

# BIO TECH



REVIEW  
ISSUE 2

BRISTOWS

---



# Index



Issue 2 | 2014 | [www.bristows.com](http://www.bristows.com)

## Introduction

**1** Dr Robert Burrows,  
Partner, Bristows LLP

## Patent litigation

**2** The broader research  
exemption

**3** How much information  
does a valid antibody patent  
need?

**5** Patentability of human  
embryonic stem cells

**7** CJEU – Bayer  
CropScience AG (C-11/13)

**7** Eli Lilly v HGS [2014]  
EWHC 2404 (Pat)

**9** UPC and unitary patents

**10** UPC and the plant  
breeding exemption

**11** Biotech trends for the  
future

## Competition

**13** Recent competition  
enforcement activity in the  
pharmaceutical sector –  
relevance for biotech?

**15** Lessons for licensing:  
the new technology transfer  
block exemption

## Commercial

**17** Dare to share? Proposed  
new directive should help  
protect your confidential  
information when doing  
business in Europe

**19** Dawn of the era of  
personalised medicine –  
the UK takes the lead

## Tax

**20** The UK – a good place  
for biotechs

## Q&A with Nick Finnie

**21** The Head of Intellectual  
Property at Novartis  
Vaccines and Diagnostics  
provides his view of the  
changing life sciences  
landscape

## Quick facts

**22** Quick facts about our  
life sciences practice

## Editorial team

**23** Meet Bristows' editorial  
team

# 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.

**robert.burrows**  
**@bristows.com**  
**+44 (0)20 7400 8000**

Welcome to the latest edition of Bristows' Biotech Review. Once again this publication is designed to provide an update on some of the key developments in this area in recent times. Articles have been organised by legal practice area and, this time around, include updates on the patentability of stem cells, recent case law on supplementary protection certificates, legislation on the protection of confidential information, the tax regime for biotech companies in the UK, and what the biotech industry can learn from competition enforcement activity in the pharmaceutical sector. We also provide more detailed analysis of UK cases to date on antibodies and ask the very important question: how much information does an antibody patent need to contain?

As many of you will inevitably be doing at present, we provide our latest thoughts on the Unified Patent Court (about which more information can be found at [bristowsupc.com](http://bristowsupc.com)) and trends we are likely to see within the biotech field in the years ahead.

With many thanks for his time and willingness to assist, we close with a Q&A with Dr Nick Finnie of Novartis Vaccines and Diagnostics.

As with all our publications, we welcome any feedback you might have and would be delighted to provide you with more detail on any of the articles featured in this Review.

# 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.

## The broader research exemption



**Liz Cohen**  
**Partner**  
**Bristows LLP**



**Aida Tohala**  
**Trainee Solicitor**  
**Bristows LLP**

In a development that is sure to be welcomed by innovator pharmaceutical companies, the exemptions from patent infringement under UK law were widened by the Legislative Reform (Patents) Order 2014 (the 'Reform Order'), which came into force on 1 October 2014.

The previous legislative framework provided exemptions for: (1) acts done for experimental purposes (known as the 'experimental use' exemption – s60(5)(b) Patents Act 1977 (the 'PA')) and (2) clinical trials and other activities required for regulatory approval of generic drugs as set out in the EU Directives (known as the 'EU Bolar' exemption – s60(5)(i) PA).

However, narrow UK judicial interpretation of these exemptions, namely by excluding innovator companies from the remit of the UK's take on the EU Bolar exemption, was widely recognised as placing the UK at a disadvantage when compared with the more generous exemptions available in most other EU countries, deterring pharmaceutical companies from choosing the UK as the location for conducting trials and studies.

In a bid to align the UK position more closely with that of continental Europe, the Reform Order broadens the experimental use exemption to now include, *"anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention"*. 'Medicinal product assessment' is defined as meaning any testing, course of testing or other activity undertaken with a view to providing data to:

1. obtain or vary an authorisation to sell or supply, or offer to sell or supply a medicinal product;
2. comply with any regulatory requirement imposed in relation to such an authorisation; and/ or

3. enable a government or public authority or persons with functions relating to providing governmental healthcare to carry out an assessment of the suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.

Medicinal product is defined as including both products intended for human use and those intended for veterinary use. In a notable expansion of the existing regime, the Reform Order includes protection for medicinal product assessment activities involving novel drugs, as well as generics and is, critically, not limited to UK- or Europe-wide assessment activities.

It is hoped that this amendment will lead to greater certainty in the industry, thereby rendering the UK a more attractive location for pharmaceutical trials, which in turn will help with retaining the skilled workforce, as well as potentially provide greater options for patients in the UK seeking what is often last resort experimental treatments.

Despite these significant anticipated

benefits, concerns persist. For instance, concerns pertain to what some might describe as being the overreach of the new exemption. The new exemption could include post-clinical work, which some consultation respondents argued against on the basis that post-clinical work constitutes part of the commercialisation process and, therefore, warrants the necessity of obtaining a licence from the patent holder in respect thereof. A second potential overreach is in relation to 'research tool' patents, being patents covering products used for research on another invention. Whilst the exact definition of research tool is subject to varying interpretations, various consultation respondents advocated that the new exemption should exclude use of research tools to avoid undermining the value of their patents. Nevertheless, the Reform Order wording appears to include use of patented research tools by referring to "anything done in or for the purposes of...any testing, course of testing or other activity". It remains to be seen whether this will have the adverse impact on the research tools market expected by some.

Additionally, uncertainty surrounding whom exactly may benefit from the EU Bolar exemption remains throughout Europe. The question of whether the exemption applies to a third party's supply of patented active pharmaceutical ingredient to a generic manufacturer for use in clinical trials recently arose in parallel proceedings in Germany and Poland. The Polish Supreme Court adopted a narrow interpretation of the exemption, thereby finding that the third party in question, Polpharma SA Pharmaceutical Works, had infringed the underlying patent<sup>1</sup>. In contrast, the Dusseldorf Higher Regional Court took a different view and referred the question to the CJEU<sup>2</sup>. The question has, however, been withdrawn recently such that uncertainty over the scope of the exemption remains.

## How much information does a valid antibody patent need?



**Dr Greg Bacon**  
Associate  
Bristows LLP

The biotechnology revolution has not only arrived, its children number amongst the biggest-selling medicinal products of today.

With sales of such products going from strength to strength, patents protecting them have inevitably faced the scrutiny of the judiciary. Perhaps unsurprisingly in light of mostly early priority dates, questions of novelty and inventive step have rarely been central to the arguments determined by the English Courts. Instead, the focus has been on the quality and extent of the disclosure in the specification, and whether that information can support validity of what are often fairly broad claims. A common theme of recent English antibody patent cases has been the question of whether the information disclosed is sufficiently plausible to support the claimed invention.

## Is the technical contribution plausible?

In *Eli Lilly v Human Genome Sciences*<sup>3</sup>, the Court had to determine the role of plausibility in resolving whether a patent for biological material was capable of industrial application. The patent in question included claims to an antibody that binds specifically to the Neutrokin-α polypeptide. The patent disclosed no proven utility for such an antibody, with the invention being limited to the identification of the nucleotide and amino acid sequence of a previously unknown polypeptide (Neutrokin-α) and its tissue distribution. Any expectations in relation to the potential utility were merely predictions and no experimental evidence to support the predictions was disclosed in the patent. The Supreme Court held that English courts should

follow the principles established at the EPO on the question of industrial applicability. As such, a patent must disclose a practical application and some profitable use for the claimed substance. However, the absence of experimental or wet lab evidence for activity of the claimed compound is not fatal, and a plausible or reasonably credible claimed use can suffice. Moreover, such plausibility can be confirmed by later evidence, although later evidence alone will not do. In this case, due to the identification of Neutrokin-α as a member of the protein superfamily and existing knowledge regarding other members of that family, the plausibility of at least some of the patent claims was sufficient for the patent to be susceptible of industrial application.

The plausibility of an alleged technical contribution may also be relevant to the question of inventive step, as was the case in *Generics [UK] v Yeda & Teva*<sup>4</sup>. As readers will be aware, the English Courts generally apply the structured *Windsurfing/Pozzoli* approach when assessing inventive step. However, in this case the Court additionally assessed obviousness by reference



<sup>1</sup> *Polpharma v Astellas*, (SA I ACa 320/12), 23 October 2013.

<sup>2</sup> *Polpharma S.A. Pharmaceutical Works v Astellas Pharma Inc.* I-2 U68/12, 5 December 2013; *Astellas Pharma Inc.* C-661/13.



## Patent litigation

to the question of whether there was a lack of technical contribution. According to the Court of Appeal, the first step was to identify the technical contribution and then to decide whether the specification made that contribution plausible, which meant no more than that there was some real reason for supposing it to be true. Plausibility did not require a strict test, and the general trend disclosed by the results made it plausible that, as a general proposition, the claimed copolymer-1 was superior to the previously disclosed copolymer-1 which fell outside the claims.

