Brexit – a practical guide

by Susanna Heurung, Dr Stefanie Parchmann, Elke Wurster and Matthias Görich

Meanwhile, Britain has left the EU. There is still a transitional period until 31 December 2020, during which the United Kingdom will be treated as a Member State. After this transition period, the Brexit will have some profound effects. In the following, we will inform you what you need to know and what you can do.

What you need to know:

Patents

European Patents (EP): Brexit has no direct effect on proceedings before the European Patent Office (EPO), as the UK remains a party to the EPC. EP patents granted remain in force and applications are also not affected. Representatives based in Britain remain entitled to represent their clients. However, in terms of representation before UKIPO in the context of validation in the UK there could be changes in the future.

UK patents:
Brexit also has no impact on national patents filed directly with UKIPO.

Exhaustion of patents:
In the United Kingdom, a patent is currently considered exhausted when a protected product is placed on the market in the EU or the EEA with the permission of the patent proprietor. This scheme will be maintained at least during the transitional period.

Conversely, as of 1 January 2021, it will no longer be possible to assume that a placing on the market in the UK will lead to exhaustion of patent protection in the EU Member States. This could, for example, have an impact on parallel imports of medicines from the UK into the EU.

Supplementary Protection Certificates (SPC)

The UK is expected to retain EU legislation on SPCs which has long been transposed into national law. This also applies to paediatric term extensions. However, it is to be expected that the British case law will increasingly and sustainably move away from the case law of the countries remaining in the EU and develop its own standards of assessment and principles in terms of protection issues as well as the conditions for grant.

Existing EMEA approvals will be converted into UK approvals.

Trademarks and designs

As a result of the Brexit, EU trademarks and designs will no longer have any effect in the UK as of 1 January 2021. The British Government has therefore provided a mechanism for „cloning" registered EU trademarks and designs. This means that, as of 1 January 2021, holders of such EU rights will automatically have a British trademark or design identical to the counterparts under EU law.

These 'cloned' intellectual property rights confer the same protection in the UK as the existing intellectual property rights in the EU, in particular, the original filing date relevant for protection is retained.

Data protection law

The protection of personal data within the European Union is governed by the General Data Protection Regulation (GDPR), which regulates the permissibility of the processing of personal data and the transfer of data to third countries. Until the end of the

transitional period, the United Kingdom will still be treated as a member, so that there will be no changes to the permissibility of the transfer to Great Britain compared to the current situation. However, as of 1 January 2021, Great Britain will be a third country within the meaning of the GDPR. This means that the transfer of personal data to Great Britain is only permitted under strict conditions: either the European Commission must take a decision on the adequacy of the level of data protection in Great Britain or appropriate safeguards must be provided, such as standard safeguard clauses issued by the Commission.

Antitrust law

In addition to merger control issues, antitrust law is particularly relevant relating to the permissibility of business cooperation, both among competitors and in vertical relationships. The conditions under which such co-operations are permitted are regulated by the relevant EU Block Exemption Regulations, in which inadmissible clauses but also those not covered by the prohibition of cartels and thus permissible clauses are specified (e.g. for genuine commercial agent relationships). As matters stand, the Block Exemption Regulations are expected to be transferred into British law, so that a business cooperation will probably be allowed under the same conditions.

Compliance

The UK Bribery Act prohibits and sanctions active or passive bribery in Great Britain and (worldwide) the bribery of foreign officials and requires sufficient bribery prevention – otherwise serious criminal consequences for both the company and natural persons are to be expected. This UK anti-corruption law is aimed not only at companies based in Great Britain, but also at companies with business ties to Great Britain. The Bribery Act and its relevance to non-British companies is independent of Britain's membership in the EU; it must therefore be fully taken into account by individuals and companies in any business relationship with Britain after Brexit.

Representation before UKIPO

As matters stand, lawyers without a seat in Great Britain will remain eligible to represent their clients at the UK Intellectual Property Office not only during the transition period but also afterwards. This also applies to national proceedings, i.e. national UK patents.

Medicines

No changes are expected before the end of the transitional period, as EU law is still in force or has been adopted as a basis.

However, after the end of the transitional regime, it is to be expected that for both territories (EU and UK) certain functions will have to be mapped independently, which until now was harmonised throughout the EU. This applies, for example, to the approval holder, QP, QPPV, release manufacturer and similar persons. Since it is to be expected that the transitional arrangements will not be extended and will not be incorporated into a similar regulatory structure, these issues must be implemented by then and included in the respective authorisations.

Since the marketability of the relevant products depends on this, it is important to take into account the corresponding recommendations for action below.

