Vital Signs

Our quarterly round-up of topics that matter to you in the life sciences sector

Summer 2025

Contents

Introduction

Every year my newspaper recommends top choices for vacation reading. This year I'm wading through "The Singularity Is Nearer" by Ray Kurzweil which predicts artificial intelligence will reach human intelligence by 2029. It's a substantial 419 pages, and clearly a relevant topic for all lawyers, but if you are looking for something much shorter for your beach, we are pleased to offer here the CMS summer edition of Vital Signs!

In this edition we discuss the European Commission's decision to fine Teva €462.6 million after finding that it had abused its dominant position to delay competition to its blockbuster medicine Copaxone, in part by its choice of patent strategy, and we consider the impact on future patentee behaviours. We also provide a commentary on the implementation of the Procurement Act 2023 and consider whether the life sciences sector is starting to see the impact of these changes. We review the UK Employment Rights Bill and consider key amendments for businesses operating in the life sciences and healthcare sector, as well as providing a DEI update. Finally, in view of the significant demand over the past few years from life science occupiers for new space, we consider some of the issues life science occupiers should think about when leasing property.

Get in touch

Robert Stephen
Partner,
Co-Head Life Sciences & Healthcare
T +44 20 7367 2559
E robert.stephen@cms-cmno.com

Is your Patent Strategy anticompetitive in the EU?

The European Commission last year fined Teva €462.6 million, finding that it had abused its dominant position to delay competition to its blockbuster medicine Copaxone for the treatment of multiple sclerosis. The Commission found that Teva artificially extended the patent protection of Copaxone and systematically spread misleading information about a competing product to hinder its market entry and uptake.

The Commission's reasoning was recently published and comes in at a whopping 567 pages. This will be of interest to competition lawyers but also of particular interest to those designing patent strategies, as the decision centres on the filing strategy for European patent office (EPO) "divisional" applications, which are patent applications that are divided out from a pending parent patent application.

The EU Commission found that Teva filed divisional applications on a staggered basis in time which, once granted, formed the basis for warning letters and injunctions to prevent competition. The Commission found that some divisional patents were strategically withdrawn before a final decision on validity was made at the EPO, leaving other overlapping divisional applications in place which was considered to extend the overall duration of uncertainty regarding the validity of Teva's patent rights. Teva's conduct was considered to have forced potential market entrants to challenge patents one by one over a protracted period of time.

Teva has appealed this decision and argues (at a headline level) that the decision has failed to examine and has misconstrued the relevant legal and factual context of the EPO system, and as a result has incorrectly found Teva's use of divisional patents protecting Copaxone to be abusive, when in fact Teva's patent filings were perfectly legitimate, and consistent with competition on the merits.

The case therefore raises uncertainly about when it is legal to seek protection by filing a divisional application.

Issues that may now need to be considered by patent applicants include: the timing of filing divisionals and number of divisionals filed; the timing of withdrawing approval of the text of a patent during EPO opposition/ appeal proceedings; the degree of relatedness of divisionals; the strategic reasons for the filing strategy and possible documentation of that strategy, and whether there is a monopoly position already in place by a granted patent covering a product or whether there are only pending applications.

Many of the actions of Teva (filing multiple divisionals iteratively, withdrawal of patent text in opposition) are not uncommon. Whilst the Commission suggests that such filing and withdrawal strategies extends the window of uncertainty, companies will often need to make an assessment of the likelihood of a patent application validly covering its future activities, regardless of when a patent is obtained during the 20-year possible lifetime.

Declarations of invalidity or non-infringement and "Arrow" declarations before national courts can also be used to clarify the position regarding the possibility of a future divisional covering a product, and that may be a potential strategy before the UPC as well.

Moreover, it is noteworthy that – even if the commission is correct in its conclusion – any such divisional strategy relies upon patents actually being granted at the EPO. Therefore, if the subject matter was truly prima facie unpatentable, a patent would not have been granted in the first place. Therefore, this "strategy" cannot simply be implemented without a patent application that appears valid over the prior art to the EPO examining Division.

Public Procurement

The implementation of the Procurement Act 2023

The landscape of public procurement regulation in the UK has undergone significant transformation since the Procurement Act 2023 came into force in February 2025. Now, a few months into its implementation, we comment on whether the life sciences sector is starting to see the impact of the changes.

A new regime in force

The Procurement Act 2023 came into force on 24 February 2025, ushering in a more transparent and flexible approach to public procurement. On the same day the new National Procurement Policy Statement (NPPS) came into effect. The NPPS sets out the Government's strategic priorities for public procurement, and emphasises value for money, economic growth, social and environmental objectives, the importance of innovation, and that procurement can support delivery of the Government's mission to build a National Health Service fit for the future —all areas of particular relevance to life sciences businesses seeking to partner with the public sector.

