# THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

THIRD EDITION

**Editor**
Daniel A Kracov

THE LAWREVIEWS

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**Editor**
Daniel A Kracov

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# PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries, with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials; however, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions.

In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns –it can be critically important to tailor approaches to the local legal environment despite general concepts that may be shared across jurisdictions.

Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in determining its sustained success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. This is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability have been a constant source of political scrutiny, as well as patient and physician concern.

The ongoing global response to the covid-19 pandemic has re-emphasised the importance of rapid drug and biologic product development to public health around the world, and the critical need to maintain incentives to enable such innovations; however, the stakes in demonstrating the need to maintain such protections for innovation have grown even higher as the pandemic has spurred an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments.

Our objective in framing this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*. They have produced what we believe is a very useful tool for managing global risks in this area.

**Daniel A Kracov**
Arnold & Porter
Washington, DC
July 2022

**Chapter 10**

# UNITED KINGDOM

*Sally Shorthose, Peter Willis, Chris de Mauny and Pieter Erasmus*[1]

## I OVERVIEW

For many years, the pharmaceutical industry has been and remains an important sector in the UK. It has a vibrant research and development community within universities, hospitals and companies, from the largest multinationals to start-ups, and it continues to have significant manufacturing activity.[2]

As well as the innovator manufacturers in the UK, there are a significant number of generic manufacturers. Many commentators would say that there is a healthy balance (or even a virtuous circle) between the incentives and stimulus to the originators to maintain their research-based activities and the activities of the generic manufacturers to secure access to reasonably priced medicines.

The government has expressed its support for the sector in 'The Life Sciences Sector Deals',[3] which were designed to help ensure that new pioneering treatments and medical technologies are produced in the UK and to drive economic growth. The deals involve substantial investment from private and charitable sectors, and significant commitments in research and development from the government.

In July 2021, the government further put in place the Life Sciences Vision[4] initiative, which sets out the government and life sciences sector's goals for the sector over the next decade, including how to address some of the UK's most significant healthcare challenges, including cancer, dementia and obesity.

Notwithstanding the current buoyancy of the sector, to some extent its future remains a little uncertain in light of Brexit: the UK exited the European Union (EU) on 31 January 2020, and EU law continued to apply in the UK until 31 December 2020. The EU treaties, EU free movement rights (including access to the single market) and the general principles of EU law have since ceased to apply in relation to the UK, and prior EU regulations only continue to apply in domestic law if not already revoked or amended by the UK.

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1 Sally Shorthose, Peter Willis and Chris de Mauny are partners and Pieter Erasmus is an associate at Bird & Bird LLP. The authors would also like to acknowledge the contribution of Bróna Heenan, a former associate at Bird & Bird (Belgium) LLP, who participated in the preparation of earlier versions of this chapter, as well as the contribution of Chloe Birkett, a former trainee solicitor at Bird & Bird LLP, who participated in the preparation of this chapter.

2 There is, however, a move to bring more drug manufacturing within the United Kingdom to reduce the risk of shortages, which have been experienced during the covid-19 pandemic and as a result of the uncertainty caused by Brexit.

3 GOV.UK policy paper, 'Life Sciences Sector Deal 2, 2018'.

4 GOV.UK policy paper, 'Life Sciences Vision'.

The effects of Brexit on the life sciences sector are likely to be substantial. This is because, as a third party to the EU, the UK no longer has access to the benefits of the EU single market, such as the centralised procedure for marketing authorisations (MAs), the EU portal for clinical trials and the pharmacovigilance database.

On the other hand, the UK Medicines and Healthcare products Regulatory Agency (MHRA) was seen to show agility and flexibility in permitting the emergency use of covid-19 vaccines and was quick to put in orders for the same, which gave it a head start in the implementation of its vaccination plans. The EU was not pleased when the Anglo–Swedish company AstraZeneca seemed to give priority of supply to the UK, resulting in legal action for breach of contract. It remains to be seen if this conflict is a one-off or a sign of relations to come.

Competition law is enforced by the UK Competition and Markets Authority (CMA). Recent cases have dealt with unlawful market[5] and information[6] sharing activity, excessive pricing[7] and investigations into 'pay-for-delay' cases where the innovator company pays a generic competitor to delay or give up completely its plans to enter the market.[8]

In this chapter, we set out the pharmaceutical legislative and regulatory framework, how to bring a product to market, and the use and challenge in using patent litigation for product launch. We also provide an overview of the competition law environment in the UK, including a review of the rules on anticompetitive agreements and abuses of dominance, merger control and an assessment of case law.

## II LEGISLATIVE AND REGULATORY FRAMEWORK

Pharmaceutical products and medicines are regulated in accordance with the Human Medicines Regulations 2012, as amended[9] (HMR), which retain Directive 2001/83/EC[10] and other key EU legislation (as at 31 December 2020 and with necessary Brexit-related changes) and consolidate relevant UK laws.

### i Patent duration

Patent protection is governed by the Patents Act 1977. Patents have a maximum duration of 20 years from their filing date, subject to payment of renewal fees and remaining valid.[11] Under Regulation (EC) No. 469/2009[12] (as retained in the UK), a supplementary protection certificate (SPC) may be granted in certain circumstances to extend the duration of a patent relating to a medicinal product.[13]

5 For example, Case 50511-1, *nitrofurantoin tablets* and Case 50511-2, *prescription-only prochlorperazine tablets*.

6 For example, Case 50507.2, *nortriptyline tablets*.

7 For example, Case 50277-1, *hydrocortisone tablets*.

8 For example, Case 50455, *fludrocortisone acetate tablets*.

9 The Human Medicines Regulations 2012 (SI 2012/1916), as amended.

10 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended.

11 Section 25 of the Patents Act 1977, as amended.

12 Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products as amended, in particular by the Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (SI 2020/1471).

13 Following Brexit, a new supplementary protection certificate (SPC) in the UK must, in most cases, be based on a UK marketing authorisation. EU marketing authorisations still have effect in Northern Ireland; therefore, an SPC may be based on such an authorisation but will have effect only in Northern Ireland.

### ii Marketing authorisation

The MHRA is the competent enforcement authority for the regulation of pharmaceutical products. As an executive agency of the Department of Health and Social Care (DHSC), the MHRA is responsible for managing licences and MAs under the HMR.

