent one, have indicated that the risk of patent infringement has made the UK a less attractive place for clinical trials than some other countries, e.g. Germany. The consequences could have a negative impact on the UK economy,

due not only to loss of the clinical trial work but also loss of associated skills and expertise and potentially other losses such as the manufacturing of the final drug product.

The precise wording of the amended legislation is yet to be finalised and some respondents have requested inclusion of definitions of certain terms, such as "activities", to ensure clarity. Although the government's consultation document proposed that any change to the legislation be implemented on 1 October 2013 it is currently thought that this may not happen before April 2014.

Patentability of human embryonic stem cells



Dr Shauna Garvey
Associate
Bristows LLP

In January 2013 the German Federal Supreme Court (BGH) published its

Patent litigation

judgment in *Brüstle v Greenpeace* (Case no. X ZR 58/07), a case involving a patent covering neural precursor cells and the processes for their production from human embryonic stem cells (hES) and their use for therapeutic purposes. Greenpeace challenged the validity of the patent at the German Federal Patent Court on the basis that it was contrary to public policy and morality as it concerned use of hES for industrial or commercial purposes (unpatentable under Article 6(2)(c) of the EU Biotech Directive 98/44 (the "Directive")). The patent was held invalid insofar as it covers precursor cells obtained from hES cells. *Brüstle* appealed to the BGH who stayed proceedings referring various questions to the CJEU. The CJEU held that:

1. Any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo' within the meaning of Article 6(2)(c). Furthermore, it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c);
2. The purpose of the Directive is not to regulate the use of human embryos in the context of scientific research; it is limited to the patentability of biotechnological inventions. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) also covers the use of human embryos for purposes of scientific research - only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable; and

3. Article 6(2)(c) excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.

Applying the CJEU's decisions, the BGH found the invention was not patentable insofar as the subject-matter required the destruction of a human embryo. However, it upheld the patent insofar as other methods not leading

If ECJ decides that parthenotes are not human embryos, stem cells from parthenotes may be capable of patent protection.

to the destruction of embryos were concerned, such as removing cells at the blastocyst stage. The BGH's reasoning was that hES taken without destroying the embryo were not to be considered as embryos themselves under the Directive, since they were not capable of developing into a human being.

The effect of the CJEU's decision in *Brüstle* has also been considered in the UK. In August last year, the UKIPO issued its decision in *International Stem Cell Corporation* (BL O/316/12), a case concerning applications for two patents relating to methods of producing human stem cells and corneal tissues derived from such cells, using parthenogenesis (i.e. the development of an embryo without fertilisation) to activate a human oocyte. The Hearing Officer held that in applying *Brüstle*, he was required to conclude that the subject matter was not patentable. However, the

Hearing Officer had only been shown the UK observations in *Brüstle* at the time of his decision. In light of additional information submitted to the Comptroller of Patents, the Comptroller agreed that the issue of whether parthenotes are properly to be regarded as human embryos is not *acte clair*, and supported a further reference to the CJEU on this point. On appeal in April 2013 ([2013] EWHC 807), Henry Carr QC (sitting as a Deputy Judge of the High Court) agreed, and the UK High Court has made a reference to the CJEU, requesting whether the term "human embryos" in Article 6(2)(c) includes unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova contain only pluripotent cells and are incapable of developing into human beings.



Patent litigation

Unified Patent Court - Common questions



Alan Johnson
Partner
Bristows LLP

The new Unified Patent Court (UPC) will bring the biggest change in the patent litigation landscape Europe has ever seen. Here, Alan Johnson answers a couple of the most common questions regarding this change.

Q Why do I need to understand the new system now? Can't it wait until the Court is nearly open for business?

A The operation of the Court will influence patent filing strategies. Patents being applied for now will be subject to the new regime. Hence an understanding of the future litigation options is vital in assessing whether or not to modify your current strategy. You will also need time to consider the full implications for opting your existing EPs out of the UPC, bearing in mind that if you do wish to take this step, it will best be done the day the Court opens. You may also wish to reassess whether it is worthwhile filing oppositions at the EPO. You may even decide that long term investment decisions (such as where to site R&D and manufacturing facilities) may be influenced by the availability of injunctions having broad geographic effect.

Q When is it really likely to come into force?

A The Commission says the first part of 2014, but that is based on ratification by sufficient countries by November 2013. That is unrealistic. Ratification will be slower than the Commission expects. The UK for example expects not to ratify until about mid-2014, indicating that the earliest potential start date would be late 2014. There is also uncertainty as to how long another essential step will take, namely amendment of the Brussels Convention Regulation. This is subject to a rather lengthy legislative process. In our view, the earliest realistic date the system could become operational is 2015/16.

For more common questions, please visit our dedicated UPC site or contact Alan Johnson (alan.johnson@bristows.com)



Visit our UPC site where you can keep up to date with all the latest UPC news, including:

- Legislation and documents
- Commentary
- Cases
- Latest news
- Forthcoming events
- Q & A

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Unitary patents – a useful new tool?



Alan Johnson
Partner
Bristows LLP

Now that the ink is dry on the Treaty creating the Unified Patent Court ("UPC"), it is necessary for all users to assess how the new regime will affect them when it comes into existence – probably in the first half of 2016. For the biotech industry, the new regime definitely has some positive aspects.

One central creation of the new system is the European patent with unitary effect – more widely known as the unitary patent. It will be granted by the EPO in the same way as "classical" European patents. It will be possible to obtain a unitary patent for a large

number of EU states, as well as a "bundle" of other patents covering non-participating EU states and other EPC states. The precise geographic scope of the unitary patent is a minimum of 12 states, which will include the UK, France and Germany, and may be as many as 24 states, depending upon the speed of ratification of the UPC Treaty by states (some such as Eire and Denmark requiring referenda may be rather slow). The cost of obtaining the unitary patent will certainly be lower than the combined fees for national designations for the same territories. Whilst there are major uncertainties over the level of renewal fees, they are likely to be less than the total of renewal fees in all these states. Hence, for those patentees who require broad geographic protection for their inventions, the unitary patent makes economic sense.