### Is the disclosure sufficient?

The teaching of the Neutrokine- $\alpha$  bioinformatics patent was also the subject of a further dispute when the case was remitted to the Court of Appeal<sup>5</sup>. This concerned whether the patent was sufficient. This argument was framed as 'classical insufficiency', in that it was alleged that whilst the person skilled in the art would know how to raise antibodies against Neutrokine- $\alpha$ , it would involve an undue burden to identify which were useful as this information was not disclosed in the patent. It was

argued that as the patent was directed to antibodies with a valuable use, the claim should be so limited. However, the Court of Appeal rejected the argument on the basis that at the level of generality of the patent in question, all antibodies to Neutrokine- $\alpha$  had a use. Each member of this class was susceptible of industrial application and that was enough. Moreover, the claim itself did not contain any limitation to "useful" antibodies in its context, and there was no reason why the person skilled in the art would read the claim as being so limited.

In the *ReGeneron v Genentech*<sup>6</sup> case, the parties seeking revocation raised wider-ranging insufficiency attacks, again based on the limited nature of the disclosure in the specification in the patent. The patent was to vascular endothelial growth factor (VEGF) antagonists for the treatment of a range of non-cancerous diseases. The claimed antagonists included antibodies to VEGF and the VEGF receptor and the patent described novel antibodies having an effect *in vitro*.

The claimants raised two insufficiency attacks of relevance to this discussion. It was alleged that it was not possible to make a reasonable prediction from the data in the patent that anti-VEGF therapy would be effective in the whole range of diseases claimed (insufficiency for excessive claim breadth). Alternatively, it had since been shown that certain VEGF antagonists are not therapeutically active against some of the diseases claimed. It was thus alleged that the patent did not enable the skilled person to identify without undue effort which diseases could be treated, nor which VEGF antagonists are therapeutically active against which diseases (classical insufficiency).

In this case the Court of Appeal held that a principle of general application was disclosed in the patent, namely the role of VEGF in excessive blood vessel growth and the prediction that non-cancerous diseases characterised by pathological angiogenesis could be treated by targeting VEGF. This therefore justified the breadth of the claim. It was enough to be able to make a reasonable prediction from the data in the patent that the product would

work across the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim must be plausible or credible. According to the Court, if it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case. On the other hand, if it is not possible to make such a prediction or if it is shown the prediction is wrong, then the scope of the monopoly will exceed the technical contribution the patentee has made and the claim will be insufficient. It may also be obvious.

A common theme of recent English antibody patent cases has been the question of whether the information disclosed is sufficiently plausible to support the claimed invention.

With regard to classical insufficiency, the claimants contended that the process of getting the invention to work in the form of an approved treatment for certain diseases falling within the class identified would involve too much by way of research and experimentation. However, the Court held that this was not the correct approach and the fact that a claim may extend to further inventions which make use of the principle disclosed in a patent does not necessarily render the patent insufficient. The absence of an approved treatment was not an adequate evidential approach to an allegation of classical insufficiency in a case such as this, as this would impose too high a standard.

To be contrasted with the favourable decisions (to the patentee) in the *Eli Lilly v Human Genome Sciences* and *ReGeneron* cases is the *Eli Lilly v Janssen*<sup>7</sup> case. The patent claimed

<sup>3</sup> [2011] UKSC 51.

<sup>4</sup> [2013] EWCA Civ 925.

<sup>5</sup> [2012] EWCA Civ 1185.

<sup>6</sup> [2013] EWCA Civ 93.

<sup>7</sup> [2013] EWHC 1737 (Pat).



## Patent litigation

the use of a class of antibodies against  $\beta$ -amyloid for the treatment of Alzheimer's disease and related disorders. As in the *ReGeneron* case, the patent was attacked for failing to enable the invention to be performed without undue burden (classical insufficiency) and for failing to enable the invention to be performed over the whole scope of the claim (excessive claim breadth).

The argument again focussed on whether the disclosure in the patent made it plausible that any antibody to  $\beta$ -amyloid could be used for the claimed uses. The specification contained *in vivo* data generated from an established animal model of Alzheimer's disease, in which a number of antibodies were tested. The specification thus predicted that antibodies against  $\beta$ -amyloid might be useful in treating Alzheimer's disease, a hitherto incurable disease. On excessive claim breadth, the Court followed the approach of the Court of Appeal in *ReGeneron*, in that it must be possible to make a prediction that the invention would work with substantially everything falling within the claim. In this case, it was plausible that immunisations with a suitable antibody against  $\beta$ -amyloid would be effective to prevent and/or treat a disease characterised by amyloid deposit. However, it was not plausible that this could be achieved with any such antibody. Examples in the patent specification suggested that only antibodies against the N-terminal of  $\beta$ -amyloid would work and so the patent was insufficient for excessive claim breadth. Moreover, the patent was held to be invalid for classical insufficiency as it did no more than invite the skilled person to perform a very significant research project with a high prospect of failure and, if that was successful, then claim the fruits of that research. The patentee in this case therefore appeared to be in a worse position than that in the *ReGeneron* and *Eli Lilly v Human Genome Sciences* cases, as in those cases the patentee was able to rely on having demonstrated a principle of general application, having done less lab work (in the latter case none at all).

### Post-filed data

The English Courts have also clarified the role of post-filed data in determining the plausibility of the technical disclosure of a patent. The Court of Appeal in *Generics [UK]* determined that post-filed evidence could be confirmatory of the plausibility of the alleged technical advantage supporting inventive step, but could not by itself demonstrate plausibility. Moreover, if the post-filed data subsequently demonstrated that the alleged technical contribution was no longer plausible, that could be relied on by the other party to undermine a patent. In *Eli Lilly v Janssen*, the Patents Court made the same observations on post-filed data in relation to the question of whether it was plausible that the invention would work across the full scope of the patent claims.

### Conclusion

The English courts have to date taken a generous approach to first generation antibody patents, where a principle of general application can be identified. When the questions of technical contribution and plausibility are tested at this level, the patentee has been given the benefit of the doubt to claim entire antibody classes, even where there is no or little evidence in the patent that the claimed antibodies will have any clinical utility or where the therapeutic pathway has yet to be established. However, it is already clear that second generation antibody patents are unlikely to fare so well. In the future it will not be possible to disclose a principle of general application as this will already form part of the prior art. In those cases it would appear that the disclosure will be subject to greater scrutiny, particularly as to whether it can support a broad claim. Due to the nature of antibodies, patent claims limited to the exact structure of an identified clinical candidate are likely to be of limited value to patentees and thus lack of broad, functional patent protection in the future causes will cause concern. Furthermore, due to the increased level of scrutiny it is likely that patentees will be expected to include data from multiple example antibodies in order to identify a technical advance over the prior art, exposing patents to excessive claim breadth insufficiency challenges as seen in the *Eli Lilly v Janssen* case.



## Patentability of human embryonic stem cells



**Dr Laura von Hertzen**  
Associate  
Bristows LLP

With the fast pace at which stem cell research is advancing, having clarity on the patentability of technology based on the use of human embryonic stem cells ('hESCs') is essential to the biotechnology sector, where funding for R&D is very much dependent on patent portfolios. It is not surprising, therefore, that in recent years the patentability of such technology has been the subject of considerable consideration, including by the Court of Justice of the European Union (CJEU), and by the European Patent Office (EPO).

In our last edition we reported on the CJEU decision in *Brüstle v Greenpeace* (C-34/10) and its application by the German Federal Supreme Court. Although *Brüstle* provided some clarity in this field, two main issues



## Patent litigation



remained uncertain. First, would the EPO, an international organisation not legally bound by the decisions of the CJEU, change its practice with regard to the patentability of hESC-related applications in light of this decision? Second, were parthenotes, which do not have the capacity of developing into a human being, patentable?

An answer to the first question was provided by the Technical Board of Appeal ("TBA") of the EPO on 4 January of this year in T2221/10. Since the Enlarged Board of Appeal ("EBA") decision in WARF (G2/06), the Examination Division of the EPO had adopted a pragmatic approach allowing hESC-related patent applications if deposited hESC-lines were available on the filing date of the patent. This was based on the reasoning that since hESC lines were available that did not necessarily involve the destruction of a human embryo, the patents should escape the exclusion from patentability. In *Brüstle*, the CJEU held, inter alia, that "an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires

the destruction of human embryos. The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere reproduction of which implied the destruction of human embryos is, in that regard, irrelevant". This decision appeared to go further than that of the EBA in WARF.

In T2221/10, the TBA confirmed that the decision of the EBA in WARF was not limited to patent applications with a filing date at which no established cell lines were available. Consequently, it held that inventions which make use of publicly available hESC lines which are initially derived by a process resulting in the destruction of the human embryos are excluded from patentability.

The TBA noted that its decision was in line with the CJEU's decision in *Brüstle* and, although CJEU decisions are not legally binding on the EPO or its boards of appeal, they should be considered persuasive.

However, the possibility of obtaining patents in this field may not be entirely negative. On 17 July 2014, Advocate General Cruz Villalón addressed the question of patentability of parthenotes in his opinion in International Stem Cell Corporation (C-364/13). He opined that the term "human embryos" in Article 6(2)(c) of the Biotech Directive (98/44/EC) does not include parthenotes, as long as they are not capable of developing into human beings and have not been genetically manipulated to acquire such a capacity.