Until the end of the post-Brexit transition period, the UK came under the auspices of the European Medicines Agency (EMA), which regulates pharmaceutical products on a pan-European level. This includes evaluating applications and providing recommendations to the European Commission (EC) for the grant of an MA through a centralised European procedure. Applications are assessed on the principles of safety, quality and efficacy set out in the Medicines Regulations, Community Code and Regulation (EC) No. 726/2004.[14]

### iii Pricing

The DHSC manages the pricing and reimbursement of medicines in the National Health Service (NHS), on the guidance and advice of the National Institute for Health and Care Excellence (NICE). Companies typically consult the DHSC before setting a reimbursement price, which is published in the Drug Tariff. NICE analyses the cost and potential benefit of a new drug to decide whether it should be recommended for use in the NHS.

The Voluntary Pricing and Access Scheme (VPAS) is a non-contractual agreement between the DHSC and the Association of the British Pharmaceutical Industry. Under VPAS, NHS spending on branded medicines is capped at 2 per cent growth of the total annual bill, with spending above this cap being paid back by members as a percentage of product sales. To encourage innovation, exemptions are available for products containing new active substances and for small and medium-sized companies.

Companies not participating in VPAS are subject to the statutory scheme, governed by the National Health Service Act 2006 and the Branded Health Service Medicines (Costs) Regulations 2018.[15] Under this scheme, companies pay rebates based on a percentage of their UK revenues.

### iv Public purchasing

Medicines are procured using collective purchasing and framework agreements. Formerly governed by the Public Contracts Regulations 2015,[16] purchasing is now governed by the Health and Care Act 2022.

Uniform rules across the whole of the UK are complicated by differences in devolved administrations. England is expected to apply these through the new Provider Selection Regime, which is planned to take effect ahead of the new Procurement Bill. The Commercial Medicines Unit of NHS England is responsible for awarding and managing frameworks across regional pharmacy purchasing groups, while hospital trusts are responsible for managing the contracts awarded.

14 Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

15 Branded Health Service Medicines (Costs) Regulations 2018 (SI 2018/345), as amended.

16 Public Contracts Regulations 2015 (SI 2015/102), as amended (PCR 2015). The Health and Care Act 2022 now governs such purchasing (excluded from the PCR 2015 and all successor regimes). The level of coherence and consistency in the rules that apply to purchasing medical supplies across the UK system as a whole is currently difficult to predict.

In Wales, the contract process is managed by the NHS Wales Shared Services Partnership, while the All Wales Drug Contracting Committee acts as the awarding body and ensures compliance with legal and governance requirements.[17]

Following Brexit, the UK became a signatory to the World Trade Organisation's Government Procurement Agreement in its own right. It intended to simplify the procurement rules by having one set of rules (replacing public sector, utilities, concessions and defence);[18] however, living up to this objective is proving to be somewhat of a challenge, as witnessed by the length of the UK Procurement Bill and the exclusions already included.[19]

There is as yet no certainty on the position in Scotland.

### v Competition laws

UK-specific legislation comprises the Competition Act 1998 (Chapters I and II), which prohibits anticompetitive agreements and abuse of dominance that may affect trade within the UK, and the Enterprise Act 2002. Anticompetitive agreements that extend beyond the UK to other EU Member States are prohibited by Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU), which continue to apply post-Brexit to agreements or the conduct of UK businesses that have an effect within the EU, in much the same way as agreements or conduct of US and Asian businesses are currently subject to EU competition law where their agreements or conduct affect EU markets. A UK participant in a global cartel will, therefore, continue to face investigation and fines by the EC.

A key difference is that the EC now has no power to carry out on-site investigations (dawn raids) in the UK, nor to ask the CMA to do so on its behalf; the EC's powers of investigation are limited to making written requests for information, as it does on a regular basis to businesses based outside the EU.

Since 1 January 2021, the UK has complied with its commitments on subsidy control set out in its free trade agreements with other countries, including the UK-EU Trade and Cooperation Agreement (TCA). The TCA includes a commitment by both parties to maintain effective competition laws to address anticompetitive agreements and abuses of a dominant position, essentially maintaining the status quo of the existing EU and UK competition law rules. A number of changes have already been made to the UK rules, including those outlined below.

On 28 April 2022, the Subsidy Control Bill received royal assent, becoming the Subsidy Control Act 2022. It aims to move away from the 'bureaucratic' EU state aid rules and to adopt an approach based more on self-assessment in accordance with a set of principles.

Instead of requiring that all subsidies, except those falling under a block exemption, be notified, as is the EU approach, the UK rules will operate on the basis of an assumption that the subsidy is permitted once certain UK-wide principles are followed; namely, that

17 Tim Root, 'An overview of Procurement of Medicines and Pharmaceutical Products and Services for NHS hospitals', National Health Service (NHS) Specialist Pharmacy Service (12 November 2021).

18 The PCR 2015 (which implemented Directive 2014/24/EU); the Utilities Contracts Regulations 2016 (which implemented Directive 2014/25/EU); the Concession Contracts Regulations 2016 (which implemented Directive 2014/23/EU); and the Defence and Security Public Contracts Regulations (which implemented Directive 2009/81/EC).

19 The UK Procurement Bill was introduced to Parliament in May 2022 and reached the Committee stage in the House of Lords in July 2022. Royal assent is expected in mid-2023, with a six-month transition period to follow.

the subsidy delivers good value for the British taxpayer while being awarded in a timely and effective way. Importantly, more power is being delegated to the devolved governments of Scotland, Wales and Northern Ireland, who will now be responsible for deciding on the issuance of subsidies in their own jurisdiction.

The CMA is responsible for advising issuing authorities on the compatibility of certain subsidies with the applicable principles. Unlike the EC, it has no power to adopt binding decisions in respect of subsidies. A newly established government body, the Office for the Internal Market, will also help the CMA to monitor the market and subsidies in the UK, between England, Wales, Scotland and Northern Ireland. The Competition Appeal Tribunal (CAT) will have jurisdiction to judicially review decisions to award subsidies.

On 16 March 2021, a multilateral working group – including the US Federal Trade Commission (FTC), the US Department of Justice, the Canadian Competition Bureau, the EC's Directorate-General for Competition and the CMA – was launched at the initiative of the FTC to analyse the effects of mergers in the pharmaceutical sector. The EC stated that, because of the increasing number of mergers in the pharmaceutical sector, there is a need 'to scrutinise closely to detect those that could lead to higher prices, lower innovation or anticompetitive conduct'.[20] A public consultation was carried out between 11 May and 25 June 2021 with a view to gathering ideas and views from stakeholders.