Unitary patents will be available as soon as the UPC comes into force, including in respect of applications pending

at that time. Hence, applications in prosecution now can be used to obtain unitary patents if they are still pending at the time the UPC comes into operation.

Of course, patentees need to be aware that the unitary patent carries with it a commitment to pay these renewal fees without the ability to "prune" the coverage later in the life of the patent to restrict the geographic coverage to save costs, but this is not usual in this field if a successful product results or a licence is granted. Likewise there is a commitment to use the new (and untested) UPC, which includes the possibility of central revocation. However, this is a risk to be balanced against the savings on patent fees early in the life of the patent, and if short-term budgetary considerations are paramount, whilst it remains essential to have broad coverage, then the unitary patent is certainly worth considering.

Patent litigation

Myriad Genetics: US Supreme Court holds human genes unpatentable



Dr Alan McBride
Associate
Bristows LLP

In June 2013, the US Supreme Court delivered its judgment in *Association for Molecular Pathology v Myriad Genetics* regarding the patentability of human genes. The court had two issues to consider: (1) are DNA sequences eligible for patent protection? and (2) if DNA sequences are unpatentable then what about cDNA sequences (i.e. complimentary DNA sequences which are often used in gene cloning or as gene probes)?

In a rare unanimous decision the US Supreme Court held that DNA sequences are products of nature and therefore human genes are not considered patentable. The court noted:

"Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention... Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes 'new...composition[s] of matter'...that are patent eligible."

However, regarding cDNA, the court explained:

"cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments... Creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring...The lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the

DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible..."

cDNA is not a "product of nature" and is patent eligible..."

Some biotech companies in the US had previously warned that a ruling to strike down Myriad's patents would hamper research but the initial reaction from some doctors and scientists in the US is that the decision is a victory for the field of genetic research.

Antibody patent decisions

1. *Eli Lilly v HGS: End game for saga of bioinformatics neutrokin-α patent*



Dr Greg Bacon
Associate
Bristows LLP

The long-running neutrokin-α patent validity case between Eli Lilly and Human Genome Sciences (HGS) was recently brought to a close in the UK by the second substantive judgment of the Court of Appeal ([2012] EWCA Civ 1185).

By way of background, HGS' patent in suit disclosed the nucleotide and amino acid sequence of what was then (in 1996) a novel member of the tumour necrosis factor (TNF) ligand superfamily, neutrokin-α. After identifying the neutrokin-α polypeptide through bioinformatics rather than "wet-lab" work on isolated protein, HGS applied for the patent, which included claims to isolated antibodies that bind to neutrokin-α and to a pharmaceutical composition comprising the claimed antibodies. The patent correctly identified neutrokin-α as a member

of the TNF ligand superfamily and gave a long description of its activities and uses. However, being the early product of bioinformatical research, that description was not supported by data obtained from *in vitro* or *in vivo* studies with neutrokin-α. Instead, it was an informed prediction based on what was known about the other members of the TNF superfamily.

Eli Lilly had applied to revoke the patent on a number of grounds. The case was previously the subject of an appeal to the Supreme Court which, in a landmark judgment, held that the claims of the patent were capable of industrial application. As a result, the case was remitted to the Court of Appeal to consider the outstanding issues, primarily whether the antibody claims were sufficient. The trial judge (Kitchin J) had held that in light of the skilled person's common general knowledge, it did not require undue effort to make and identify antibodies specific to neutrokin-α in 1996 even though the patent did not disclose the isolation of any such antibodies. Eli Lilly sought to argue that although it was possible to make the individual antibodies, it



Patent litigation

was not possible to tell from the patent which, if any, would have practical use and it would take undue effort to find those that did. As the patent was aimed at products that have a valuable use, particularly as potential pharmaceuticals, the antibody claims should be confined to products with a practical use. Given that it required undue effort to identify such 'useful' antibodies, the claims were alleged to be insufficient.

The Court rejected this argument. At the level of generality of the patent, and following the Supreme Court's decision on industrial application, all the claimed antibodies had some potential use on the basis that they bound to neutrokine- α . Furthermore, the correct construction of the claims in suit did not include a limitation to "useful" antibodies. All that mattered was that antibodies falling within the claim, i.e. that bind to neutrokine- α , could be made and identified.

On the pharmaceutical composition claim, Kitchin J had held that it would require a substantial research programme with an uncertain outcome

to develop a candidate antibody to neutrokine- α for any therapeutic application based on the teaching of the patent. As the patent did not disclose any 'workable prototype' of a pharmaceutical composition, he ruled the claim insufficient. However, the Court of Appeal did not agree with this approach. The patent made clear that the patentee had not disclosed any pharmaceutical composition and there was no reason to suppose that the patentee intended any specific application for the claimed compositions. At the level of generality of the invention disclosed in the patent, all that the pharmaceutical composition claim meant was a composition which could be formulated as suitable for administration as a pharmaceutical, which could be done. The claim was thus sufficient.

2. *Regeneron & Bayer v Genentech*



Katie Hutchinson
Associate
Bristows LLP

In February 2013, the Court of Appeal handed down its decision in *Regeneron Pharmaceuticals Inc & Bayer AG v Genentech Inc* ([2013] EWCA Civ 93). The case concerned Genentech's patent for the use of human vascular endothelial growth factor (hVEGF) antagonists for the treatment of certain diseases characterised by angiogenesis. Regeneron and Bayer sought to revoke the patent on a number of grounds, including obviousness and insufficiency. They also sought a declaration of non-infringement in respect of Regeneron's product VEGF-Trap. The Court of Appeal dismissed the appeal on all grounds, upholding the High Court's decision that the patent was valid and infringed.