First impressions of pipeline notices and preliminary market engagement

An early milestone in the implementation of the new regime was the requirement for large contracting authorities (those expecting to spend over £100 million under relevant contracts in the coming financial year) to publish their first tranche of pipeline notices by 26 May 2025. These notices, now live on the central digital platform (an enhanced Find a Tender service (FTS)), are intended to provide early visibility of public contracts valued over £2 million that are going to be procured over the next 18 months.

For suppliers, the information in the notices should provide greater foresight into the procurement pipeline of buyers operating across the NHS and health and social care sectors, enabling better resource planning and partnership formation.

The Cabinet Office has reported an increase in the transparency of preliminary market engagement exercises since the Act came into force, pointing to the increase in the number of preliminary market engagement notices being published on FTS.

Transparency around pre-market engagement is welcomed, and we encourage suppliers to engage: it allows early dialogue with procurement teams, the opportunity to shape requirements, and a clearer understanding of future tenders.

To ensure equal treatment, a supplier does risk exclusion from a procurement process where it has gained an unfair advantage from their involvement in the related preliminary market engagement. For that reason we recommend that suppliers exercise caution if discussions move out of the parameters which have been set for the engagement.

Overall, it is too early to say whether there is an increase in the volume or quality of pre-market engagement taking place under the Act, compared with the engagement that took place under the previous procurement rules (i.e. the Public Contracts Regulations 2015, the Concession Contracts Regulations 2016, the Utilities Contracts Regulations 2016 and the Defence and Security Public Contracts Regulations 2011).

Looking ahead, including to further reforms

The implementation of the Act is in an early stage. Many contracting authorities are getting to grips with running their first procedures until the new rules, and suppliers to the public sector may not yet have participated in a procedure being run under the Act. Due to the transitional rules we have in place, a number of procurements will take place under the 'previous' procurement rules for some years to come.

Despite still being in the early stages of implementation, further reforms seem to be on the way. For ten weeks until 5pm on 5 September 2025, the Government is running a consultation on proposals to amend the Act to ensure that public procurement is aligned to the Government's industrial strategy. The aim of the consultation is *"to ensure that public procurement improves domestic competitiveness, strengthening the UK's economic resilience and supporting British businesses"*. We will be providing updates on these further reforms as they arise.

In the meantime, suppliers should monitor pipeline notices and pre-market engagement opportunities closely, ensuring they are well-positioned to respond to the evolving needs of the NHS and wider public sector.

People & HR Related Issues

Employment Rights Bill – what's new?

Despite the Employment Rights Bill (ERB) being published in October 2024, it remains subject to extensive debate during its passage through Parliament where it is currently at the Committee Stage in the House of Lords. The ERB has been amended in some key respects, including as a result of the Government's responses to its ERB-related consultations on (i) strengthening statutory sick pay, (ii) fire and rehire and collective redundancy, (iii) industrial relations, (iv) zero hours contracts and agency workers, and (v) tackling non-compliance in umbrella companies.

The key amendments for businesses operating in the life sciences and healthcare sector to be aware of are as follows.

Time limit. The time limit for bringing most employment related claims in the employment tribunals will be extended from three months to six months, with the aim of reducing pressure on the employment tribunal system by allowing parties more time to resolve their disputes without recourse to litigation. However, the extension of the time limit together with the removal of the two-year qualifying period for most unfair dismissal claims may in fact see an increase in claims.

Zero hours contracts. Zero hours contracts provisions have been clarified and strengthened, and have been extended to apply to agency workers which will make agency arrangements more complex.

Collective redundancy. The maximum period of the protective award for failing to comply with collective consultation requirements will increase from 90 to 180 days' actual pay. Although the 'at one establishment' test will be retained, a second threshold trigger (the details of which are not yet confirmed) will be introduced targeting multi-site redundancies.

Statutory sick pay (SSP). The 3-day waiting period for SSP will be removed meaning that SSP will be paid from day one, rather than the fourth day of sickness. A new SSP rate will be introduced set at 80% of average weekly earnings or the flat rate (currently £116.75 per week) whichever is lower.

Industrial relations. The new workplace access rights for trade unions will be extended to cover digital access to the workplace (e.g. via an employer's intranet). Notice to employers of industrial action will be reduced from 14 to 10 days.

Umbrella companies. Umbrella companies will be defined and brought within the definition of an employment business which means they will be regulated by the Fair Work Agency (once it is established in due course) in order to address concerns of non-compliance and exploitative employment practices.