## III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

### i Overview of the national and international marketing authorisation pathways

Generally, prior to placing a new medicine on the UK market, irrespective of whether it is an innovative medicine, a biological medicine, a generic or a biosimilar, an MA must be obtained. While the majority of MAs in the EU continue to be applied for under the decentralised procedure or the centralised procedure, following Brexit, the UK has established its own system for independent MA approval through the MHRA.

The MHRA carries out all functions previously performed at the EU level, including the making of decisions on applications, variations and renewals. It has also taken over the renewal process for MAs granted through mutual recognition or decentralised procedures that were underway at the end of the Brexit transition period.

With effect from 1 January 2021, (EU) centrally authorised products were, pursuant to the Human Medicines Regulations (Amendment etc) (EU Exit) Regulations 2019, converted from EU to UK MAs (effective in Great Britain[21] only), as if they were granted on the date the corresponding EU MA was granted. Such conversion was subject to the provision of essential baseline and other data being submitted electronically by the MA holder by 31 December 2021.[22] As a result of the implementation of the Northern Ireland Protocol, existing (EU) centrally authorised products will remain valid for marketing products in Northern Ireland.

20 European Commission (EC) press release, 'Competition: The European Commission forms a Multilateral Working Group with leading competition authorities to exchange best practices on pharmaceutical mergers' (16 March 2021).

21 That is, England, Wales and Scotland.

22 GOV.UK guidance, 'Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs), "grandfathering" and managing lifecycle changes' (31 December 2020).

Currently, all new UK and Great Britain national MA applications must be submitted through the MHRA submissions portal.[23] There are a number of routes to obtain an MA in the UK, Great Britain or Northern Ireland, and the choice of an option depends on the intended market and type of application.[24] In summary, the available routes include:

*a* the 150-day assessment for national applications for medicines, which is available for all high-quality MA applications, aiming at accelerating the availability of medicines (particularly new active substances and biosimilar products) for patients in the UK within a 150-day timeline;[25]

*b* the rolling review for MA applications, which is a new route for MA applications, where an applicant for an MA for a new active substance submits modules of the electronic common technical document dossier incrementally for pre-assessment by the MHRA rather than as part of a consolidated full dossier submission;[26]

*c* the EC decision reliance procedure, which is another new route in terms of which, for a period of two years from 1 January 2021, when determining an application for a Great Britain MA, the MHRA may rely on a decision taken by the EC on the approval of a new MA in the EC centralised procedure. The intention is that the MHRA determines the Great Britain MA as soon as possible after EC approval, but within 67 days;[27]

*d* the decentralised and mutual recognition reliance procedure for MAs, in terms of which the MHRA may have regard to MAs approved in EU Member States (or Iceland, Liechtenstein or Norway) through decentralised and mutual recognition procedures with a view to granting the MA in the UK or Great Britain within 67 days of MA application validation;[28]

*e* the unfettered access procedure for MAs approved in Northern Ireland, in terms of which holders of MAs approved in Northern Ireland or Member States of the EU or the European Economic Area (EEA) apply to bring a product to market in Great Britain. The intention is that acceptable MAs should be granted within 67 days of MA application validation;[29] and

*f* the Project Orbis process coordinated by the US Food and Drug Administration, which provides a framework for concurrent submission and review of oncology products among international partners (including the MHRA and the equivalent authorities of Australia, Canada, Brazil, Switzerland and Singapore).[30]

23 GOV.UK guidance, 'Apply for a licence to market a medicine in the UK' (18 December 2014). Submission portal: https://pclportal.mhra.gov.uk (last accessed: 21 July 2022).

24 GOV.UK collection, 'Licensing: how to apply' (4 May 2021).

25 GOV.UK guidance, '150-day assessment for national applications for medicines' (31 December 2020).

26 GOV.UK guidance, 'Rolling review for marketing authorisation applications' (31 December 2020).

27 GOV.UK guidance, 'European Commission (EC) Decision Reliance Procedure' (4 January 2021).

28 GOV.UK guidance, 'Guidance Decentralised and mutual recognition reliance procedure for marketing authorisations' (4 January 2021).

29 GOV.UK guidance, 'Unfettered Access Procedure for marketing authorisations approved in Northern Ireland (4 January 2021).

30 GOV.UK guidance, Project Orbis (10 December 2020).

### ii New medicines and biological medicines

#### *Legal basis*

With regard to new innovative medicines (including biological medicines), Part 5 of the HMR contains the basic requirements for an application for an MA in respect of such medicines (regardless of the pathway to be followed).

#### *Fees*

Fees payable to the MHRA depend on the type and pathway of application.[31] As at the time of writing, the fees vary from £18,437 for the 'unfettered access route' to £92,753 for the 'National fee (any other case including hybrid application)' process.

#### *Expedited approvals for new or innovative medicines*

Applications may be expedited where it can be shown that there is compelling evidence that a medicine could provide a major breakthrough in the treatment of certain conditions, such as:

*a* chronic, debilitating, life-threatening or severe diseases for which available treatments are ineffective or otherwise inadequate;

*b* the emergence of a disease with widespread resistance to currently available treatments; or

*c* the emergence of a new disease entity that has severe or life-threatening effects and for which currently available treatments are ineffective or inadequate.

Applications may, subject to the approval of the DHSC, also be expedited if there is shortage of supply of essential medicines.[32] More recently, with the outbreak of the covid-19 pandemic and the unprecedented conditions arising from it, the MHRA put in place certain measures to expedite the applications of any medicines aimed at the prevention or treatment of covid-19.[33]

From a practical perspective, for an application to be fast-tracked, the applicant must contact the MHRA via email[34] and provide a short letter that includes a brief description of the relevant disease category, the major clinical properties of the product and evidence supporting the claimed benefits of the product for the proposed indication or indications. The fast-tracking of an application is free of charge.

#### *Regulatory incentives*

The HMR implements the EU concept of regulatory data protection and data exclusivity in the UK. For generally 10 years[35] after the granting of the first MA in the EEA for the product, applications for MAs for generic versions of the product cannot be granted because, according to legislative provisions defining the 'regulatory data protection' period, for the

31 GOV.UK statutory guidance, 'MHRA fees', especially item 14 (updated 1April 2021).

32 In these cases, the Department of Health and Social Care (DHSC) should first be contacted via email at DHSCmedicinesupplyteam@dhsc.gov.uk.