The case on obviousness concerned the question of whether something is "obvious to try". The Court of Appeal confirmed that when considering

this question it is relevant to take into account whether there was a fair expectation of success; the expectation of success depending on the facts in each case. In this case it was appropriate for the judge to consider how optimistic the skilled team would have been and whilst there was "the strongest of motivations" to find a therapy for the disease, VEGF was only one of many options being investigated. While the prior art provided a motive for a researcher to carry out and test a hypothesis, that did not mean there was optimism about the outcome.

Regarding sufficiency, the Court of Appeal upheld that the patent disclosed a principle of general application – namely, that anti-VEGF therapy would be an effective treatment for the diseases identified. A patent was said not to be insufficient simply because it does not demonstrate or prove efficacy; it is enough that it is possible to make a reasonable prediction from the data in the patent that the product will work across the scope of the claim. For a use patent, the Court of Appeal noted that it is not always necessary to report results of clinical trials or even animal tests to support sufficiency provided appropriate experiments show an effect on a disease process so as to make the claimed therapeutic effect plausible. Further, there is no requirement that the therapy be suited for use in all patients for the patent to be sufficient.

On infringement, the Court of Appeal upheld that the phrase "hVEGF receptor" includes variants of naturally occurring receptors which retain the ability to bind VEGF. As VEGF-Trap was such a variant that was able to bind to VEGF it was held to fall within the scope of the claims of the patent.



3. *Eli Lilly v Janssen*



Rowena Stent
Professional
Support Lawyer
Bristows LLP

A third antibody patent case – *Eli Lilly v Janssen* ([2013] EWHC 1737) – was ruled on by the High Court in June 2013. In this case, Mr Justice Arnold held that a patent claiming a class of antibodies for use in preventing/treating Alzheimer's and related diseases was invalid for insufficiency as the patent did not contain sufficient disclosure to make it plausible that it would work over the whole scope of the claim.

Eli Lilly had sought revocation of Janssen's patent and a declaration of non-infringement in relation to its Alzheimer's drug under development. In relation to insufficiency and in circumstances where the party challenging the patent wishes to rely upon post-published evidence in support of its position, the Judge held that the court must conduct the following two-stage enquiry:

1. Determine whether the disclosure of the patent, read in the light of the common general knowledge of

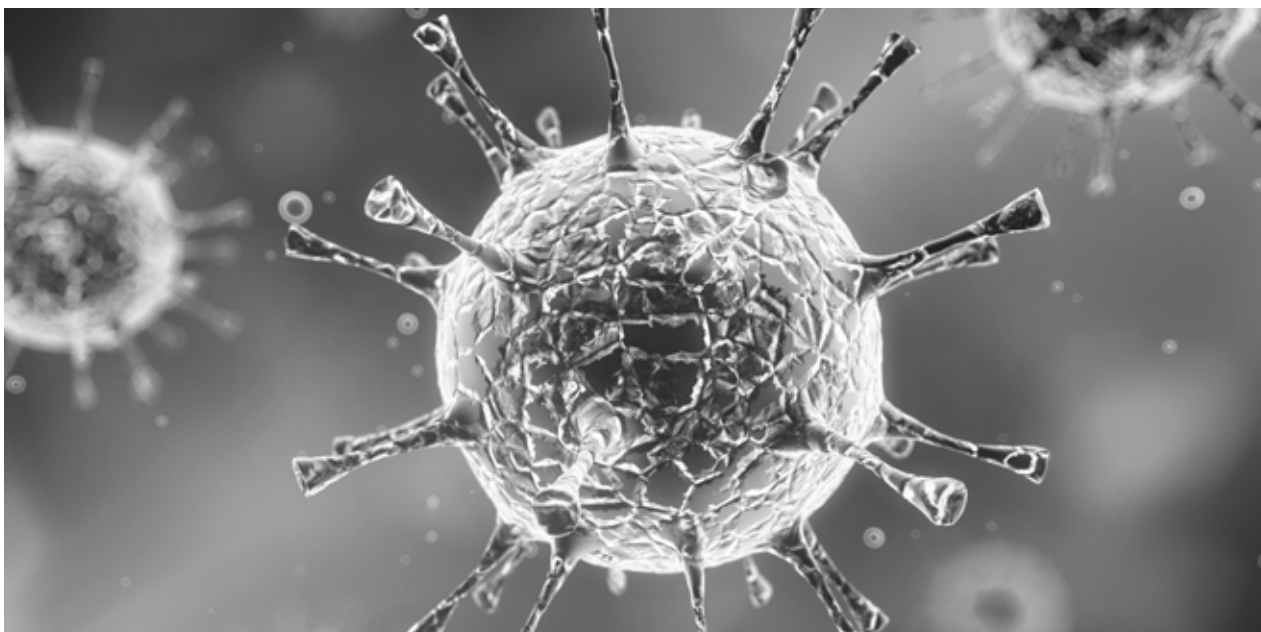
the skilled team, makes it plausible that the invention will work across the scope of the claim. If yes,

2. Consider whether the later evidence establishes that in fact the invention cannot be performed across the scope of the claim without undue burden. This second stage can conveniently be divided into two:

- consider whether the invention can be performed without undue burden at all; and then
- consider whether the claim is of excessive breadth.

The patent claimed: "A *pharmaceutical composition comprising an antibody to A β (β -amyloid peptide) and a pharmaceutically acceptable non-toxic carrier or diluent, for use in preventing or treating a disease characterised by amyloid deposit in a patient, wherein the isotype of the antibody is human IgG1.*" The Judge concluded that the disclosure did not make it plausible that any antibody to A β (provided it was of IgG1 isotype) would be effective to prevent and/or treat such a disease. He considered that the disclosure only made it plausible that N-terminal antibodies to A β would be effective

(such that the patent was insufficient). In case he was wrong on the "plausible" point, he went on to stage 2 of the test and found the patent insufficient in both respects.



Regulatory

Our regulatory practice

Our regulatory practice serves the most heavily regulated industries globally, including leading pharmaceutical and biotechnology companies and major manufacturers of medical devices and chemical products. Our team has a wide variety of backgrounds, including the fields of bioscience, neuroscience and reproductive medicine in the clinical setting.