Although the ERB was expected to receive Royal Assent in 2025, that may now be in doubt as a result of delays in its parliamentary journey. Employers should nevertheless start to prepare for the wide-ranging changes expected because they will present a significant compliance challenge in 2026 and beyond.

DEI update

Within days of taking office in January 2025, President Trump issued executive orders requiring a rollback from diversity, equality and inclusion (DEI) initiatives. The orders follow the 2023 decision of the US Supreme Court outlawing affirmative action in respect of race in university admissions programmes. The executive orders have led to many US-led businesses scaling back their DEI activities, and have generated a lot of press attention.

While the impact of these developments will be felt most keenly by US headquartered companies, UK or European-led businesses with operations in the US may also come under pressure to rollback their DEI activities. Any such change in approach should however be carefully considered because of important differences in the legal regimes in relation to DEI in the UK and across the EU. The general direction of travel in the UK is to broaden existing equality related protections in the workplace.

Importantly, affirmative action in the US is not the same as positive action in the UK. Affirmative action would not be permitted in the UK. Positive action is, however, permitted under the Equality Act 2010. Positive action is much more restrictive and applies in more limited circumstances than affirmative action. The move away from affirmative action in the US actually brings their regime closer to the UK regime.

Also, the UK Government remains focused on improving equality at work. Proposals include the introduction of mandatory disability and ethnicity pay gap reporting (alongside the existing gender pay gap reporting regime, introduced in 2017, as well as wider developments in this area across the EU) and strengthening existing workplace protections against sexual harassment via the ERB following the introduction of a new duty to prevent sexual harassment at work in October 2024.

For these reasons, UK businesses scaling back their DEI initiatives in response to the position in the US should carefully weigh up the commercial imperatives to do so against the risk of discrimination related claims which can be reputationally and financially damaging.

Discrimination in providing goods and services

The competitiveness of the life sciences and healthcare sector continues to place an imperative on bringing products including software and devices to market as quickly as possible, and to leverage technological advances and innovation to provide the best customer experience. But with this brings a more acute risk that the user experience leaves some protected groups behind.

Individual goods and services discrimination claims under the UK's equalities legislation are not typically particularly expensive or time-consuming to defend. However, the increasing trend within the UK for class actions, and of claims being supported by special interest groups representing particular minorities or those with particular disabilities, presents heightened publicity risks and can also expose underlying gaps in product design or the manner in which services are delivered, which can be extremely costly to address.

Private sector companies competing for public contracts face even greater scrutiny, through an ongoing focus on bidders' records on discrimination claims as part of the tendering process. Successful bidders are also likely to be subject to stringent equality clauses in public sector contracts, to reflect the UK's public sector equality duty which requires public bodies to give due regard to achieving equality objectives when exercising public functions.

This heightened scrutiny emphasises the importance of considering the obligations imposed under the UK's equalities legislation at all stages in the research, development and delivery process, in order not only to improve compliance, but also reduce the likelihood of protracted litigation and the reputational harm that such claims can bring.

Life Science Occupiers - some of the issues to think about when leasing property

There has been significant demand over the past few years from life science occupiers for new space as the sector has grown substantially. There are a range of different types of space available. Some space on bespoke life science campuses or new purpose built accommodation as well as refurbished traditional office space. Landlords leasing space range from universities and specialist life science developers/investors to traditional real estate investors looking to take advantage of what has been a relatively strong sector compared to the normal office real estate market.

Because of the cost of fitout life science occupiers (excluding startups who will have a very different requirement) generally look to take leases of a reasonable length (and longer than, say, normal office occupiers) so as to achieve a return on their investment.

Life science companies letting space need to be aware of a number of different issues to ensure that their requirements as occupiers are protected as much as possible. Issues to think about include:

1. Their business plans often lead to life science companies looking for additional space in a building quite quickly. If they can, they should look to negotiate from the outset expansion rights with a landlord, either in the building or other buildings on any campus, so as to give future flexibility as the business grows. Obviously, from a landlord's perspective, they will want to ensure that any such rights do not lead to sterilised empty space because of the impact on their own returns.

2. The last 18 months have seen significant changes in the real estate market in terms of including in leases "green lease" requirements. Historically, most traditional real estate investors have taken a light touch approach with limited obligations on landlord and tenant to share information and work to improve energy performance. There is a growing variety of light, medium and dark green clauses being used by landlords and occupiers will need to look carefully at these (particularly the darker green clauses which may be quite onerous). All landlords are increasingly very sensitive to their own sustainability requirements and landlords may have very different requirements (e.g. universities are likely to have a pretty advanced sustainability policy

for all the space they own and day to day operations compared with a normal institutional real estate investor) and they may be looking to pass these on to their tenants to comply with as well.