33 GOV.UK collection, 'MHRA guidance on coronavirus (COVID-19)' (19 March 2020).

34 As at June 2022, at RIS.NA@mhra.gov.uk. If the reason for expediting the application is because of a shortage of supply, it is recommended that this be discussed with DHSC by emailing DHSCmedicinesupplyteam@dhsc.gov.uk.

35 For the first eight years, no generic MA application may be filed using the data in the innovator's MA dossier. For a further two years, any generic MA application may not be granted. The overall 10-year period may be extended to 11 years if, during the first eight years, the same product is authorised for a new therapeutic indication with significant clinical benefits compared to pre-existing therapies.

first eight years of that period, generic competitors cannot cross-reference the originator company's MA dossier data. The data protection period runs concurrently with any patent or SPC protection.

Authorised orphan-designated drugs (to treat rare diseases) also qualify for a period of market exclusivity. The basic period is 10 years from the date of MA (extended to 12 years if approved paediatric studies have been completed, in which case the SPC paediatric extension referred to above is not available). This market exclusivity is different in scope from regulatory data protection.

Subject to certain exceptions (notably, if a competitor develops a clinically superior medicine), market exclusivity prevents authorisation of any other 'similar' product for the same therapeutic indication, notwithstanding full independent development of that alternative product. As with regulatory data protection, market exclusivity runs concurrently with any patent (or SPC) protection, and runs concurrently with any remaining regulatory data protection for the product. The government had said that as far as possible it will replicate this incentive after Brexit, and this remains the case.

### iii Generics and biosimilars

#### *Legal basis*

With regard to new generic medicines (and biosimilars) being placed on the market, Part 5 of the HMR contains the basic requirements for an application for an MA in respect of those medicines (regardless of the pathway to be followed).

With regard to generics, Regulation 51 of the HMR provides the legal framework for obtaining an MA for generic products by reference to an originator's product registration dossier, which essentially results in the MA application process being an abridged form of the 'full' Article 8 process.

With reference to biosimilars, because of the nature of those medicines, Regulation 53 of the HMR states that where a biological medicinal product that is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the similar biological medicinal product and the reference biological medicinal product, the results of appropriate preclinical tests or clinical trials relating to those conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I of Directive 2001/83/EC (as retained as at 31 December 2020) and related detailed guidelines.

#### *Fees*

Fees payable to the MHRA depend on the type and pathway of the abridged application.[36] For example, as at the time of writing, the fee is £9,402 for abridged (standard) applications for the 'national fee (all other cases)', etc.

#### *Expedited approvals for generics and biosimilars*

The fast-track process in the context of new medicines and biological medicines also applies to MA applications pertaining to generics and biosimilars.

36 See footnote 31.

***Regulatory incentives***

Unlike in the United States, where an exclusivity period of a certain period may be obtained for the first-approved generic or biosimilar, there are currently no specific regulatory incentives in the UK to encourage generics and biosimilar manufacturers to bring their product to market.

## IV PATENT LINKAGE

In England and Wales, patents may be challenged in court or in the UK Intellectual Property Office (UK-IPO). The majority of patent revocation actions commence in the High Court, which has a division for patent disputes staffed by specialist judges. A minority of patent disputes, mostly relating to mechanical or other simpler kinds of technologies, commence in the IP Enterprise Court, which is a specialist forum for IP disputes, staffed by specialists but designed for lower-value and more straightforward disputes involving, for example, small and medium-sized enterprises or simpler technologies. Very few patent revocation actions are commenced in the UK-IPO because there is no clear cost saving in using that forum.

These three forums are exclusive of each other,[37] meaning that a challenger must choose which to proceed in. Patents may also be challenged in the courts of Scotland or, in principle, of Northern Ireland, each of which are separate legal jurisdictions within the United Kingdom alongside the jurisdiction of England and Wales.

During the opposition period – nine months following grant – European patents may also be challenged by opposition in the European Patent Office (EPO). This forum, where available, operates in parallel to the three above, meaning that a patent challenger may potentially have two chances of revoking the patent. If successful in the EPO, the revocation will have European-wide effect, whereas if successful in the English courts the decision will, formally, only have effect in the UK, although the reasons for the decision may be persuasive in other European countries in some cases. Where an opposition is ongoing, a person threatened with or sued for infringement may file an opposition within the existing opposition proceedings.

Revocation actions are neither dependent upon nor are they formally linked to MAs for medicinal products. There is no specific procedural link between the forums discussed above and the process for obtaining marketing approval; however, English courts operate under a doctrine known as 'clearing the path' in the medicinal products sector.

The effect of this is that a person wishing to launch a product (whether this is a generic pharmaceutical or a biosimilar) must revoke the relevant patent or patents or seek other relief from the courts, such as a declaration of non-infringement (DNI) prior to launching their product; otherwise, they will, in most cases, be subject to an interim injunction restraining the launch. An interim injunction does not follow as of right to a patentee and will be assessed according to principles, taking account of, in particular, whether the damage caused to either party by the grant or refusal of the injunction may be adequately compensated in damages later.

The clearing the path doctrine applies up to at least the first appellate level: product launches for products protected by patents must be planned a significant time in advance because the usual time to trial is approximately one to one-and-a-half years, and a similar

37 There is a mechanism of transfer between the High Court and the IP Enterprise Court, but a claim cannot be maintained in more than one of those forums in respect of the same patent or patents.

time frame applies until appeal. Expedited trials or appeals, or both, may be ordered in certain cases to speed up this process. The fastest resolution of which we are aware was six months from commencement of proceedings to determination of appeal, but this case involved a declaration of infringement only.[38]

In addition to revocation and a DNI, the High Court has jurisdiction to grant declarations that serve a useful commercial purpose. One now-recognised form is the *Arrow* declaration, which is intended to provide commercial certainty in the face of pending patents.

Such a declaration, if available, will be to the effect that a certain product or process was known or obvious at a particular date (e.g., the priority date of known pending patents). The product or process that is the subject of the declaration will be that of the third party seeking to launch, thereby giving an indirect defence to that third party against future infringement on the basis that any patent that it would putatively infringe would be invalid.

Patents may be revoked in the UK courts, the UK-IPO and the EPO on essentially the same grounds, although the differing procedures in the courts, the UK-IPO and the EPO make some bases better suited to one forum than another. The main grounds are:

*a* the patent is not novel;
*b* the patent does not involve an inventive step (i.e., it is obvious);
*c* the patent is not capable of industrial application;
*d* the patent is not disclosed sufficiently;
*e* the patent has been amended in an impermissible way (e.g., to extend its subject matter or to add matter not comprised in the application as filed); and
*f* the patent claims excluded subject matter.