Transparency in clinical trials



Lauren Wilks
Associate
Bristows LLP

The proposed EU Regulation on clinical trials (the "Regulation") was endorsed by the Environment, Public Health and Food Safety Committee ("ENVI") on 29 May 2013. The primary aim of the Regulation, which was first adopted by the Commission in July 2012, is to boost clinical research in Europe by simplifying the rules for conducting clinical trials. The Regulation will repeal Directive 2001/20/EC.

Back in March 2013, the ENVI published a series of draft reports suggesting amendments to the Regulation that built on the existing theme of transparency. Key transparency aspects of the Regulation as it now stands are set out below:

- Where the clinical trial was intended to be used for obtaining

a marketing authorisation for the medicinal product, the sponsor shall submit to the EU database the clinical study report ("CSR") 30 days after marketing authorisation has been granted, the decision-making process on an application for a marketing authorisation has been completed, or the sponsor has decided not to submit an application for marketing authorisation.

Full clinical trial data publicly accessible under proposed EU regulation.

- The CSR will contain all of the results and supporting data including the full protocol and its eventual subsequent modifications, a statistical analysis plan, summarised efficacy and safety data on all outcomes and individual

anonymised patient data.

- A summary of the results of the clinical trial, the CSR and the full dataset of clinical trial data shall be publicly accessible through the EU database.

In June 2013, the European Medicines Agency ("EMA") released a draft policy on publication and access to clinical-trial data for a three-month public consultation ending 30 September 2013. Notably, a recital to the Regulation – which is a non-legally binding statement – refers to the EMA's policy, stating that "[t]hose standards on transparency and access to documents should be upheld and reinforced". The EMA expects the policy to come into force on 1 January 2014.

The Regulation is by no means agreed, with the first reading of the European Parliament scheduled for October 2013.

Whilst the biopharmaceutical industry recognises the benefits to public health of responsible reporting and publication of clinical research and safety information, there are important factors to be taken into consideration. For

example, it is important that information on medicines made available to the public is contextualised, understandable and effective in order to counterbalance media 'scare stories' about medicines. The EMA will not be absolved of its duty to assess the quality, safety and efficacy of medicinal products and provide appropriate information to the public and medicinal practitioners by the proactive and indiscriminate publication of all clinical trials data.

'Early Access to Medicines Scheme' in the UK



Joanna Hook
Associate
Bristows LLP

In July last year, the Medicines and Healthcare products Regulatory Agency ("MHRA") published a consultation on proposals to introduce a scheme in the UK that will provide access to certain new medicines before they are formally licensed. This is welcome news for pharmaceutical and biotechnology companies who are under increasing pressure from healthcare professionals and patients for access to medicines that are still undergoing clinical trials or awaiting marketing authorisation ("MA"). As outlined in the consultation, the key features are that:

- the scheme will apply to promising new medicines with a positive risk/benefit balance that will treat, diagnose or prevent life threatening, chronic or seriously debilitating conditions without adequate treatment options;
- the scheme will be available for medicines prior to authorisation but at the end of Phase III trials;
- the scheme is voluntary - the company developing the new medicine can decide whether to request an opinion from the MHRA (for a fee) as to the medicine's

suitability for being made available under the scheme; and

- the MHRA's opinion will be made available to clinicians and it will be up to NHS purchasers to decide whether to fund the new medicine.

The MHRA has not ruled out a review at an earlier stage (for example based on Phase II data) in exceptional circumstances where the information available merits it. The scheme could therefore provide an early access opinion on a new medicine around a year before the regulatory process delivers an MA.

Whilst the proposals are fairly general at this stage, the MHRA is clear that the scheme will only apply to particularly promising medicines being developed. It anticipates that only one or two medicines will be made available each year under the scheme. In addition, the manufacturer must still complete the MA process.

The consultation does not address one important aspect – the question of whether access under the scheme would start the clock for the purposes of regulatory data protection and the SPC term. Companies will need to seek clarity on this issue in order to develop their strategy for gaining access of their medicines to the UK market.

Since the consultation closed in October 2012, the MHRA is finalising details of the scheme and is expected to make an announcement as soon as discussions have concluded.



Anti-trust

Our anti-trust practice

Our lawyers are recognised as leading experts in the fields of both national and EU competition law, and our firm has a long track record of representing clients before the competition authorities and courts in Brussels, Luxembourg and the UK. Drawing on the firm's wider IP and technical expertise, we advise on everything from current licensing policy through to dealing with competition investigations and the latest changes in competition law.



The law in reverse: developments in the treatment of patent settlements in the EU and US



Sophie Lawrance
Associate
Bristows LLP

The third week in June 2013 saw two important developments in the legal treatment of patent settlement agreements in the EU and US.

On 17 June, the US Supreme Court handed down its judgment in *Federal Trade Commission v. Actavis*. The FTC was appealing a finding that a patent settlement agreement involving a substantial payment from the patentee (i.e. the pharmaceutical originator) to a would-be generic entrant was legal if the terms of the agreement did not restrict the generic beyond the scope of the patent. This position had been supported in a number of different

cases by a number of the US Courts of Appeal, and was based on the idea that a granted patent is presumptively valid.

Whilst a strong dissenting opinion was expressed by three of the judges, the majority of the US Supreme Court disagreed with this position. They held that pharma patent settlements where a "reverse" payment (from originator to generic) is in play are not immune from the antitrust rules. Whilst this ruling endorses the approach of the FTC, which has pursued a number of antitrust cases on this basis over the past few years, the Court also held that a "rule of reason" analysis must be carried out to determine if a patent settlement is in fact anti-competitive. The FTC had asked the Court to approve a stricter approach which would make reverse payment patent settlements presumptively illegal. Further litigation can therefore be expected to establish the parameters of the analysis which will be carried out under US law to determine if particular patent settlement agreements comply with the rules. However, the judgment also notes that large payments may be viewed as a "surrogate" for the weakness of the litigated patent. This approach is questionable, overlooking

factors such as the risk of being unable to obtain a preliminary injunction and to receive full compensation for the devaluation of the originator product in the event that the patent is ultimately upheld, as well as the disruption and cost associated with litigation.