3. Generally, leases give landlords quite wide rights to access premises for a wide range of purposes. Tenants will need to think about the extent to which these rights should be limited – for example to protect sterile environments or because of concern about the confidential nature of research being undertaken.

4. Remediation of the space at the end of the lease will be important to the landlord. Occupiers will often find a lease contains specific "decontamination" requirements which need to be complied with by the occupier to ensure that the space when handed back can easily be re-let. There will therefore normally be procedures for some form of tenant led remediation certification process which occupiers should make sure they are fully aware of.

5. UK leases generally have a five year rent review pattern. Occupiers may want to consider some form of index linked rent review rather than an open market review (which involve comparing the rent for the building with the rent for comparable buildings for a similar use) (perhaps with annual minimum and maximum increase).

6. When looking at space which is being refurbished, occupiers should think carefully about exactly what areas are to be rentalised. The traditional definitions of **"net"** and **"gross"** internal area which the real estates sector usually may not be appropriate where, for example, there is significant laboratory space/ additional risers/extraction systems.

All of these sorts of issues are easily dealt with but it is important that they are addressed at an early stage of lease negotiations.

Contacts

Is your Patent Strategy anticompetitive in the EU?

Robert Stephen
Partner,
Co-Head Life Sciences & Healthcare
T +44 20 7367 2559
E robert.stephen@cms-cmno.com

The implementation of the Procurement Act 2023

Emma Blundell
Senior Associate,
T +44 131 200 74707
E emma.blundell@cms-cmno.com

Wendy Nicolson
Partner,
T +44 20 7367 3725
E wendy.nicolson@cms-cmno.com

Employment Rights Bill – what's new?

Aisleen Pugh
Professional Support Lawyer,
T +44 20 7067 3256
E aisleen.pugh@cms-cmno.com

Hannah Netherton
Partner,
T +44 20 7067 3634
E hannah.netherton@cms-cmno.com

Ed Arnold
Of Counsel,
T +44 20 7071 7303
E edward.arnold@cms-cmno.com

Life Science Occupiers - some of the issues to think about when leasing property

Candice Blackwood
Partner,
T +44 20 7524 6726
E candice.blackwood@cms-cmno.com

Henrietta Stretton
Of Counsel,
T +44 20 7524 6135
E Henrietta.Stretton@cms-cmno.com

CMS Law-Now™

Your free online legal information service.

A subscription service for legal articles
on a variety of topics delivered by email.
cms-lawnow.com

CMS Cameron McKenna Nabarro Olswang LLP
Cannon Place
78 Cannon Street
London EC4N 6AF

T +44 (0)20 7367 3000
F +44 (0)20 7367 2000

The information held in this publication is for general purposes and guidance only and does not purport to constitute legal or professional advice.

CMS Cameron McKenna Nabarro Olswang LLP is a limited liability partnership registered in England and Wales with registration number OC310335. It is a body corporate which uses the word "partner" to refer to a member, or an employee or consultant with equivalent standing and qualifications. It is authorised and regulated by the Solicitors Regulation Authority of England and Wales with SRA number 423370 and by the Law Society of Scotland with registered number 47313. It is able to provide international legal services to clients utilising, where appropriate, the services of its associated international offices. The associated international offices of CMS Cameron McKenna Nabarro Olswang LLP are separate and distinct from it. A list of members and their professional qualifications is open to inspection at the registered office, Cannon Place, 78 Cannon Street, London EC4N 6AF. Members are either solicitors or registered foreign lawyers. VAT registration number: 974 899 925. Further information about the firm can be found at cms.law

© CMS Cameron McKenna Nabarro Olswang LLP

CMS Cameron McKenna Nabarro Olswang LLP is a member of CMS LTF Limited (CMS LTF), a company limited by guarantee incorporated in England & Wales (no. 15367752) whose registered office is at Cannon Place, 78 Cannon Street, London EC4N 6AF United Kingdom. CMS LTF coordinates the CMS organisation of independent law firms. CMS LTF provides no client services. Such services are solely provided by CMS LTF's member firms in their respective jurisdictions. CMS LTF and each of its member firms are separate and legally distinct entities, and no such entity has any authority to bind any other. CMS LTF and each member firm are liable only for their own acts or omissions and not those of each other. The brand name "CMS" and the term "firm" are used to refer to some or all of the member firms or their offices.

2507-0199119-5

© CMS Cameron McKenna Nabarro Olswang LLP 2025