In *Brüstle*, the CJEU interpreted "human embryo" somewhat broadly, holding that it covered any cells that, following fertilisation, are subsequently "capable of commencing the process of development of a human being", and, in answer to one of the questions referred, that it included "unfertilised human ova whose division and further development have been stimulated by parthenogenesis". Struggling with that answer, the English Patents Court – considering an appeal of the decision

the UK Intellectual Property Office that two patent applications relating to methods of producing human stem cells using parthenogenesis be refused pursuant to Article 6(2)(c)) – asked the CJEU whether the ruling in *Brüstle* applies in relation to parthenogenetically activated unfertilised human ova "which in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings".

A parthenote does not, per se, have the required inherent capacity of developing into a human being and hence does not constitute a human embryo.

According to the Advocate General, the Court in *Brüstle* had not been made aware of the fundamental difference between parthenotes and non-fertilised ova subjected to somatic cell nuclear transfer and consequently were under the impression that both possessed the inherent capacity to develop into a human being (as did fertilised ova) – according to current scientific knowledge, genomic imprinting prevents human parthenotes from developing to term. Given the facts stated unequivocally by the referring court and the parties to these proceedings, he was of the view that a parthenote does not, per se, have the required inherent capacity of developing into a human being and hence does not constitute a human embryo. Consequently, in his opinion the question referred by the Patents Court should be answered in the negative. However, this answer should be subject to the caveat that such parthenotes are not capable of developing into a human being and have not been genetically manipulated to acquire such a capacity.

It remains to be seen whether the CJEU follows the opinion of the Advocate General. If it does, it will provide some relief to biotechnology companies working in this area.

## CJEU – Bayer CropScience AG (C-11/13)



**Katie Hutchinson**  
Associate  
Bristows LLP

On 19 June 2014 the Court of Justice of the European Union ("CJEU") gave its ruling on a preliminary reference from the Bundespatentgericht (Germany). This reference asked the CJEU to determine whether a safener may be granted a Supplementary Protection Certificate ("SPC") under the SPC regulation on plant protection products (Regulation 1610/96). In its ruling the CJEU held that a safener can be an "active substance" and so the subject of an SPC.

The reference related to Bayer's application for an SPC for a safener (isoxadifen). Safeners reduce the toxic effects of plant protection products on certain plants and are used to increase their effectiveness by improving their selectivity and by limiting their toxic or ecotoxic effects. Because a safener does not protect plants against harmful organisms, but is intended to prevent the harmful effects of a herbicidal active substance in order to increase its effectiveness, the German Court questioned whether it was an "active substance" and, therefore, a "product" for which an SPC may be granted under the Regulation.

In its decision, the CJEU followed the AG's opinion and held that the terms "product" and "active substance" should be interpreted as covering a substance intended to be used as a safener *"where that substance has a toxic, phytotoxic or plant protection action of its own"*. The Regulation defines "active substances", in summary, as substances having general or specific "action" against harmful organisms, or on plants or plant products. The CJEU held that, since the Regulation makes no distinction according to whether that action is direct or indirect, there was no

need to restrict "active substance" to a substance whose action is direct. The CJEU recognised that a safener may increase the effectiveness of a plant protection product, and held that it is for the national court to ascertain, in light of the relevant factual and scientific evidence, whether the safener is acting in such a way and so can be classified as an "active substance".

A substance which does not have a toxic, phytotoxic or plant protection action cannot be an "active substance".

The CJEU noted that its interpretation that a substance which does not have a toxic, phytotoxic or plant protection action cannot be an "active substance" corresponds to the interpretation already applied in respect of medicinal products – the CJEU having held that a substance with no pharmaceutical effect of its own, such as an excipient or an adjuvant, is not an active ingredient and so cannot give rise to the grant of an SPC (*MIT* C-431/04, *GSK Biologicals* C-210/13). However, it is interesting to note that in the *GSK* case the CJEU attached weight to the distinction made between "active ingredient" and "adjuvant" in the Medicinal Code (Directive 2001/83) whereas in this case the CJEU noted that, although there was a distinction made between "active substances" and safeners in the Directive concerning the placement of plant protection products on the market (91/414 and its replacement, 1107/2009), this did not lead to the definitive conclusion that safeners could not be the subject of an SPC.

## Eli Lilly v HGS [2014] EWHC 2404 (Pat)



**Laura Reynolds**  
Of Counsel  
Bristows LLP

In December last year the CJEU handed down its decision in the *Lilly v HGS* (C-493/12) reference, which concerned Supplementary Protection Certificates ("SPCs") and, in particular, the correct interpretation of Article 3(a) of the SPC Regulation – when is a product "protected" by a basic patent? The issue arose in Lilly's claim that any SPC based on HGS' EP (UK) patent relating to a new protein and to antibodies binding to that protein, and on an MA for Lilly's specific antibody, tabalumab, would be invalid as the antibody was not "specified in the wording in the claims" (following the CJEU's interpretation of Article 3(a) in *Medeva* (C-322/10)). The relevant patent claim was broadly worded, referring to "An isolated antibody... that binds specifically to...", and this functional definition would cover an unknown number of otherwise unspecified antibodies, including tabalumab, which Lilly accepted would infringe the patent. The CJEU held that to be "protected" by a basic patent it was not necessary for an active ingredient to be identified in the patent claims by a structural formula. It was sufficient if the active ingredient was covered by a functional formula in the claims, provided that it was possible to conclude from the claims that they, implicitly but necessarily and specifically, related to the active ingredient (which was a matter to be determined by the referring court).

The CJEU also commented upon an aspect of the Lilly case which had been abandoned by Lilly and was not included in the reference – should a third party (HGS) be allowed to apply for an SPC based upon an MA obtained by another, unconnected party (Lilly) ("piggybacking"). The CJEU noted that refusing an SPC application may

## Patent litigation

be justified where the patentee had *"failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of [Recital 4 of the SPC] Regulation"*.

The case was then restored before Warren J in the High Court, who faced the unenviable task of implementing the CJEU's ruling. Following a hearing which took place over two days in May and June 2014 (in which both parties argued strenuously the CJEU had found in their favour), Warren J refused to grant the declaration sought by Lilly that any SPC granted to HGS for tabalumab, (based on HGS' patent) would be invalid.

Warren J considered that the CJEU ruling was unclear and unsatisfactory in many respects. However, in his view, the most important aspects of the decision were: (i) that the CJEU had held that the protection conferred by a basic patent was to be assessed with reference to the *"extent of the invention"* covered by the patent as provided for by section 125 UK Patents Act and Article 69 EPC and (ii) that the CJEU had again expressly rejected the infringement test.

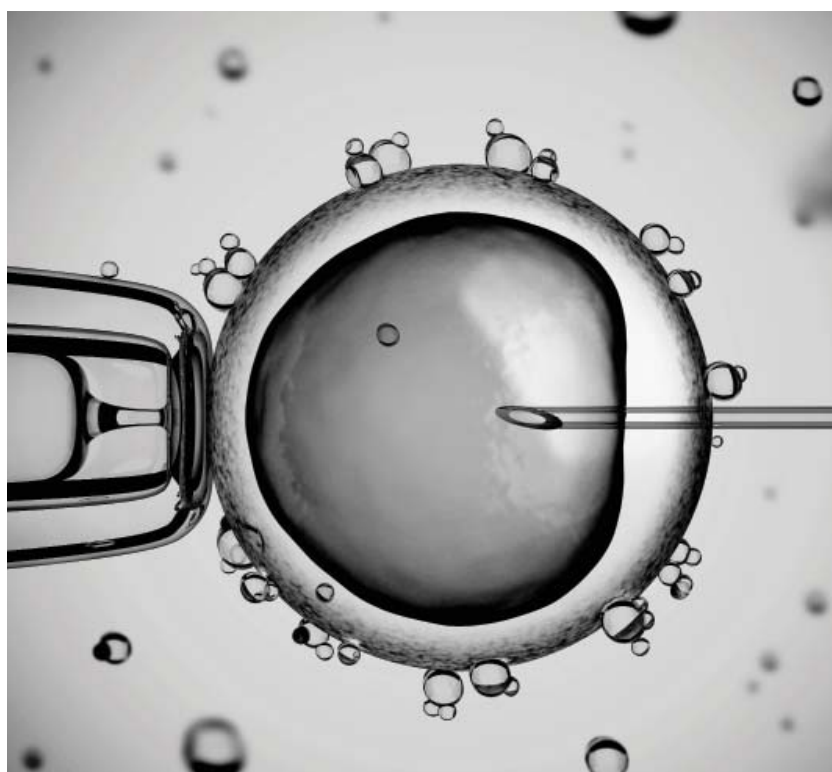
The judge considered that assessment using the *"extent of the invention"* test should be subject to one proviso – namely that where the claims contain some general word or words extending their scope beyond the principal wording of the claims, a product would not be considered to be *"specified"* unless it fell within the claim absent the general words. In other words, if a patent is directed to *"A"* but contains a claim to *"a pharmaceutical composition comprising A"*, A+B would not be protected by this patent even though *"comprises"* means *"contains but is not limited to"* under EPC drafting

conventions. Warren J set out that the task of the Court is to consider *"what a patent is and is not 'really about'"* and noted that, although this is not the (rejected) infringement test, it will give the same result as the infringement test *"in many cases"*.

In relation to the *"piggybacking"* issue, Warren J noted that the purpose of the SPC Regulation was to encourage all kinds of pharmaceutical research. On this basis, the judge thought it was not right in principle that the satisfaction of Article 3(a) depended on who carried out the research leading to the MA for the product for which the SPC had been sought. He noted the comments from the CJEU on this aspect were in relation to an issue which had been formally abandoned and that the CJEU had exceeded its jurisdiction insofar as it had found as a fact that HGS had failed to carry out the research to identify its invention specifically.