Medical devices

In this respect, changes are likely to occur only after the transitional period, as EU law has been adopted as a basis for the time being. It must be assumed that for both territories (EU and UK) certain functions must be mapped independently, which until now had to be presented harmonised throughout the EU. This concerns the notified body and the manufacturer.

What you should do:

Patents and SPCs

No action is currently required, except in individual cases concerning exhaustion or if the rules on representation before UKIPO should be amended as of 1 January 2021.

Trademarks and designs

EU trademarks and designs already registered on 31 December 2020 will be automatically cloned without application. It is therefore important to ensure that representatives are appointed for all new intellectual property rights so that the UK Office can contact them if necessary. It should also be ensured that these new intellectual property rights are renewed separately, as renewal of the EU intellectual property rights is not sufficient for renewal of the new "cloned" UK rights.

EU trade marks and designs filed at the cut-off date but not yet registered will not be cloned. However, holders of such rights can file a new application in Great Britain within nine months, requesting that the filing date on which the protection is based for the EU trade mark or design also apply to the new British property law.

Data protection

It should be checked whether personal data are transferred to Great Britain as part of your business activities. In this case, supplement your processing directory accordingly and provide appropriate safeguards unless the European Commission takes an adequacy decision (which is not to be expected, at least in the short term). You may need to review your privacy impact assessment.

Anti-trust law

Keep an eye on legal developments. If the proposed transposition of the Block Exemption Regulations into British national law is not carried out, any situations falling within the scope of these Block Exemption Regulations would have to be reassessed and, if necessary, redesigned.

Compliance

If your company has business relations with Great Britain, you should check whether your compliance system complies with the UK Bribery Act.

Contracts

Check important agreements to see if there are any consequences of the Brexit, for example because the EU has been agreed as the relevant contractual territory. Take this into account in ongoing contract negotiations.

Medicines

The changes mentioned above require time because of necessary variations, so that if changes are still necessary those should be initiated as soon as possible. Where necessary, the competent authority should be contacted to ensure timely implementation.

In the case of the releasing manufacturer it should be noted that goods released and imported are in-definitely marketable before the end of the transitional period in accordance with the authorisation. This does not apply if goods released before the end of the transitional period are to be imported from the UK to the EU only after the end of the transitional period. Such products are not marketable, as the previous releasing manufacturer or the holder of the authorisation (mentioned in the package leaflet) may no longer be permitted and must be replaced by a resident in the EU. This must also be implemented in the approval documents! In order to avoid unnecessary complications, in such cases the entire batch should be imported before the end of the transitional period, so that it is already on the market in the target territory at the end of the transitional period.

You should also check if additional activities are necessary in the context of the Sunset Clause.

Medical devices

The changes mentioned above at the Notified Body and the Manufacturer have a large lead-forward. Due to the Medical Device Regulation and Brexit, the pool of notified bodies responsible for the respective territory has shrunk significantly, so that there is a very timely need for action in this regard. The reporting obligations should also be reviewed.

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Susanna Heurung provides comprehensive advice and assistance to clients in matters relating to German, European and international trademark law, design law, competition law, copyright law and food law. Her work involves preparing and processing applications for registration as well as legal and out-of-court proceedings in opposition, cancellation and infringement proceedings, warning notices and temporary injunctions.

Susanna represents clients before the competent German and European bodies and courts and has also successfully appeared on behalf of clients before the European Court of Justice. In 2018 she became head of the firm's trademark department.

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Having worked for many years as laboratory supervisor and project coordinator in custom manufacturing with a large chemical-pharmaceutical company, Stefanie has first-hand knowledge of the needs of industry with regard to intellectual property protection.

Stefanie lectures on patent law at the Technical University of Munich. As of 01.01.2020 Stefanie Parchmann has been appointed as member of one of the Examination Committees for the European Qualifying Examination for professional representatives (European patent attorneys).

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Elke Wurster is a highly experienced lawyer primarily specializing in compliance, antitrust and insolvency law, although her expertise also includes contract and commercial law. She advises and supports companies on all aspects of compliance, including establishment of compliance management systems, employee training, internal investigation of compliance issues, and also offers regular compliance counselling. Her particular legal expertise is in antitrust and anti-corruption law.

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Matthias has been a pharmacist since 1985 and, in 1996 he became a Drug Information Specialist. Previously, he worked as a research assistant under Prof Dr Richard Neidlein at the Institute of Pharmaceutical Chemistry, in the renowned Ruprecht Karl University of Heidelberg. Matthias gained his first experience in the pharmaceutical industry as Regulatory Affairs Manager at STADA AG. Most recently, he worked for more than 25 years at Mundipharma in Limburg, where he occupied various positions, such as Senior Regulatory Affairs Manager and Head of their Admissions Department. Matthias has been advising Maiwald's clients since 2017.

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