Two days after this Supreme Court ruling, the European Commission confirmed that it was taking a similar approach with the announcement that it had decided to fine Danish pharmaceutical company Lundbeck €93.8M and generic companies (Alpharma, Merck/Generics UK, Ranbaxy and Arrow) a total of €52.2M for entering into reverse payment settlements. The settlements in question arose out of litigation in relation to a patent covering citalopram in the 2000s. Commissioner Almunia (a Vice President of the European Commission, responsible for the Directorate for Competition), giving a speech announcing the fine, referred to Lundbeck's patent having expired when the agreements were entered into. This may suggest that the case is based around the scope of patent type test previously used in the US, rather than the new approach described above. The Commissioner confirmed that it has a number of further cases in the pipeline, and Lundbeck also immediately announced its intention to appeal the decision.

The EU Courts will therefore have to look carefully at these issues in due course. It remains to be seen how these cases will affect companies' incentives to settle litigation, and whether they may even have effects upon companies' incentives to innovate or to bring litigation in the first place. It is, however, certain that with patent settlement monitoring set to continue on both sides of the Atlantic, pharma companies will need to be very cautious about the terms of their patent settlement agreements.

Data protection

Our data protection practice

We have one of the largest teams of data protection lawyers in Europe, and have acted on many of the highest profile and most complex projects of recent years, several of which have made the headlines in the national and international press. This has enabled us to build close working relationships with EU data protection authorities as we deal with them regularly in relation to both advisory and litigious matters.

Data protection aspects of new Regulations on clinical trials and medical devices



Nicola Fulford
Associate
Bristows LLP

There are many regulatory hurdles to overcome when conducting clinical trials for medicinal products. One issue that may get overlooked is how to protect the personal information of those involved.

The European Commission has recently adopted proposals for two new Regulations, one dealing with medical devices and one with *in vitro* diagnostic medical devices. A common feature of each of the proposed Regulations is that they develop Europe-wide databases to record information about the drug/device and corresponding vigilance and market surveillance

information. Much of this information will then be publicly available.

The European Data Protection Supervisor has reviewed and commented on these new Regulations. He is concerned that individuals' sensitive health information will be recorded and potentially available. He urges clarification to the provisions to ensure data protection laws are complied with. He stresses that whilst there may be a need for traceability, and identifiable information to be available to those involved, there should not be recognisable personal data in the European databases.

Although the Regulations are not yet in force, data protection laws must be complied with when recording personal information as part of the data around clinical trials/medical devices. Consideration should be given to using pseudonymisation techniques for data sharing and minimising personal data where possible.

Getting data protection compliance right also includes giving appropriate information to the individuals concerned about the processing of their personal

information and recording informed consents where appropriate. It also means ensuring that sufficient and accurate information is retained and adequately protected in accordance with the law.

Commercial

Our commercial practice

Consistently ranked among the world's top IP firms, Bristows has a wealth of experience in handling a wide range of deals involving intellectual property rights. Our clients range from multinational household names to small start-ups, and they seek our advice on protecting and extracting value from their most valuable assets – their inventions and ideas, their brands, their reputation, their secrets and their designs.

UCL business licences gene therapy program for haemophilia A to BioMarin



Lizzie Carter
Associate
Bristows LLP

Earlier this year, Bristows advised client UCL Business ("UCLB") on licensing a Factor VIII gene therapy program for haemophilia A to BioMarin Pharmaceutical ("BioMarin"). The program is based on research by Professor Amit Nathwani and his team at University College London ("UCL"), and St. Jude Children's Research Hospital, a Tennessee not-for-profit corporation.

UCLB is a technology transfer company which commercialises research and innovations developed by UCL. BioMarin is a California based company which develops and commercialises

innovative biopharmaceuticals for serious diseases and medical conditions, expertise which it will apply to the licensed gene therapy products for the treatment of haemophilia A under this collaboration.

The current market for haemophilia A products is about \$6 billion worldwide. Haemophilia A is a genetic condition that affects the blood's ability to clot, caused by a deficiency of the clotting factor "Factor VIII", a protein encoded by the human F8 gene. Haemophilia A is the most common type of haemophilia, and its incidence is estimated at 1 in every 5,000 male births. The current standard of care for severe haemophilia A patients is intravenous infusions of genetically engineered clotting factors three times per week.

The gene therapy program uses an optimised version of the Factor VIII gene with a novel promoter and increased levels of expression of the sequence for the clotting protein Factor VIII. Under the licence agreement, BioMarin plans to confirm selection of a development candidate this year, initiate and complete IND-enabling toxicology studies next year and initiate proof of

concept human studies by the end of 2014.

The case of the vanishing licence – sub-licensees beware!



Dr Sahar Shepperd
Associate
Bristows LLP

Most, if not all, biotech companies spend their infancy as part of a larger entity such as a university laboratory, a government organisation or a corporate entity. Often, as part of the spin-out of the new biotech entity, the parent entity grants the new company an exclusive licence to the IP in the new technology. Often, such licence includes a right for the parent company to terminate the licence under certain circumstances, e.g. if the new entity becomes insolvent. From the perspective of the parent company, these termination rights are important as it would enable it to seek alternative means of commercialising the technology if the spin-out fails to commercialise the technology.

It is not uncommon for early stage biotech companies to conduct early development/validation work before out-licensing further development and commercialisation to a larger established company. The sub-licensee in this case, would understandably wish to ensure that its sub-licence is secure. But what happens if the head licence between the parent company and the spin-out is terminated? Does the downstream sub-licence between the spin-out company and its licensee also terminate?