For the author, a curious aspect of the judgment was where the judge found that the CJEU used the same words *"specified/identified"* to mean different things in its ruling. In essence, the judge's finding was that, following Medeva, in order to satisfy Article 3(a) a product must be specified/identified in the claims of the basic patent and that when the CJEU used the word *"identified"* in that context it meant *"fell within the scope of protection of"*. However, when the CJEU opined that tabalumab could not be *"identified"* in the HGS patent it meant *"described as such"* in a more restrictive sense. Thus, although the CJEU had expressly held: (i) it was necessary for a product to be identified in the claims of a patent for Article 3(a) to be satisfied; and (ii) tabalumab was not identified by the claims of HGS' patent using the same word in virtually consecutive paragraphs of the ruling, this did not mean that tabalumab was not protected by the basic patent for the purposes of Article 3(a).

As expected, the judgment has been appealed and it will be interesting to see what the Court of Appeal makes of the CJEU's latest pronouncement. In the meantime, the piggybacking issue remains ripe for a further reference.



## UPC and unitary patents



**Alan Johnson**  
Partner  
Bristows LLP

On 19 February 2013, the agreement was signed to create a new Unified Patent Court for Europe and the European Commission announced that it hoped the new system would start by early 2014. Within months that date had been pushed back to "early 2015". Recently it was pushed back further to "not before the end of 2015". Hence, the official position is that the new regime is actually further away than when it was announced. In truth it now seems unlikely that it will start for at least two years from now, and more likely not before 2017. Nonetheless, it remains highly probable that within the foreseeable future, the new system will be in place: it is simply that there is an awful lot to do. This is the first time Europe (or perhaps anyone) has set up a new first instance international court. It will probably operate in a dozen or more different languages, have no less than 17 different first instance divisions located in at least 10 different countries, plus an appeal court in another country, arbitration centres in two more countries, and a training centre in a yet further country. The EPO also has to organise itself to grant the new unitary patent. Numerous sets of rules need to be agreed, systems (including IT) have to be set up, buildings fitted out, and staff (not least of all judges) appointed and trained. Perhaps most difficult of all, the costs (and fees) need to be worked out, and the money found to pay for it all.

Does this mean that readers can safely sit back and worry about the new system another day? To some extent, yes, but in other respects it is vital to understand what is coming. This is not just by way of long-term planning, but for one or two shorter term practical reasons.

One crucial matter to be aware of is that the patents being applied for now at the EPO will be in the new system.



The way this works is that the day the system goes live, all existing "classical" European patents are automatically under the jurisdiction of the UPC. It is possible to opt them out, but the way in which the opt out works is not yet truly clear. There is a conventional view that one can opt these patents (and their SPCs) out for their entire life, and that this opt out excludes the UPC jurisdiction totally. However, that may not be correct, and it is at least possible that one way or another, these patents may be subject to the UPC regime. Put graphically, one might be happy thinking that a competitor seeking to revoke one's patent would have to knock it out in multiple courts at significant cost, but less happy to discover that in fact it could be knocked out in a single action in the central division of the UPC. Hence, an awareness of the risks seems at least sensible.

Even if the conventional view is correct, giving consideration to whether one would actually want to opt patents out or not can never be done too early. One reason for this is the complication presented by licensing arrangements. It is the proprietor (meaning all proprietors of all national parts existing in all UPC Contracting States) who must opt out. Licensees do not formally have a say and certainly cannot themselves opt out. However, licensees may very well want a say. Existing licence agreements are unlikely to deal with this matter of the opt out, so negotiations will be needed and may take some time.

Likewise, licences being negotiated now should be drafted so as to take the opt out regime into account. In the same manner, any collaboration agreements being negotiated now should deal with the new possibility of the unitary patent being sought instead of the "classical" European patent. In this regard, it is noteworthy that any EPO application pending at the time the system goes live can, upon grant, be the subject of a request for unitary protection. So again decisions about this need to be considered in advance, and policies agreed between collaborators. There are other surprising factors to take into account too, such as that it may affect applicable law which applicant among joint applicants is listed first on the application.

There will, of course, be budgetary implications of the new system. Notable among these is the cost of seeking unitary protection and maintaining such patents. Normally budgets will be set many months in advance, and hence if the system were to start in (say) late 2016, this will require budgetary decisions in 2015 at latest. In fact, no adequate information on fees etc. is likely before early 2015, but patentees need to be alive to the issues as soon as possible after the fees are known.

The changes which are happening are the most important in Europe for 40 years. There is much to think about. Getting to grips with the new system now is vital.



## UPC and the plant breeding exemption



**Alan Johnson**  
Partner  
Bristows LLP



**Steven Willis**  
Trainee Solicitor  
Bristows LLP

On 10 June 2014 the UK government published a draft Statutory Instrument, pursuant to the authority conferred by s17 of the Intellectual Property Act 2014, concerning proposed changes to UK legislation designed to give effect to certain provisions of the Unified Patents Court Agreement ("UPCA"). The draft legislation was open for consultation until 2 September 2014 and it is intended that the proposed changes will come into force when the UPCA itself enters into force.

Among the proposed changes is the addition of a new subsection in section 60(5) Patents Act 1977 to provide for an exemption to patent infringement for "the use of biological material for the purposes of breeding, or discovering and developing other plant varieties" (the "Plant Breeding Exemption"). Such an exemption is included in Article 27(c) of the UPCA and is already provided for in the national legislation of a number of major EU jurisdictions including France and Germany.

---

### **The introduction of the Plant Breeding Exemption into UK law is likely to have a significant impact on companies involved in the development of plant varieties in the UK.**

---

The introduction of the Plant Breeding Exemption into UK law is likely to have a significant impact on companies involved in the development of plant varieties in the UK. Although it is not

possible to patent plant varieties per se, it is possible to patent inventions relating to plants if the invention does not concern a single plant variety. As such, as patent law currently stands in the UK, plant breeders wishing to make use of patented biological material in the development of new plant varieties could not do so without risking liability for patent infringement.

The Plant Breeding Exemption will apply equally to Unitary Patents, European Patents and GB Patents. It is notable that it will not apply to the commercialisation of new plant varieties. It is possible however that patented biological material could be used in the development phase and then "bred out" before commercialisation. The proposed amendment will be welcome to companies involved in plant-based research with UK-based research capabilities and those wishing to transfer plant varieties in development between countries.





## Biotech trends for the future



**Dr Dominic Adair**  
Partner  
Bristows LLP

*"Trying to predict the future is like trying to drive down a country road at night with no lights while looking out the back window".* Austrian management consultant Peter Drucker's quotation doesn't lend much encouragement to the exercise of predicting the future trends in the world of biotech, but looking backwards is not a bad place to start. In this short article, we will offer some tentative predictions based on recent history.

## 1 Biologic drugs will dominate the market

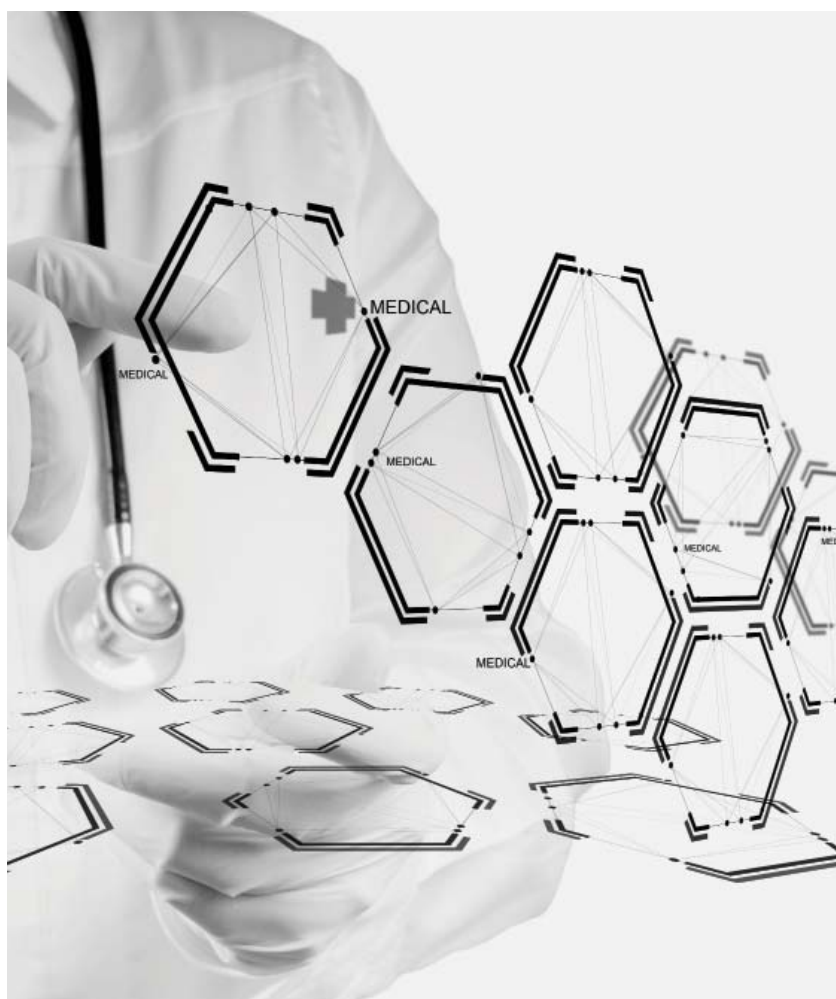
In the past few years, sales of biologic drug products have grown rapidly. In 2012, biologic sales in the US grew by 20%, compared to pharmaceutical sales which grew by 2%<sup>8</sup>. For years, predictions of top drug sales have been dominated by biologic products and at least in this regard, predictions have been accurate. Seven out of the global top 10 selling blockbuster drugs of 2013 were biologics. In 2007, only one of the top 10 was a biologic. It is safe to say that the commercial importance of biologic drugs is here to stay. Many of the top selling products treat autoimmune diseases and cancer, conditions where patient populations are large and the willingness to pay high prices is strong.