The category in point (f) includes inventions of which the exploitation would be contrary to public policy or morality and inventions falling within certain defined categories. These categories include methods of treatment or diagnoses; however, use-limited therapeutic claims have been permitted to give novelty for second medical uses of known medicinal products.

In particular, 'Swiss-form' claims (use of X in the manufacture of a medicament for the treatment of Y) were permitted until legislative changes at the end of 2007 abolished such claims, with prospective effect only, and introduced instead 'EPC 2000' (X for use in the treatment of Y). The abolition of Swiss-form claims and the introduction of EPC-2000 claims mean therapeutic use claims were previously in the form of a process and now in the form of a product. This may have knock-on effects on infringement that are yet to be explored.

## V COMPETITION ENFORCERS

### i Brexit

The UK left the EU on 31 January 2020, and the transition period ended on 31 December 2020; however, the fundamental principles of the EU, namely the prohibitions on anticompetitive agreements and abusing a dominant position, based on Articles 101 and 102 of the TFEU, continue to operate much as before in the UK, as they formed the basis for the corresponding prohibitions in UK competition law.[39]

38 *Napp v. Dr Reddy's Laboratories* [2016] EWCA Civ 1053. The court permitted one issue of validity to be raised by way of a 'squeeze' on interpretation of the claims for the purpose of infringement.

39 Competition Act 1998, Chapter I and Chapter II.

The UK has now replaced the EU's Vertical Block Exemption Regulation (VBER) with the Vertical Agreements Block Exemption Order (VABEO).[40] The VABEO retains a similar structure to the previous VBER but modernises the approach.

There are some helpful changes in the VABEO that are important to note, although they give rise to minor divergences from the EU approach. There are revised approaches to territorial and customer restrictions, giving more flexibility in relation to appointing distributors and exclusivity. Previously where dual pricing (charging a distributor different prices for products to be sold online and offline) was prohibited, it is now exempted; however, the CMA notes that any dual pricing should reflect proportionally the costs and investment incurred in selling the product.

A key change is that preventing the use of the internet for sales is now considered a hardcore restriction. The VABEO and accompanying guidance also provide more detail on active versus passive sales and provide a list of excluded restrictions. Further, the use of wide retail parity clauses will now be considered a hardcore restriction.

The VABEO came into force on 1 June 2022. There will be a one-year implementation period to give businesses time to make any relevant changes to their agreements. It is also noteworthy that a leniency application made to the EC before or after the end of the transition period will not protect a firm from being subject to fines in the UK.

### ii The CMA

The CMA is the main UK national competition authority and is the investigation and enforcement authority. The CMA's antitrust law powers are set out in the Competition Act, and its merger control powers are set out in the Enterprise Act 2002.

The CMA has been very active in enforcing the Competition Act in the pharmaceuticals sector. It is actively engaged in several excessive pricing (abuse of dominance) cases.

## VI MERGER CONTROL

There is no requirement to pre-notify or obtain prior clearance for mergers under UK law, the pre-notification regime being voluntary; however, the CMA has the power to intervene and investigate mergers, including those that have not been notified or that have been completed, or both, and it frequently does so. Where the CMA reaches an adverse competition assessment following a second-phase investigation, it can prohibit an anticipated merger or impose remedial measures for a completed merger, including divestment requirements.

The acquisition of material influence, not just the acquisition of control, is subject to the UK merger control regime. For most sectors, including pharmaceuticals, the thresholds for a transaction qualifying for investigation are the target having a UK turnover of over £70 million or the parties having an overlapping share of supply of 25 per cent or more in the UK (or a substantial part of the UK). The 'share of supply' test is interpreted very flexibly: the CAT recently upheld a CMA decision finding that it had jurisdiction even where one of the parties supplied services only indirectly to UK customers.

In 2018, the UK amended the Enterprise Act to lower the applicable threshold for intervention in mergers or acquisitions in three specified sectors: dual-use goods, quantum technology and computing hardware. In 2020, these thresholds were again lowered, resulting

40 Competition Act 1998 (Vertical Agreements Block Exemption) Order 2022 SI No. 516

in the CMA having jurisdiction to investigate a transaction where the target business has a UK turnover of above £1 million or has a share of supply of 25 per cent or more of relevant goods or services in the UK (or a substantial part of it), even if the transaction does not lead to an increase in the merging parties' share of supply. Three additional categories were added: artificial intelligence, advanced materials and cryptographic authentication.

The National Security and Investment Act 2021 (NSIA) adds another layer of complication for merging entities. The NSIA came into force on 4 January 2022, after receiving royal assent in April 2021.

This regime is focused on reviewing transactions on the grounds of national security, giving the government wide powers to intervene where it has concerns. It goes further than just M&A transactions and covers certain minority investments, acquisitions of voting rights and acquisitions of assets, including IP.

The regime requires mandatory filings of more substantial investments in businesses involved in 17 'sensitive sectors', including synthetic biology (i.e., applying engineering principles to biology to produce components or systems that do not exist in the natural world). The 17 sensitive sectors also include other activities that may be less directly relevant to pharmaceuticals, including artificial intelligence, computing hardware, data infrastructure and certain supplies to the government. Failure to comply with the requirements of the NSIA may lead to a transaction being void, heavy fines or criminal liability.

The CMA's investigation and enforcement powers apply to foreign-to-foreign mergers where the parties (and especially the target) supply the UK market and the relevant criteria for investigation are met. The definition of 'supply' is broad. For example, in the pharmaceuticals sector, in 2019 the CMA investigated, on its own initiative, the acquisition by Roche Holdings, Inc, a subsidiary of the Swiss-based Roche group, of Spark Therapeutics, Inc, a US biotechnology company active in developing gene therapy treatments. Roche was supplying the relevant UK market, but Spark's relevant products were still in clinical development. The ultimate test in UK merger control is whether the merger is likely to result in a substantial lessening of competition in the UK. The CMA concluded that there would not be in this case.

Following Brexit, mergers in the UK may now be subject to parallel investigations by the CMA and the EC, as the 'one stop shop' principle no longer applies.

## VII ANTICOMPETITIVE BEHAVIOUR

### i Competition Act, Chapter I – Restrictive Agreements

***Reverse payment agreements (pay-for-delay)***

Under specific circumstances, it is clear that a settlement agreement between a holder of a pharmaceutical patent and a manufacturer of generic medicines can be contrary to UK competition law.