Provided that there are no express provisions in the head licence or sub-licence, under English law the sub-licence would also terminate on termination of the head licence under the doctrine of *nemo vat quot non*

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habet ("no one gives what he doesn't have"). However, this understanding was recently departed from in *VLM Holdings Limited v Ravensworth Digital Services Limited* ([2013] EWHC) where the High Court held that a sub-licence is capable of surviving the termination of a head licence in certain circumstances.

The facts of this case were that a parent company, VLM Holdings, owned copyright in some online printing software and granted its subsidiary, VLM UK, an informal licence to exploit the copyright in the software. VLM UK then granted a formal sub-licence to the software to a third party, Spicerhaart. VLM UK unfortunately went into liquidation, which prompted VLM Holdings to terminate its licence with VLM UK and grant an exclusive licence to another print service provider, Ravensworth. Ravensworth notified Spicerhaart that as the exclusive licensee, Ravensworth had not consented to Spicerhaart using the software. Spicerhaart responded by saying that its licence from VLM UK was pending and could only be terminated by VLM UK.

The issues before the court were whether Spicerhaart's sub-licence survived termination of the head licence between VLM Holdings and VLM UK and, if so, how did this affect the exclusive licence subsequently granted to Ravensworth?

In answer to the first question, Mr Justice Mann found on the facts, that the sub-licence survived termination of the head licence. The Judge noted that VLM Holdings and VLM UK were affiliates with common directors and, although the sub-licence came from VLM UK, the sub-licence had in effect also come from VLM Holdings who wanted the sub-licence with Spicerhaart in place so that the copyright in the software could be exploited. In the Judge's view, the directors of VLM Holdings had consented to the sub-licence and had thus by implication authorised VLM UK to grant the sub-licence.

Further, the sub-licence to Spicerhaart

described VLM UK as the owner of the copyright in the software which it was not. As Spicerhaart was unaware that VLM UK was not the actual owner of the copyright, and as both VLM Holdings and VLM UK shared substantially the same business aims, the Judge held that VLM Holdings was to be treated as an undisclosed principal. Therefore on normal agency principles, the permission granted to Spicerhaart under the sub-licence was granted not just by VLM UK but also by VLM Holdings.



Finally, as both VLM Holdings and VLM UK wished to exploit the copyright in the software, the relationship with Spicerhaart was important to both companies. Both affiliates also knew that the sub-licensed software was business-critical to Spicerhaart and, accordingly, the sub-licence was equally imperative. It could therefore not be the case that such an important sub-licence could simply be terminated by termination of the head licence. The sub-licence was held to survive and VLM Holdings was held to be in material breach of the exclusivity provision in its licence to Ravensworth.

So where does this decision leave parent companies, their spin-out

companies and the sub-licensees?

This case is quite fact specific in that the head licence was between subsidiaries with common directors and there is a thought that this decision is unlikely to apply to arms length licences. Nevertheless, parties that find themselves in a chain of licences would be advised to take note:

- From the head licensor's perspective, it is unlikely to be aware of the number of the sub-licences granted by its licensee and so if it wishes for any sub-licences to terminate upon termination of the head licence, this principle should be stated expressly in the licence agreement.
- As an alternative, the head licensor may consider requiring its licensee to notify it every time a sub-licence is granted or perhaps even seek the head licensor's consent before granting a sub-licence.
- In addition, the head licence should ideally address what will happen to the licensing chain in the event the licensee becomes insolvent.
- Companies within a group structure should ensure that their intra-group licensing arrangements are carefully recorded, and the head licence should expressly disclaim any agency relationship, so that the parent company does not find itself bound under common law agency principles
- From the licensee's and its sub-licensee's perspective, it would be desirable for the sub-licences to continue if the licensee becomes insolvent. A sub-licensee should consider including a provision in its sub-licence that if its licensor becomes insolvent, the head licensor would grant the sub-licensee a direct licence on similar terms. An obligation of this nature should also be imposed on the head licensor in the main licence.

Corporate

Our corporate practice

We carry out a broad spectrum of corporate work for businesses ranging from multi-national corporations, investment funds and leading institutions to start-ups and young, fast-growing companies. Our experienced lawyers advise on every aspect of corporate transactions including tax, employment, UK and EU competition/anti-trust, regulatory, real estate, IT, data protection and IP issues.

Acquisition of biotech companies: valuation of companies and their IP



Brian Horsburgh
Blue Yonder Group*



Iain Redford
Partner
Bristows LLP

Valuing biotech companies, especially early to mid-stage companies, is invariably difficult. Valuations will be dependent on a number of factors, e.g., Will the drug get approved? When will peak sales occur? How long does the patent have to run? And there are a number of approaches that can be taken when valuing biotech companies, e.g., one can:

- calculate the cost to replicate the venture; or
 - calculate risk adjusted net present value; or
 - use proxies in the market for similar ventures.
- We discuss two recent cases to demonstrate market valuations and also what "value" means in today's health economic-centric world and how that impacts valuations:
1. Human Genome Sciences ("HGS") had a novel drug (Benlysta) for lupus (an autoimmune condition) at Phase 3. In 2010, the HGS board rejected an offer by Amgen to acquire the company for \$7bn. The board felt that the offer did not value the company appropriately and so the offer was rejected. The following year, HGS won FDA approval for Benlysta, derisking the asset and adding value. However, with modest and less than expected sales and a slump in share price, HGS was acquired in a hostile takeover by GSK for less than half the amount Amgen offered for the company when it had an earlier and riskier asset and could offer investors in HGS a premium of 100% above current market share price.
 2. Pharmasset had just completed a promising Phase 2 clinical trial with an oral drug for hepatitis C infections. It had no revenues to speak of but its stock had increased 3-fold in 2011 before it was acquired by Gilead for \$11bn in November 2011. At the time of acquisition, Gilead had a market cap of \$32bn and revenue of \$8.4bn generated from 14 products on the market. Gilead valued Pharmasset at approximately 1/3 of its own value. This asset (drug) still needed to go through further clinical testing and was associated with significant risk as the likelihood of an in licensed Phase 2 molecule getting to approval is approximately 33% (DiMasi 2010). By May 2013, Gilead had conducted two successful Phase 3 trials and the drug, Sofosbuvir, is now headed for FDA approval. The market cap of Gilead is \$80bn, a net increase in value of \$37bn in a 16 month timeframe.