Some have highlighted what has been called an impending patent cliff for biologics<sup>9</sup>. Within the next 5 years some of the biggest selling biologic drugs are said to be coming off patent. But the true impact of this is less certain. Secondary patents may give some of these products a softer landing. Biologic products are sometimes tied to sophisticated delivery devices, often themselves patented, and surrounding patient care programmes also create disincentives to switch. Market penetration from competitors has historically been low and there are good reasons to assume that there will be no sudden change in that regard.

## 2 Biosimilars will rise but litigation will not follow the generic model

It is well known that the pathway to regulatory approval for biosimilars – follow-on biologic products designed to imitate approved pioneer products – is tough. Classical small-molecule generics need only prove bioequivalence with a reference product via bioavailability studies done in the lab. Biosimilars must demonstrate comparable safety and efficacy by performing extensive pre-clinical testing and potentially also clinical trials in patients. The average cost of bringing a biosimilar to market is difficult to quantify but estimates range from 100 to 250 million US dollars<sup>10</sup>, hundreds of times greater than the cost of a typical small molecule generic. There are presently 17 approved biosimilar products in Europe<sup>11</sup> but none in the US. It was reported by Sandoz this summer that they had successfully filed with the FDA the first biosimilar authorisation application under the US regulatory pathway<sup>12</sup>.

Plainly, therefore, the competitive landscape for biologic products is different from that in the world of small-molecule pharma. Innovators may face one or two competitors per product, but not 10 or 20. This is likely



## Patent litigation

to change the game when it comes to patent enforcement strategies. In the small-molecule world, one of the key arguments when seeking a preliminary injunction is that there will be a “feeding frenzy” of competition which irrevocably drives down price and results in irreparable harm unless the generic is enjoined. It is not at all clear that the same can be said in the world of biologics. Time will tell, but if and when the volume of biosimilar litigation increases, preliminary injunctions may not be a weapon that can be regularly deployed.

### 3 The character of patent challenges may change

At least in the UK courts, it is notable that the most prominent attacks against the validity of biologic patents have concerned alleged flaws with the patent specification itself – intrinsic defects such as lack of sufficiency of teaching<sup>13</sup>, lack of industrial applicability<sup>14</sup> and lack of plausibility in technical contribution<sup>15</sup>. This may reflect that biologic patents are often filed very early, high upstream, before any downstream therapeutic use is identified. It may also indicate that the field is relatively open compared to other technical areas. It seems reasonable to assume that, over time, as the technical field becomes more crowded and as patents move downstream, the character of patent challenges may shift more towards those attacks made relative to the prior art – obviousness and (in a very crowded field) novelty.

### 4 SPCs – piggy-backing will not be allowed

Given the very high cost of bringing a biologic product to market, there can be a tension between those who say they own the patent rights to a product, and those who say they have done the work to bring the product to market. This was brought to the fore last year with the CJEU decision in *Lilly v HGS*<sup>16</sup>. The CJEU indicated that such hostile

“piggy-backing” would be contrary to the objectives the SPC Regulation in circumstances where “the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically” and “had not made any investment in research relating to that aspect of his original invention”<sup>17</sup>. Hence, in the future, patent holders may not be able to extend their patent rights unless they also play in the market. The hostile MA issue is not closed, however – it was abandoned upon the case returning to the UK court to hear other arguments<sup>18</sup> so remains ripe for a further reference to the CJEU.

### 5 Litigation volume may not fall

One of the hardest predictions to make is whether we will see much litigation by biologic patent holders against biosimilar follow-on products. Some suggest that the patent hurdle to biosimilar market entry is illusory, and that it is the regulatory, technical and financial hurdles that matter<sup>19</sup>; development times could be so long that patent terms are too short to block the path. To date in the UK, there have been very few reported cases concerning biosimilars. The reason for this is difficult to identify. Is it the aforementioned lack of a real patent hurdle or is it simply because there are fewer competitors in the market, or because there is a time lag between commercial success and patent litigation? The recent case of *Hospira v Genentech*<sup>20</sup> concerning Genentech and Roche’s Herceptin® drug (trastuzumab) and what the judge called Hospira’s “generic form” of the drug, is interesting to consider. The facts of the case reveal that an SPC founded on the basic patent for trastuzumab was still in force at the time of the dispute, with just a few months remaining – a right that Hospira did not wish to challenge. The patents in suit in the case were secondary patents. Three were asserted but one was later dropped by Genentech. The two that were the subject of the UK case concerned a dosage regimen and a

composition with certain purity levels. Both had been held invalid by the EPO Opposition Division and were pending appeal. Both were also held invalid by the Mr Justice Birss.

Whilst generalisations cannot be made on the basis of just one case, it is nonetheless interesting that there is nothing fundamentally different about the character of this case from those that traditionally exist in the small-molecule world. Perhaps one might predict that there will be more litigation in biosimilars than in small molecules. The number of players is smaller but the incentives to litigate, reflecting higher product investments, are greater. Only time will tell.

<sup>8</sup> Nature Biotechnology volume 32, issue 1, page 32 (January 2014).

<sup>9</sup> Calo-Fernandez and Martínez-Hurtado (2012) Pharmaceuticals 2012, 5, 13-93-1408.

<sup>10</sup> Blackstone & Fuhr (2013): The Economics of Biosimilars. Business Vol 6, No.8.

<sup>11</sup> [www.ema.europa.eu](http://www.ema.europa.eu)

<sup>12</sup> [www.sandoz.com/media\\_center/press\\_releases\\_news/global\\_news/2014\\_07\\_24\\_FDA\\_accepts\\_Sandoz\\_application\\_for\\_biosimilar\\_filgrastim.shtm](http://www.sandoz.com/media_center/press_releases_news/global_news/2014_07_24_FDA_accepts_Sandoz_application_for_biosimilar_filgrastim.shtm)

<sup>13</sup> *Lilly v Janssen Alzheimer Immunotherapy* [2013] EWHC 1737 (Pat)

<sup>14</sup> *Lilly v HGS* [2011] UKSC 51.

<sup>15</sup> *Mylan v Yeda & Teva* [2013] EWCv 925.

<sup>16</sup> CJEU judgment in Case C-493/12 dated 12 December 2013.

<sup>17</sup> *Ibid* at §43.

<sup>18</sup> *Lilly v HGS* [2014] EWHC 2404 (Pat).

<sup>19</sup> *Extending Rewards for Innovative Drug Development – A report on SPCs for the Intellectual Property Institute.*

<sup>20</sup> *Hospira v Genentech* [2014] EWHC 1094 (Pat).

# Competition



## Our competition practice

Our lawyers are recognised as experts in both national and EU competition law, with 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.

## Recent competition enforcement activity in the pharmaceutical sector – relevance for biotech?



**Sophie Lawrance**  
Associate  
Bristows LLP



**Maria Georgiou**  
Associate  
Bristows LLP

The past few years have seen European regulators increasingly clamp down on pharmaceutical companies. This has resulted in a spate of fines across the industry amounting to hundreds of millions of pounds. There is the possibility that such fines could spill over into the biotech industry where the market dynamics may be perceived by regulators to be similar. Below is a brief round-up of the most significant cases.

### 'Pay for Delay' Cases

The European Commission ("Commission") launched its inquiry into the pharmaceutical industry back in 2008 with a series of Dawn Raids. Since its inquiry, the Commission has increasingly focused on settlement agreements in patent litigation. According to the Commission, a patent settlement agreement involving a 'value transfer' from the originator company to the generic company in return for the latter's restrictions on entry results in that agreement being categorised as a restriction of competition by object, the most serious kind of competition infringement. To date, the Commission has adopted two decisions on this basis. The first was adopted in June 2013 against Lundbeck, Alpharma, Merck, Arrow and Ranbaxy resulting in fines totalling €145 million. The second was adopted a year later in July 2014 against Servier, Niche/Unichem, Matrix, Teva, Krka and Lupin resulting in fines totalling €427.7 million. In the latter case, the Commission has identified an abuse of a dominant position, suggesting that the trend towards the use of very narrow market definitions in this sector has been maintained.

The UK's Competition and Markets Authority ("CMA") has also been active in pursuing patent settlement agreements following the issue of its Statement of Objections in relation to certain agreements entered into by GlaxoSmithKline (GSK) and various generic companies concerning GSK's product paroxetine. No decision has yet been adopted but, given the Commission's stance on such agreements, it is likely that the CMA will follow suit.