In 2016, the CMA adopted its first decision on reverse payment agreements. GlaxoSmithKline (GSK) and various generic medicines manufacturers concluded patent settlement agreements whereby the generics suppliers agreed to refrain from entering the market with their own generic medicines, in return for payments and supply by GSK of specified volumes of generic paroxetine tablets for resale on the UK market. The CMA found that the agreements infringed the prohibition of restrictive agreements under Article 101 of the TFEU and its UK equivalent (Chapter I of the Competition Act) and constituted an abuse of GSK's dominant position in the relevant market on the basis of Chapter II of the Competition Act.

The CMA's 2016 *GSK* decision[41] was appealed to the CAT, which made a reference for a preliminary ruling to the EU Court of Justice (CJEU).[42]

The CJEU formulated general principles to be applied to reverse payment agreements, on fundamental issues relating to the application of potential competition, objects, effects, the definition of the relevant market and abuse. The court held that reverse payment settlement agreements may be considered as 'by object' infringements of competition law, thus breaching antitrust rules by their very nature, without needing proof of the effects that the conduct had on the market.

Following the CJEU's judgment, the CAT applied the ruling to the facts of the four referred cases in its decision of 10 May 2021.[43] It reduced the imposed fine from £37.6 million to £22 million and also reduced several other related fines. The CMA had advocated for a smaller reduction of closer to 10 per cent; however, the CAT held that on grounds of proportionality, a reduction of closer to 40 per cent was more appropriate.

### ii Recent and ongoing CMA Chapter I investigations

#### *Nortriptyline*

In a decision on 4 March 2020, the CMA found that four drug makers, including Lexon, were involved in the exchange of commercially sensitive information – including about prices, volumes and entry plans – to try to keep the price of nortriptyline high. The companies were collectively fined £3.4 million, with Lexon appealing to the CAT.

On 1 June 2020, the CMA announced that it had secured a legally binding disqualification undertaking from Amit Patel, a former director of Auden Mckenzie (Pharma Division) Limited and Auden Mckenzie Holdings Limited. Patel gave an undertaking not to act as a director of any UK company for five years from 13 July 2020.

On 21 August 2020, the CMA secured a legally binding disqualification undertaking from Robin Davies, director of Alissa Healthcare Research Limited. Davies gave an undertaking not to act as a director of any UK company for two years as of 24 November 2020; however, on 10 November 2020, Davies applied to the High Court for permission to act as director and take part in the management of certain companies, and on 17 December 2020 he was granted that permission, subject to strict conditions. The court was influenced by Alissa's status as a pharmaceutical supply company during the pandemic, the fact that Davies was the only executive director and the lack of a suitable replacement for him.

On 27 August 2020, the CMA issued proceedings in the High Court of Justice, Business and Property Courts, seeking the disqualification of Pritesh Sonpal, a director of Lexon (UK) Limited; however, given the pending appeal against the CMA's decision before the CAT, the assigned judge made an order transferring the disqualification proceedings to

41 Case 1252/1/12/16, *GlaxoSmithKline PLC v. Competition and Markets Authority*.

42 Case C-307/18, *Generics (UK) Ltd and Others v. Competition and Markets Authority*, 30 January 2020, ECLI:EU:C:2020:52.

43 Case 1251/1/12/16, *Generics UK Limited v. Competition and Markets Authority*; Case 1252/1/12/16, *GlaxoSmithKline PLC v. Competition and Markets Authority*; Case 1253/1/12/16, *(1) Xellia Pharmaceuticals APS (2) Alpharma LLC v. Competition and Markets Authority*; Case 1255/1/12/16, *Merck KGaA v. Competition and Markets Authority*; Case 1251-1255/1/12/16, *Generics UK Limited v. Competition and Markets Authority* [2021] CAT 9.

the CAT so that both could be heard together. On 25 February 2021, the CAT upheld the CMA's findings and dismissed the appeal, while also unanimously determining that the first condition of the disqualification proceedings was fulfilled.[44]

***Prochlorperazine and nitrofurantoin***

On 7 April 2020, the CMA announced a pause in two investigations concerning alleged anticompetitive agreements in the supply of prochlorperazine and nitrofurantoin, respectively, to reallocate resources to enable the CMA to focus on urgent work during the covid-19 pandemic. Each of those investigations was the subject of statements of objections issued in 2019.

Both cases resumed in July 2020. On 25 April 2021, the CMA announced it needed further time to consider the responses to the statement of objections sent in the nitrofurantoin investigation. In the prochlorperazine investigation, the CMA announced on 22 January 2021 that it had taken the administrative decision to focus on the overarching agreement rather than individual breaches.

The CMA published its infringement decision on 3 February 2022 and fined the parties £35 million for the pay-for-delay agreement. From 2013 to 2017, the prices paid by the NHS for prochlorperazine rose from £6.49 per pack of 50 tablets to £51.68, which amounts to an increase of 700 per cent. The parties have appealed the fine at the CAT, and a final judgment is awaited.

### iii Competition Act ,Chapter II – Abuse of Dominance

***UK Court of Appeal clarifies the legal test to be applied in excessive pricing cases***

*Phenytoin sodium – Pfizer/Flynn*

In December 2016, the CMA imposed a record fine of £84.2 million on Pfizer Limited and £5.2 million on Flynn Pharma Limited for charging excessive prices and abuse of dominance in the market for the manufacture and distribution of phenytoin sodium capsules.

The CAT quashed the CMA's decision (June 2018), finding that the CMA had misapplied the legal test for excessive pricing, not properly applied the evidence adduced by the companies by not taking sufficient account of the prices of comparable products (phenytoin sodium tablets in particular) and not properly considered the economic value of phenytoin sodium capsules. The CMA appealed the CAT judgment to the Court of Appeal (supported by the EC), and on 20 March 2020, the Court of Appeal broadly upheld the CAT's ruling.

Pfizer supplied phenytoin sodium, a prescription anti-epilepsy drug, in capsule form under the brand name Epanutin in the UK. In 2012, it transferred to Flynn the marketing authorisation for the capsule form that it continued to manufacture for Flynn, which in turn supplied it to the NHS. Flynn de-branded Epanutin and supplied it as a generic.

As a consequence of this de-branding, the capsule form was no longer subject to price regulation. Pfizer increased its manufacturing price to Flynn for capsules by between 783 per cent and 1,615 per cent. Flynn raised its price to the NHS by between 2,387 per cent and 2,656 per cent.