So what do these examples mean for valuation of biotech companies? Despite forecasting by analysts and dissection of risk, we believe that value remains in the eye of the beholder; a company is worth what someone will pay for it.

value remains in the eye of the beholder

The need to control cost is going to be a huge factor in investor's valuations of intellectual property in the future. Value is becoming increasingly important for biopharma, as healthcare costs are reaching unsustainable levels and thus value for money has become centre stage. Currently, the US spends about 18% of GDP on healthcare, effectively 1 in every 6 dollars; the UK spends about 10% and the projected costs can only rise. But where will the money come from?

We believe there are three main reasons why costs are rising:

1. Populations are ageing and with aged populations comes increased chronic conditions that are expensive to treat;
2. Western governments can no longer afford expensive healthcare - pricing pressures are increasing the demand for cheaper generic medicines; and
3. There is continued increased cost for new medications that stretch limited healthcare budgets.

These factors are driving a new paradigm; value. Healthcare is moving from fee for service to value-based pricing. Historically, decisions were made on whether or not to reimburse, not to set price. In the UK, from January 2014, pricing will be value-based. The maximum price for reimbursement of a drug will be linked to the value that drug adds over and above existing drugs. If the drug provides no additional therapeutic benefit then reimbursement will be set

at the price of the existing drug on the market. Although the UK market is small, it and the German market are the most referenced in the world for pricing. Effectively the drug price in the UK and Germany sets the price in at least 50 other countries. It is clear that new drugs will need to demonstrate clear value for money. To put this in context, in 2012, NICE rejected 11 of 19 drugs from companies such as GSK, Roche, Novartis and J&J because they did not represent value for money. The cost to develop those 11 rejected drugs must run into many billions of pounds.

When acquiring new drugs or companies with novel drug assets, the purchaser will need to understand how that drug provides value in the future. To determine the value-metric, biotechs will need to engage with various stakeholders including payers early in development to get consensus on what value-metrics will be acceptable. To win higher pricing, new drugs will need to demonstrate treatment value; better safety, efficacy, value for money, better compliance, be innovative, and tackle diseases with high unmet need.

Of course intellectual property is a critical factor when assessing companies with drug assets. However, it is worth looking at patentability in non-Western markets and how projected sales are factored into value for acquisition. There is a move to increase shareholder value by selling drugs into these emerging markets, but this can come at a cost; witness the recent bribery debacle with GSK. Furthermore, both China and India have overhauled parts of their IP laws to allow its drug makers to make cheap copies of medicines still under patent protection. This allows copies of branded drugs to be manufactured and made available to the consumer at vastly reduced cost. This activity will need to be taken into account when valuing sales in emerging markets.

In summary, there are numerous methods for valuing biotech companies and their IP, but we suggest that value is in the eye of the beholder and that biopharma is firmly centre stage in a value-based world.

*** Blue Yonder Group, LLC New Canaan, Connecticut, USA**



Tax

Our tax practice

Our tax experts enable clients from multi-nationals to start-ups to minimise tax exposure and do business while complying with the UK's maze-like tax system.

We offer advice on the full range of tax issues affecting corporates, including VAT, stamp duties and other specialist areas. Core areas of expertise include helping clients, both UK based and overseas to structure corporate and commercial transactions.

UK tax breaks for biotech companies



Miranda Cass
Partner
Bristows LLP

Over the last few years the UK Government has continually reiterated its desire to create the most competitive corporate tax regime in the G20. This has resulted in a gradual reduction in the main corporation tax rate, which currently stands at 23% but is due to go down to 20% from April 2015.

Of particular interest to biotech companies has been the additional focus on increasing tax incentives for companies involved in innovation. For several years now companies that are involved in scientific research and development have been able to claim enhanced tax deductions for money spent on R&D, and this year has seen the advent of the UK patent box which introduces a 10% corporation tax rate on profits derived from patented technologies and other related

intellectual property rights.

For biotech companies that are profit-making, the patent box offers a huge tax saving and, if not already doing so, these companies should be looking in detail at how the regime will apply to them and whether their activities and

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arrangements with other companies are structured in the best way to enable them to benefit. The benefit of the patent box is being phased in gradually over a 5 year period so that in 2013 only 60% of patent box profits will qualify for the 10% rate, then 70% for 2014, 80% for 2015, 90% for 2016 with the full 100% of patent box profits qualifying for the 10% rate in 2017.

For companies that are in the spending and development phase of their life, the UK R&D tax relief regime can be of real financial benefit. The relief works by giving an enhanced deduction for

expenses (e.g. staff salaries) incurred. For a small or medium sized company, it is treated as spending £225 for every £100 it actually spends (a large company is treated as spending £130 for every £100 it actually spends). Assuming that the company is loss-making and that the deemed extra expenditure increases the company's loss, the company has two options. It can either roll the loss forward to reduce future profits and thus its future tax bill or, if profits are not imminent, it can surrender the enhanced loss to the UK government in exchange for a cash payment equal to 11% of the loss: a very useful source of funding.

Q&A with Dianna DeVore



Dr Dianna DeVore
Vice President,
Intellectual Property
and Legal Affairs
Ariosa Diagnostics

Dianna DeVore is head of IP and legal affairs of Ariosa Diagnostics. Dianna has over 16 years of legal experience, with a focus on IP and technology transactions. She was a founder of the Silicon Valley-based law firm, Convergent Law Group, and served as legal counsel at numerous companies, including Complete Genomics, Cambridge Antibody Technology and Elan Pharmaceuticals. Dianna received her B.A in Biology and Art History from Johns Hopkins, her Ph.D. in Genetics from Yale University, and her J.D. from Stanford Law School.

Bristows LLP's associate, Dr Sahar Shepperd, runs through a few questions with Dianna.