The categorisation of such agreements as by object is novel and unprecedented. Such categorisation is usually reserved for agreements involving classic cartel type conduct, such as price-fixing and market sharing, which is plainly harmful to consumers and society. For less obvious or novel infringements, a full effects-based analysis is usually required. Indeed, in the US a recent finding by the US Supreme Court in *Actavis v FTC* found that patent settlement agreements should be subject to anti-trust scrutiny under the 'rule of reason' approach which bears greater similarity to an effects-based analysis. In view of the novelty of the offence, the extent of the

## Competition

fines in both *Lundbeck* and *Servier* is striking and certainly worrying for the industry.

The Commission's approach to the legality of patent settlements under the competition rules means that parties to patent litigation will find it difficult to reach a genuine compromise in circumstances where both parties continue to advance their respective cases, but have other reasons for wishing to extract themselves from the litigation. The effect of the Commission's stance is that either one side must give up or both parties must fight to a judicial outcome. The reason for this is the very broad approach which has been adopted by the competition authorities to the concept of 'value transfer'. This includes not just cash payments, but also agreements which contain, for example, a licence or product supply agreement from the originator to the generic. As a result of the Commission's new policy, companies will be deterred from achieving a genuine settlement to a patent dispute and many pro-competitive agreements will be shelved. This surely represents an unintended consequence of the Commission's competition policy because such agreements are generally regarded as beneficial: they free up court resources and in some jurisdictions, such as the UK, companies are actively encouraged by the courts to settle litigation.

The existence of a 'value transfer' can often be explained by the asymmetry of risk between the originator and generic company.

The existence of a 'value transfer' can often be explained by the asymmetry of risk between the originator and generic company. A generic company threatening to launch a potentially infringing product has very little to lose if it does not launch (the development and production costs for generic

companies are comparatively low given that they are simply a copy of the originator product). On the contrary, the risks for the originator company are often very high because generic launch results in an almost immediate and irremediable downward spiral in the reimbursement price of the originator product. In those circumstances, it is impossible for the originator company to regain its pre-generic market position if the patent is ultimately upheld. This is a particular concern where interim injunctive relief is difficult to obtain. This asymmetry of risk may be less prominent in the biotech industry because a company launching a biosimilar product will have incurred a significant amount of time and money in the development of its product, typically on a completely different scale from where a generic of a traditional pharmaceutical is launched. This is likely to result in smaller price differences between the original biotech and the biosimilar products, compared to the difference between original and generic medicines. However, as companies focus their efforts on biosimilars, patent litigation in the biotech industry is likely to become increasingly common. If such patent litigation is settled, the terms of that settlement must be carefully scrutinised to ensure they are in line with competition law.

### Pharmaceutical distribution and pricing

A number of investigations have been carried out in relation to the distribution of pharmaceuticals, both at national and Commission level.

In 2009, the Commission launched an anti-trust investigation into generic pharmaceutical companies in France. The investigation focused on suspected co-ordination between generic pharmaceutical companies when negotiating an initial price with the French pricing authority before launching a new generic product. According to the Commission, the regulatory framework had the potential to allow for such pricing co-ordination between generic competitors. The inquiry was closed on 9 July 2014 without any further action. However,

in its press release closing the investigation, the Commission referred to its recent decisions concerning so-called 'pay for delay' agreements as well as ongoing proceedings against Teva and Cephalon. Whilst the Commission did not appear to find any unlawful conduct as a result of its inquiry into generic pharmaceuticals in France, it is clear that the Commission continues to take inspiration from its recent 'pay for delay' cases.

Issues concerning the potential for using drug pricing to limit parallel trade are also back on the agenda following an appeal by the European Association of Euro-Pharmaceutical Companies ("EAEPC") of the Commission's decision to close an investigation into a 'dual pricing' strategy used by GSK in Spain. This case has a long history, with the Commission originally finding that the scheme – whereby GSK's drugs in Spain were sold at a higher price if destined for export – infringed, but the Court of Justice eventually ruling that the Commission needed to reassess its conclusions in the light of the specificities of the pharma sector. It appears that the Commission will now have to defend its subsequent decision to drop the investigation before the General Court. In parallel, the Commission is also understood to have an investigation running into the use of dual pricing in Spain more generally.

In the UK, the CMA announced an investigation into distribution and pricing of pharmaceutical products in May 2014. No further details have yet emerged. The CMA has a number of other ongoing investigations in relation to the pharma sector.

### Promotion and denigration

Another issue which has attached the competition authorities' attention is the promotion of originator products, in particular at around the time when generics come onto the market. The French Competition Authority has been particularly active in this area, fining Sanofi-Aventis and Schering Plough in separate cases for abuse of a dominant position, arising from the companies'



'denigration' of generic drugs. For more detail about this issue, please see Bristows' Microsite: [bristowsclipboard.com](http://bristowsclipboard.com).

The French decisions are in line with the European Commission's findings in its 2009 Pharmaceutical Sector Inquiry Report, as well as the Commission's decisions in the 'pay for delay' cases. As such, there is a risk that the Commission and other national competition authorities will pursue similar behaviour as anti-competitive in future. The principle underlying these cases could also be applied to the denigration of branded competitor products in the biotech/biosimilar context. Given the narrow way in which the competition authorities define the relevant market in the pharmaceutical sector a cautious approach should be taken by companies when mentioning competitors' products to healthcare professionals.

## Conclusion

Whilst the above cases relate to the pharmaceutical sector, it cannot be excluded that the regulators' stance will spill over into the biotech sector given that the market dynamics have some similarities. The importance of such products for consumers and the unrelenting pressure on national health budgets makes it worthwhile for regulators to keep the sector under review. Practices of biotech companies are particularly likely to attract close anti-trust scrutiny as the biotech industry continues to grow. Companies should carefully consider the practices which they adopt when competing in the EU internal market and if in doubt take a cautious approach. As the recent 'pay for delay' cases demonstrate, even novel infringements can attract significant fines.

## Lessons for licensing: the new technology transfer block exemption



**Sophie Lawrance**  
Associate  
Bristows LLP

On 1 May 2014, a new technology transfer regime came into force in Europe. Like the previous regime, the European Commission's revised technology transfer block exemption regulation ("TTBER") and accompanying guidelines ("the Guidelines") cover the bilateral licensing of IP rights (including patents, know-how and software licenses) for the manufacture of goods and services. Agreements which fulfil the criteria set out in the block exemption will benefit from its safe harbour, automatically being deemed compliant with the prohibition on anti-competitive agreements in Article 101(1) TFEU.

Although the new regime does not mark a drastic departure from the old one, some significant changes have been made to areas including 'terminate-on-challenge' clauses. This will have important implications for licensing in the pharmaceutical and biotechnology sectors.

### No-challenge / terminate-on-challenge clauses

'No-challenge' provisions prevent licensees from challenging the validity of an IP right. Classed as "excluded restrictions" under both the old and the new regimes, they cannot benefit from the block exemption's safe harbour.<sup>21</sup> 'Terminate-on-challenge' provisions, on the other hand, which allow licensors to terminate the agreement if the licensee launches such a challenge, were protected under the old regime. They are commonly used in the biotechnology sector and in IP licensing more generally, providing helpful contractual protection for licensors.

During the consultation, the Commission

controversially proposed removing terminate-on-challenge clauses from the safe harbour entirely. Under the terms of the draft proposal, such clauses were excluded restrictions and their compliance with Article 101 TFEU was therefore to be individually assessed. However, the Commission's proposed stance generated widespread opposition and in the new block exemption, terminate-on-challenge clauses in exclusive licensing agreements will therefore still benefit from the safe harbour: the Commission recognised that in an exclusive agreement, licensors could otherwise find themselves "*locked into an agreement with an exclusive licensee which no longer makes efforts to develop, produce and market the product*".

Terminate-on-challenge provisions in non-exclusive agreements, by contrast, are now confirmed as falling outside the block exemption's protection and must be individually assessed. The Guidelines stress that this assessment must weigh the public interest in encouraging out-licensing against the public interest in eliminating invalid IP rights, also emphasising that such clauses are unlikely to be enforceable where the licensed IP is either standard essential or commercially essential. However, licensors wishing to rely on this exemption should consider their market share very carefully as if the market share thresholds (30% for agreements between non-competitors) are not met, the provision will no longer benefit.

### Grant back provisions

Significant changes have also been made to other areas in the new regime, including grant back provisions. The distinction between 'severable' and 'non-severable improvements'<sup>22</sup> has been abandoned and all exclusive grant-back obligations (which prevent licensees from exploiting their own improvements) now fall outside the scope of the TTBER. Non-exclusive grant-back obligations, meanwhile, continue to be exempted. This change was prompted by the Commission's concern to ensure that there are sufficient incentives for follow-on innovation.



## Competition



### Passive sales

In contrast to the previous block exemption, which covered restrictions on passive sales by existing licensees to a territory/customer group reserved exclusively to a new licensee for a period of up to two years, the new regime excludes all passive sales restrictions from the TTBER. They must also now therefore be assessed on an individual basis. Nonetheless, the Guidelines indicate that such restrictions may be tolerated if they are *“objectively necessary for the licensee to penetrate a new market”*.