44 Case 1344/1/12/20 *Lexon (UK) Limited v. Competition and Markets Authority* [2021] CAT 5.

The Court of Appeal considered the application of the legal test for excessive pricing established by the CJEU in its seminal *United Brands* judgment.[45] In that case, the court stated that the excessive nature of a price could be determined, among other things, through the application of a two-limb test:

*a* the price must be excessive when the difference between the cost of production and the selling price of the product is excessive (the excessive limb); and

*b* the price must be unfair either in itself or when compared to competing products (the unfair limb).

However, the Court of Appeal said that this two-limbed test is not the only method for assessing excessive pricing and that the CMA has a margin of manoeuvre or appreciation in deciding which methodology to use and which evidence to rely upon.

On 8 June 2020, the CMA announced the timetable for its investigation in the *Pfizer/Flynn* excessive pricing case, following remittal of issues by the CAT and by the Court of Appeal judgment. The initial re-investigation was carried out between June and October 2020, and in March 2021 the CMA took the decision to continue with the investigation. In August 2021, the CMA issued a statement of objections. The investigation is ongoing.

*Liothyronine*

The CMA investigation relates to suspected unfair and excessive pricing by Advanz Pharma (formerly Concordia International RX (UK) Limited) in the supply of liothyronine tablets, including to the NHS).

The CMA's case, contained in two statements of objections, alleged that Advanz Pharma/Concordia abused its dominant position, in breach of the Chapter II prohibition of the Competition Act and Article 102 of the TFEU, by charging excessive and unfair prices to the NHS.

The CMA issued a third statement of objections in July 2020, which addressed issues arising from the Court of Appeal's judgment of 10 May 2020 in the *phenytoin* investigation, discussed above, and stated that the CMA maintained its provisional finding of a breach of competition law. The CMA published an infringement decision on 29 July 2021. Advanz Pharma appealed against the decision, and the judgment is awaited.

Liothyronine tablets are primarily used to treat hypothyroidism. Until 2017, Concordia was the only supplier. The CMA found that the amount that the price that the NHS paid per pack of this drug rose from around £4.46 before it was de-branded in 2007 to £258.19 by July 2017, an increase of almost 6,000 per cent, while production costs remained broadly stable.

*Hydrocortisone*

On 12 February 2020, the CMA joined together three separate investigations into alleged excessive and unfair pricing, anticompetitive agreements and abusive conduct in relation to the supply of hydrocortisone tablets in the UK. It issued statements of objections between December 2016 and February 2019, and on 15 July 2021 it published its infringement decision.[46]

45 Case EU:C:1978:22 *United Brands Company and United Brands Continentaal BV v. Commission*, paragraphs 251 and 252.

46 August 2017 (Case 50277-1), March 2017 (Case 50277-2) and February 2019 (Case 50277-3).

The CMA found unfair pricing abuses and anticompetitive agreements in relation to the hydrocortisone tablets and imposed total fines of £260 million.[47] It found that the price increased by over 10,000 per cent compared to the original branded version of the drug.

In real terms, this meant that the amount paid by the NHS for a single pack of 10mg tablets rose from 70p in April 2008 to £88 by March 2016. For the 20mg strength, prices rose from £1.07 to £102.74 per pack over the same period. This meant that for the investigation period, the NHS had gone from spending approximately £500,000 per year on hydrocortisone tablets in 2008 to over £80 million by 2016. This explains the level of fines imposed on the companies. The companies appealed against the decision, and a final judgment is awaited.

*Lithium-based medication for the treatment of bipolar disease*

On 5 October 2020, the CMA opened an investigation into Essential Pharma's intention to discontinue the supply of Priadel, a lithium-based medication for the treatment of bipolar disorder. The DHSC requested the CMA to impose interim measures on Essential Pharma, preventing it from following through with the discontinuation until the investigation was concluded; however, Essential Pharma agreed to continue supplying the drug to facilitate continued discussions on pricing.

On 24 November 2020, the CMA announced its intention to accept commitments from Essential Pharma and sought input from stakeholders on the suitability of the proposed commitments. On 18 December, following minor modifications, the CMA officially accepted the commitments and closed the investigation.

### iv Market definition in abuse cases

In its *GSK* preliminary ruling, the CJEU provided guidance on the key issue of market definition in the context of abuses of dominance, which will have wider implications for the pharmaceutical industry than patent settlement agreements alone. The guidance from the CJEU is that if the generic medicines are as a matter of fact (to be determined by the national court) in a position to enter the market within a short period with sufficient strength to compete with the originator, they are to be considered as being within the relevant market.

This reasoning has already been applied in the *Lundbeck* judgment, where the CJEU confirmed that the General Court was correct in upholding the EC's finding that at the time the agreements were concluded, Lundbeck and the manufacturers of generic medicines were potential competitors.[48]

The court also stated that it is for the national court to determine whether the strategy to conclude settlement agreements with the object or effect of delaying generic entry has the capacity to restrict competition and, in particular, whether it has exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy.

47 CMA decision, Case 50277, *Hydrocortisone tablets: alleged excessive and unfair pricing, anti-competitive agreements and abusive conduct*, 15 July 2021.

48 Case C-588/16, *P Sun Pharmaceutical Industries and Ranbaxy (UK) v. Commission*; Case C-586/16; *P Generics (UK) v. Commission*; Case C-591/16 P, *Lundbeck v. Commission*; Case C-601/16, *P Arrow Group and Arrow Generics v. Commission*; Case C-611/16, *P Xellia Pharmaceuticals and Alpharma v. Commission*; Case C-614/16, *P Merck v. Commission*; and Case C-307/18 *Generics (UK) and Others*.

On 6 November 2020,[49] the UK Supreme Court confirmed the scope of the *res judicata* principle in EU law, holding that findings of fact made in an EU General Court judgment in the course of a judgment annulling a finding of breach of Article 102 of the TFEU were not binding on a UK court assessing the damages payable for a breach of Article 101 of the TFEU.

This resulted from a damages action brought before the English High Court, in which the respective health authorities of England, Wales, Scotland and Northern Ireland sought to recover compensation for Servier's anticompetitive behaviour.[50] Servier argued that the health authorities had failed to mitigate their loss or had negligently contributed to their loss in that they failed to encourage prescribers to prescribe alternative substitutable blood pressure drugs instead of perindopril.

In that context, Servier sought to rely on findings made by the General Court about the degree of substitutability of other drugs for perindopril. It contended that those findings were binding as a matter of EU law and that it was an abuse of process for the health authorities to dispute them. The High Court rejected both arguments but granted permission to appeal on the EU law point. The Court of Appeal also rejected the EU law argument, but Servier obtained permission from the UK Supreme Court to argue that a reference should be made to the CJEU.