Dr Sahar Shepperd
Associate
Bristows LLP

Q How long have you worked at Ariosa?

A I have been at Ariosa for over two and a half years now.

Q What does your role at Ariosa involve?

A For the first two years I was solely responsible for all of Ariosa's IP and legal matters. Ariosa has expanded internationally quite quickly and so thankfully we have hired other attorneys, including an Associate General Counsel who takes the lead with all the corporate matters and the contracts. That has allowed me to focus more on IP, including patent litigation matters.

Q What challenges did you face when you started at Ariosa?

A I was immediately faced with clarifying our freedom to operate position for a test in commercial development. In addition, Ariosa had developed its own proprietary technology which needed appropriate protection, and we were still optimizing the final form of our test. In addition to our internal research efforts, we were also working with multiple clinical sites including universities and some private clinics in clinical research preparing for our clinical validation trial. So even though it was a very early stage start up, I stepped right into the midst of a number of pressing commercial issues.

Q In terms of managing your own department, how much do you rely on external counsel, and what

lessons have you learned about how to manage external counsel?

A I rely on outside counsel in many areas. We face many different legal issues, and have to rely heavily on experts in those areas outside the collective expertise of our team. In my experience, you find the best counsel you can and work with them in as cost effective a manner as possible. I try to work really closely with external counsel to make sure that things are done efficiently. You can always find counsel that are merely less expensive, but you'll end up paying for it in the long run!

Q How do you balance such a high pressured job with your personal commitments?

A It is just a matter of making sure things are appropriately prioritised and it forces you to take a good look at what is important in life. It is very much a matter of being able to decide what it is that you want to spend your time doing - for me it is very much my job and my son, and so maybe some of my hobbies have gone by the wayside.

Q What have been the key highlights of your current role?

A The ability to work with various departments within Ariosa and be more heavily involved in the strategic elements of where the company is going and making sure that I can enable the company to do what it needs to do to meet its corporate goals.

Q&A with Dianna DeVore

Q What are Ariosa's plans for the future?

A We are focussing on the global market for the Harmony™ test, and expanding outside the US to make sure women have access to it worldwide. In the US, we are working closely with our partner LabCorp and with key opinion leaders to ensure our test is adopted appropriately.

Q How would you describe the current state of the biotech field?

A I think it is a really interesting time right now in biotechnology, especially with developments in patent law in the US. There have been a number of big changes over the two years or so, and we are lucky at Ariosa that we had predicted some of those changes and were prepared when they occurred.

Q What challenges do small biotech companies face?

A I guess one of the big challenges is that everything in IP has to be co-ordinated, that includes patent prosecution, post grant procedures, and litigation - because anything you say in one forum can, and probably will, be used against you in another.

Q Have you been inspired by anyone in the biotechnology field?

A Yes. Most recently, I have been really fortunate to work closely with Ariosa's chairman, John Stuelpnagel. He is a veteran of biotechnology and a terrifically savvy person when it comes to IP. Of all the non-lawyers I have worked with, John is the most knowledgeable about patent strategy and litigation. Working closely with somebody at that level is wonderful.

Q In your experience, are there any areas of the biotech field where people need to be careful?

A Due diligence. People will often claim that certain IP is important, but if you are going to purchase an IP asset, or a company based on the position of their IP, you need to assess the actual strength of the asset to be certain of its worth. That

probably sounds very obvious, but the true strength of a patent or portfolio may not be thoroughly examined in a diligence process. A lot of times people are 'penny wise, pound foolish' in conducting diligence, and if you do not do the proper analysis you may suffer greatly later.

Q What do you think will be the "next big thing" in the biotech field?


A A lot of technologies have challenges. Some of them are development challenges, some of them are regulatory challenges, and some of them are just basic challenges in clinical adoption. One interesting question is what is going to happen with genomic sequencing? We are now able to generate genetic information on individuals at a reasonably efficient cost in a reasonably efficient time frame - but clinical use of this information is still not clear. Pre-natal testing has been one of the first applied clinical uses of this high throughput sequencing. It is a fairly straightforward use of the technology and is reasonably adaptable to existing clinical settings. But following this, how high throughput sequencing will be adopted in other clinical settings fascinates me. I think personalised medicine is an area of

I think personalised medicine is an area of biotechnology that may soon be ready for development, and we may see genomics and the therapeutic sectors intersecting at some point in the not too distant future.

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Quick facts

about our life sciences practice



Bristows has one of the most highly-regarded multi-disciplinary life science legal practices in the world.

Our clients range from multinational pharmaceutical and biotech companies and medical device manufacturers to universities, SMEs and technology start-ups, private equity and venture capital investors.

Our clients come to us for advice on a wide spectrum of IP issues including patents, trade marks and licensing, freedom to operate opinions, collaborations, mergers and acquisitions, financings and the coordination of disputes in multiple jurisdictions.

The Bristows' life sciences team is among the largest in Europe comprising 21 partners and 43 associates, many with backgrounds in chemistry, biochemistry, engineering, genetics and neurosciences as well as law. They include some of the UK's leading practitioners in this sector.

Editorial team



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Sally Field

Partner

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Sally is the head of the Life Sciences practice at Bristows and is also an IP specialist who has advised on dispute resolution issues for over 30 years. Sally has acted in many high-profile IP disputes and has been responsible for co-ordinating patent litigation in Europe and the USA for multi-national corporations. She teaches patent law on the Oxford University Diploma in Intellectual Property Law and Practice course.



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Dr Robert Burrows

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Robert advises on patent and other IP litigation matters in the UK, particularly for clients within the life sciences sector. A number of the cases he has managed in recent years have required the coordination of parallel proceedings in multiple jurisdictions within Europe and elsewhere in the world.



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Dr Alan McBride

Associate

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Alan specialises in patent litigation in the life sciences sector. Prior to joining Bristows Alan worked in the IP department of the London offices of two major US law firms. Before entering the legal profession, he was a Post-Doctoral Research Fellow at University College London and a Lecturer in Chemistry.

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