### Settlement agreements

In light of the Commission's recent investigations into settlements in the pharmaceutical sector,<sup>23</sup> changes have also been made in relation to settlement agreements. The new Guidelines emphasise that any 'pay-for-delay' settlement agreements involving a payment by the IP owner to the potential infringer, or the provision of any other benefit, in return for a limitation on the entry on the market, will be closely scrutinised. If the parties *“are actual or potential competitors and there was a significant value transfer from the licensor to the licensee, the Commission will be particularly attentive to the risk of market allocation/market sharing”*. The

Guidelines refer to such agreements as 'pay for restriction' settlements.

### Conclusion

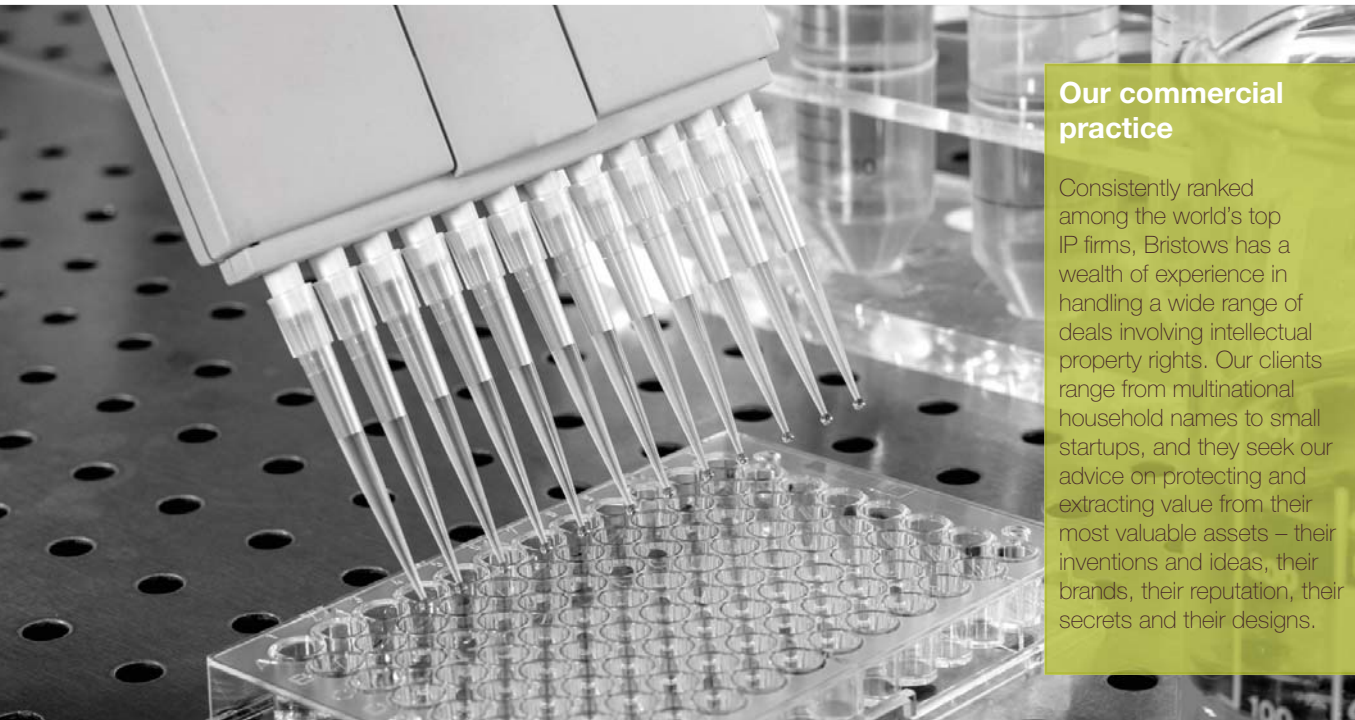
The new TTBER and Guidelines have introduced several changes of significance to the biotechnology and pharmaceutical sectors, most notably the revised rules concerning terminate-on-challenge clauses. Both licensors and licensees should be aware of the impact this might have on their activities: licensees now have greater scope to challenge the validity of licensed IP and may in certain circumstances wish to do so in order to negotiate lower royalties, whilst licensors may wish to consider other contractual protection, perhaps even preferring to exploit their technology in-house. The loss of the block exemption's protection in relation to exclusive grant backs and passive sales restrictions will also create uncertainty over the enforceability of these types of clauses in existing agreements. When revising the block exemption regime, the Commission's aim was to provide guidance on *“how to license in ways that stimulate innovation and preserve a level playing field in the Single Market”*, but the changes introduced in fact lead to less legal certainty for licensors in particular.

<sup>21</sup> Under the both the old and the new technology transfer regimes, no-challenge clauses have been classed as excluded restrictions. This means that the term itself cannot benefit from the exemption and its compliance with Article 101 TFEU must be assessed on a case-by-case basis (although the rest of the agreement may still benefit from the safe harbour). This contrasts with 'hardcore restrictions' such as price fixing, the inclusion of which will remove the entire agreement from the block exemption's safe harbour.

<sup>22</sup> "Severable" improvements were those which could not be exploited without infringing licensed technology.

<sup>23</sup> See for example Lundbeck (Case COMP/AT. 39226) and Johnson & Johnson/Novartis (Case COMP/AT. 39685), as well as Servier (perindopril) (Case COMP/AT. 39612); and Cephalon and Teva (Case COMP/AT. 39686).

# 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 startups, 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.

## Dare to share? Proposed new directive should help protect your confidential information when doing business in Europe



**Claire Smith**  
Associate  
Bristows LLP



**Steven Willis**  
Trainee Solicitor  
Bristows LLP

In November 2013, the European Commission published a proposal for a new Directive concerning the protection of trade secrets and confidential business information in Europe.<sup>24</sup> In May 2014, the European Council agreed on a general approach for the draft Directive. This triggers the start of negotiations

with the European Parliament, the aim being to reach an agreement on it at the first reading. Once implemented, the Directive should help businesses stop others from obtaining, disclosing or using their trade secrets in the EU without their permission.

### Background

Trade secrets – often referred to as “confidential business information” or “undisclosed know how” – can be important assets for any business, including those in the life sciences sector. The information might be technical in nature (e.g. know how relating to a manufacturing process) or it might be commercial (e.g. the results of market research). Often the information does not qualify for any formal type of intellectual property protection (such as a patent, or copyright), yet many companies value the knowledge just as highly, sometimes more so, than more traditional types of intellectual property rights. It's what gives their businesses a competitive edge. Keeping control of that information, and protecting its confidentiality, is paramount.

All EU Member States protect trade secrets in some way or another.

So what's wrong with how they are protected now? The Commission's studies have revealed that there is a patchwork of different national rules across the EU, which are “often outdated, opaque and have important gaps”. According to those studies, this is putting off many EU companies from sharing their know how and from doing cross-border deals – and, as a result, is stifling innovation.

### Proposals

The new Directive, which provides a set of civil (but not criminal) laws to protect trade secrets in all Member States, aims to combat this. In particular, following input from the Council, the new Directive provides:

- a uniform definition of a “trade secret”;
- a defined set of circumstances when acquiring, using or disclosing a trade secret will be considered unlawful (the key component here being the absence of consent of the trade secret holder);
- that third parties will be acting unlawfully if they use or disclose a trade secret when they are aware,

## Commercial

should have been aware, or have been given notice, that they obtained it from someone who was acting unlawfully – even if they themselves were not directly involved in the original unlawful activity. Currently, in some EU countries, it is difficult to prevent someone who innocently acquires a trade secret (e.g. through a disgruntled employee of the trade secret holder) from using it;

- for a common set of remedies for trade secret misuse to be available, including interim and permanent injunctions, withdrawal of infringing goods from the market, seizure and destruction of infringing goods and compensatory damages;
- procedures to preserve the confidentiality of trade secrets in legal proceedings. This is a problem at the moment in some jurisdictions, most notably Belgium, where in order to sue someone for misuse of a trade secret, the trade secret holder will normally have to disclose details of its trade secret in court pleadings (which can then be inspected by the public);
- Member States are allowed to have special regimes which restrict the liability of employees for damages to their employers, where they act without intent; and
- a maximum limitation period of up to six years for claims or bringing actions before courts.

According to the Council's approach, these measures are to be considered the minimum level of protection that should be in force in each Member State. If Member States wish to provide for a higher level of protection, they should be free to do so, provided that they observe certain safeguards in the Directive which try to strike an appropriate balance between the rights of a trade secret holder against those of a defendant.

### Comment

The Directive is a welcome step, particularly in current times when competition is fierce and when, increasingly, companies are facing

situations in which their trade secrets are exposed to outsiders in their efforts to make progress (e.g. through use of consultants and collaborators). Also, as IT and technological advances make it easier to steal or copy large amounts of data, it is important that legislation is seen to move with the times.

As currently drafted, the text of the Directive outlines a regime which is broadly similar to the position under English law, although changes may be introduced before the new legislation is finally adopted.