The Supreme Court held that no reference could be made while the General Court judgment remained subject to appeal. On the substance, it held that the General Court's findings were not binding in the context in which Servier sought to rely on them (i.e., seeking to borrow findings of fact from an annulment judgment made in the context of abuse of dominance under Article 102 of the TFEU and to deploy them in the entirely different context of mitigation of loss, which had nothing to do with Article 102 or with the consequences of the annulment judgment).

## VIII OUTLOOK AND CONCLUSIONS

We have referred numerous times to the issues raised by the implementation of Brexit; the relationship not only with the EU but with other major economies, including the United States and Japan, will considerably affect how the sector looks in the near future. There remains optimism in the sector, and the continued investments made in research and development facilities by both UK-based companies and others demonstrate this optimism.

The UK is seen favourably as a place for entrepreneurs in this sector, and while they, as well as the government as promised, and big pharma, continue to invest, talent will be attracted and intellectual property created. The competition regime is unlikely to change in any significant way (with the exception of the new UK subsidy regime), but it will be interesting to see whether the independence of the MHRA will result in a deviation from established EMA standards, or whether the UK will become a 'white label' territory.

49 Judgment of 6 November 2020, *Secretary of State for Health and others v. Servier Laboratories Ltd and others* [2020] UKSC 44.

50 In 2014, Servier, a French pharmaceutical company, was found by the EC to have infringed competition law in relation to the supply of Perindopril, a blood pressure drug. The EC found that Servier had breached Article 101 of the TFEU by entering into 'pay for delay' agreements, under which generic companies agreed not to enter the market for supplying Perindopril. It also found that Servier had breached Article 102 of the TFEU by both entering into those agreements and acquiring certain technology for the production of Perindopril. On appeal, the General Court upheld the EC decision in relation to Article 101, but annulled it in respect of Article 102 on the basis that the EC had erred in defining the relevant market and, therefore, in its assessment that Servier was in a dominant position. Both parties have appealed.

**Appendix 1**

# ABOUT THE AUTHORS

## SALLY SHORTHOSE

*Bird & Bird LLP*

Sally Shorthose is one of Bird & Bird's most experienced intellectual property (IP) partners, specialising in transactional IP matters. She offers a wealth of knowledge to businesses at the cutting edge of research, development and technology, in a variety of sectors for which IP is of prime importance.

Providing the full array of commercial advice and support in IP, she leads the team, delivering licensing, partnering and exploitation agreements, and research, development and marketing collaborations. She also advises clients on regulatory and 'freedom to operate' issues, and how to manage significant due diligence matters.

Before joining Bird & Bird in 2006, she was head of IP and life sciences at another global law firm, after spending 11 years in house first as senior legal adviser at ICI/Zeneca and later as legal director of Novartis UK.

She has been given a number of accolades, including recognition as a global leader in *Chambers* and *The Legal 500*, and has been named as 'a leading woman in IP' (*WIPR*) and rated as 'highly recommended' in *Who's Who's Legal: Life Sciences*. Most recently, she was named by *WIP* as 'one of the most influential IP lawyers in the world'. She is the editor of the Kluwer law publication *The EU Guide to EU Pharmaceutical Regulatory Law*.

## PETER WILLIS

*Bird & Bird LLP*

Peter Willis is a partner in the competition and EU law practice group based in London. His practice covers all areas of competition law (both EU and UK) and includes advising on investigations by competition authorities and regulators, cartel leniency applications, sector inquiries, complaints and merger filings. He brings an in-depth understanding of the interaction between competition rules and the complex technical, commercial and regulatory arrangements governing the operation of a range of technology- and knowledge-based industry sectors, particularly the technology, pharma, energy and communications sectors.

Peter's work also involves advising on disputes between businesses in which competition and regulatory issues arise, including competition follow-on damages claims. As well as authoring books and articles on EU and UK competition law, Peter is a regular contributor on competition and regulatory issues in the media and at conferences around Europe.

**CHRIS DE MAUNY**

*Bird & Bird LLP*

Chris de Mauny advises on all forms of intellectual property litigation, principally patents. In 2018, 2019 and 2020 he was identified as a 'rising star' for patent litigation by *Managing Intellectual Property*. In 2019, he was referred to as a 'key lawyer' within Bird & Bird's London patent litigation team by *The Legal 500* and in 2020 identified as a 'rising star' by *Expert Guides*. In 2021 he was one of four lawyers recognised across Europe (and the only one in the UK) by 'The Rising Star Awards 2020 – Europe' in the patents practice area.

Chris has represented a range of clients, from multinational corporations to individual traders, in disputes involving patents, trademarks and passing off, design rights, copyright, and rights in confidential or private information. His recent work has focused on patent litigation in life sciences, electronics and in sustainable technologies. Major clients have included Teva, Baxter Healthcare, Dr Reddy's Laboratories, Sarepta, BT, BAE Systems Honeywell and Johnson Matthey.

Chris was called to the Bar in 2006 and practised in specialist intellectual property chambers until early 2011 when he joined Bird & Bird. He was promoted to the partnership of Bird & Bird in 2021.

**PIETER ERASMUS**

*Bird & Bird LLP*

Pieter Erasmus is a senior associate in the intellectual property group in London. He has a keen interest in all things life sciences and healthcare, and specialises primarily in providing regulatory advice in relation to a broad range of regulatory and commercial matters in those fields, including pharmaceuticals, medical devices, general healthcare, clinical trials, and marketing and advertising of health products. His experience also includes providing regulatory advice in the context of other topics, including general product compliance, advertising and consumer protection law (regarding health products and other products), cosmetics, foodstuffs and automotive regulation.

Pieter's experience further includes general corporate and commercial work, including the drafting of a wide range of general and bespoke commercial agreements. He has also conducted a number of commercial due diligence investigations and transactional work, including in the pharmaceutical, medical devices, insurance and foodstuffs industries. Pieter is on the non-practising roll of admitted attorneys of the High Court of South Africa.

**BIRD & BIRD LLP**

12 New Fetter Lane
London EC4A 1JP
United Kingdom
Tel: +44 20 7415 6000
Fax: +44 20 7415 6111
sally.shorthose@twobirds.com
peter.willis@twobirds.com
christopher.demauny@twobirds.com
pieter.erasmus@twobirds.com
www.twobirds.com

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