Trade secret holders, however, may be disappointed to hear that the draft Directive does not provide trade secret holders with an opportunity to apply for "search and seize orders", without having to give notice to a suspected infringer, if there are good grounds to believe that they would destroy the evidence of their unlawful activity. It appears that trade secret holders will still be able to seek these orders in national courts where they are already available – but they will not exist across the board (the Commission apparently concerned that such orders could be open to abuse). The rules on trade secrets will still vary from country to country once the Directive is implemented. However, it will at least set minimum standards of protection for trade secrets across the EU and achieve a greater amount of certainty and public confidence in the way trade secret abuses are handled. Ultimately, this should help make technology transfer and investment in R&D more rewarding for companies, and make Europe more attractive as a location for that investment.

It is hoped that the Directive will be adopted later this year, following which Member States will have 2 years in which to implement the new rules into their national laws. If so, the new regime could be in force before the end of 2016.



<sup>24</sup> 2013/0402 (COD), Proposal for a Directive on the protection of undisclosed know how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

## Dawn of the era of personalised medicine – the UK takes the lead



**Dr Sahar Shepperd**  
**Associate**  
**Bristows LLP**

In the previous edition of our Biotech Review, we reported Dianna Devore (Head of Legal Affairs) from Ariosa Diagnostics predicting personalised medicine to be the “next big thing” in the biotechnology industry.

Dianna’s prediction is fast turning into a reality with the recent announcement of the 100,000 Genomes Project by the UK government. This four year project, recently introduced by the UK Prime Minister, David Cameron, will sequence 100,000 whole genomes from NHS patients with rare diseases and

common cancers. This landmark project is on a scale never seen before and it is hoped that the wealth of knowledge this project generates will transform the way in which diseases are diagnosed and treated and place UK at the forefront as the leader in genetic research.

The 100,000 Genomics Project is being run by Genomics England Limited, a wholly owned subsidiary of the Department of Health.

In August 2014, a new partnership was unveiled between Genomics England and the company Illumina to deliver infrastructure and expertise to turn the project into reality. Genomics England secured Illumina’s services for whole genome sequencing in a deal worth around £78million. David Cameron said of the 100,000 Genomes Project: “It will see the UK lead the world in genetic research within years. As our plan becomes a reality, I believe we will be able to transform how devastating diseases are diagnosed and treated in

the NHS and across the world.”

Bristows was extremely fortunate to be given the opportunity to be the sole advisor to Genomics England and to assist the company in securing its arrangement with Illumina, in what is the largest contract for sequencing ever granted globally. Under this arrangement, the NHS centres will collect DNA from cancer patients and patients with rare diseases, all of who have consented for their DNA to be sequenced. Illumina, a leading whole genome sequencing company, will sequence the patient’s entire genome sequences which will provide a rich repertoire of data to identify differences with the genetic code of healthy tissue.

This unique project required a cross-firm team consisting of lawyers from our Commercial IP, Corporate, Real Estate and Employment teams, with expertise ranging from the life sciences sector to large scale procurement and IT contracts.





# 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.



## The UK – a good place for biotechs



**Samuel Rippon**  
**Associate**  
**Bristows LLP**

Tax has been more widely discussed in the press and public domain in the last year than ever before and that has led to businesses thinking more critically about whether they have a tax structure that serves the needs of their business and their shareholders.

It is no secret that it has been the ambition of the UK government to have the most competitive corporate tax regime in the G20 since the last election in 2010. Since then a lot has changed. There is no doubt that the UK offers more advantages than it did 5 years ago and there are some who would argue that it is now one of the most attractive jurisdictions for European, if not global, operations to be based.

Thinking about that topic in particular, companies in the biotech sector of any size should consider a few of the advantages to the UK corporate tax regime that could

have a real impact on their business and whether they are making the most of what is already available. Here are a few basic points to remember.

- The UK corporation tax rate is currently 21% and set to fall to 20% in April next year. This compares very favourably with the rates around the 30% mark in France and Germany, around 35% in Japan and even 40% in the USA.
- A tax exemption on dividends received and the revised Controlled Foreign Company (CFC) rules can allow multi-national businesses with real presence in other jurisdictions to move profits back to the UK without tax.
- The tax exemption for branch profits can enable UK companies to set up foreign branches without having to pay tax in the UK on the profits they generate.
- The UK has one of the largest number of double tax treaties with other jurisdictions which ensure that profits are only taxed once, not twice and make generous provisions in relation to withholding taxes.
- Research and development tax reliefs by way of R&D tax credits are available to provide fiscal incentives for the carrying out of innovative

scientific research.

- The new Patent Box regime provides a 10% tax rate on qualifying profits arising from patented technologies and is intended to encourage companies to site research activities in the UK.
- For international businesses, employees working temporarily in the UK may not be liable to tax on the whole of their salary, depending on their working arrangements. Non-UK domiciled individuals should not have to pay tax on any income arising outside of the UK, even if they are UK tax resident, provided they do not bring it to the UK.
- Tax favoured share options (especially Enterprise Management Incentives) can offer a flexible way of incentivising and rewarding employees through giving them shares that increase in value as the value of the business increases.

All of these elements of the UK business tax landscape can offer real benefits to biotech businesses, both large and small, if they are aware of them and use them to their best advantage. Many of the benefits will be available to UK subsidiaries of a multi-national group, but with an anticipated 20% rate of UK corporation tax from 2015, the government is clearly intent on trying to attract global headquarters to the UK.



# Q&A with Nick Finnie



**Nick Finnie**  
Head of Intellectual  
Property  
Novartis Vaccines  
and Diagnostics

**Nick Finnie is Head of Intellectual Property at Novartis Vaccines and Diagnostics in Cambridge, Massachusetts. Having graduated with a degree and PhD in Biochemistry from the University of Cambridge in the UK, he trained as a patent attorney and has nearly 20 years of legal and IP experience. Previous roles include positions at Unilever, Pizzys and Novartis Pharma.**

All views and opinions expressed in this article are personal to Nick Finnie and do not necessarily reflect those of Novartis Vaccines and Diagnostics.

**Q How long have you worked at Novartis Vaccines (NVx)?**

**A** Nearly 2 years after 4.5 years with Novartis Pharma.

**Q What does your role at NVx involve?**

**A** I manage the IP department and work with senior business management, advising on top-level IP issues, and setting and executing the IP strategy for the Vaccines division. I also work closely with my colleagues in the Legal litigation team to determine litigation strategy including case settlement.

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

**A** There have been many! Being part of a company that develops and markets life-saving vaccines such as the breakthrough vaccine against meningitis B approved last year in Europe. Working with a team of highly talented and capable individuals both within the IP team and elsewhere in Legal. Engaging with colleagues throughout the different functions in the company and learning how the vaccines business works, and how it is very different to the small molecule and therapeutic biologics businesses of Pharma.

**Q What challenges do vaccines companies face?**

**A** Many pathogens against which we do not yet have a vaccine are difficult targets which have often evolved complex and effective ways to evade the human immune response. Therefore developing new and effective vaccines against these pathogens is becoming increasingly difficult. In addition, as with the rest of the pharmaceutical industry, governments are facing budget constraints which can make it difficult to secure reimbursement at a level that

supports the extensive development costs. On the IP side, the developing case law in the US in relation to biotech inventions and its broad implementation by the USPTO is making it harder to secure effective patent protection in the US as well as creating significant ongoing uncertainty.

**Q What is the most difficult thing about your job?**

**A** Managing people, especially leading them through change. The division has undergone a lot of changes in the last 2 years and we will experience many more over the next few years. However with change comes opportunities too.

**Q What changes do you see happening in the vaccines field in the next 5 to 10 years?**

**A** More advanced biotechnology being used in the development of vaccines, such as new delivery systems, as well as the introduction of more sophisticated adjuvants and other components that modulate the immune response to vaccine antigens. Traditional vaccine manufacture is often based on extracting antigens from the pathogens themselves whereas newer vaccines are making more use of recombinant technology. These developments, based on significant innovation, provide IP opportunities. The flipside of this is that it may become easier to develop generic versions of vaccines, which do not really exist at present, and make use of regulatory pathways being introduced for biosimilar versions of therapeutic biologics. This has implications for IP strategy both in terms of patents and regulatory data protection, the latter being of little value in most cases at present because competing vaccines are approved based on a full regulatory submission. The future IP strategy for vaccines may therefore change over time to become more like that of therapeutic biologics.

# 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 22 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



01

01

## **Sally Field**

Partner

[sally.field@bristows.com](mailto:sally.field@bristows.com)

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 highprofile 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.



02

02

## **Dr Robert Burrows**

Partner

[robert.burrows@bristows.com](mailto:robert.burrows@bristows.com)

Robert advises on patent and other IP litigation matters in the UK, particularly for clients within the life sciences sector. Many 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.



03

03

## **Dr Laura von Herten**

Associate

[laura.vonherten@bristows.com](mailto:laura.vonherten@bristows.com)

Laura specialises in intellectual property dispute resolution, with an emphasis on patents. Laura advises across all industries, with a focus in the life sciences sector. Her extensive scientific background provides her with a valuable understanding of the technical issues that can underlie intellectual property matters, particularly in the pharmaceutical and biotechnology fields.

[bristows.com](http://bristows.com)

[bristowsupc.com](http://bristowsupc.com)



[@bristowslawfirm](https://twitter.com/bristowslawfirm)



[linkedin.com/company/bristows](https://www.linkedin.com/company/bristows)



[facebook.com/bristowslawfirm](https://facebook.com/bristowslawfirm)



[plus.google.com/+BristowsLawFirm](https://plus.google.com/+BristowsLawFirm)



