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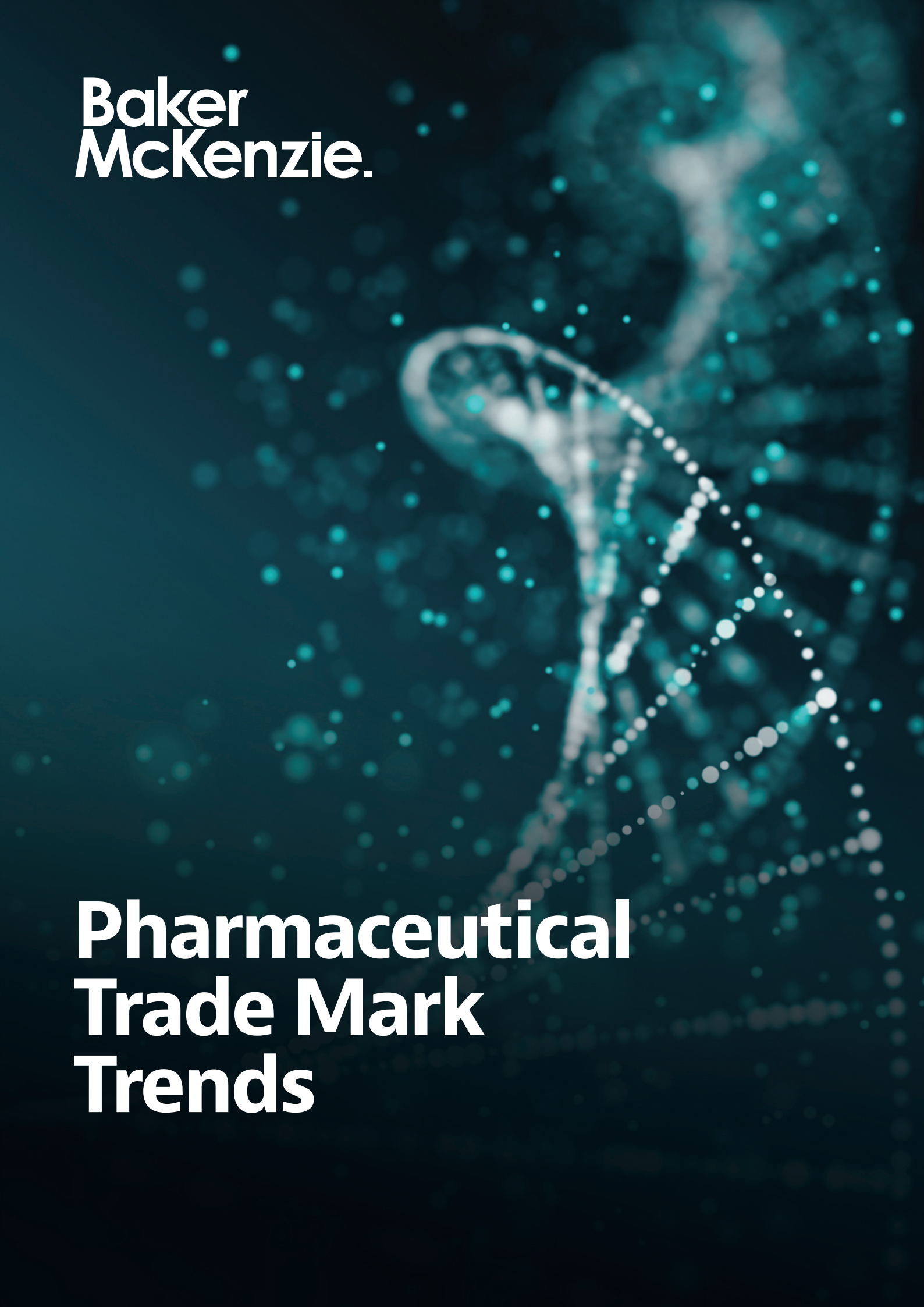
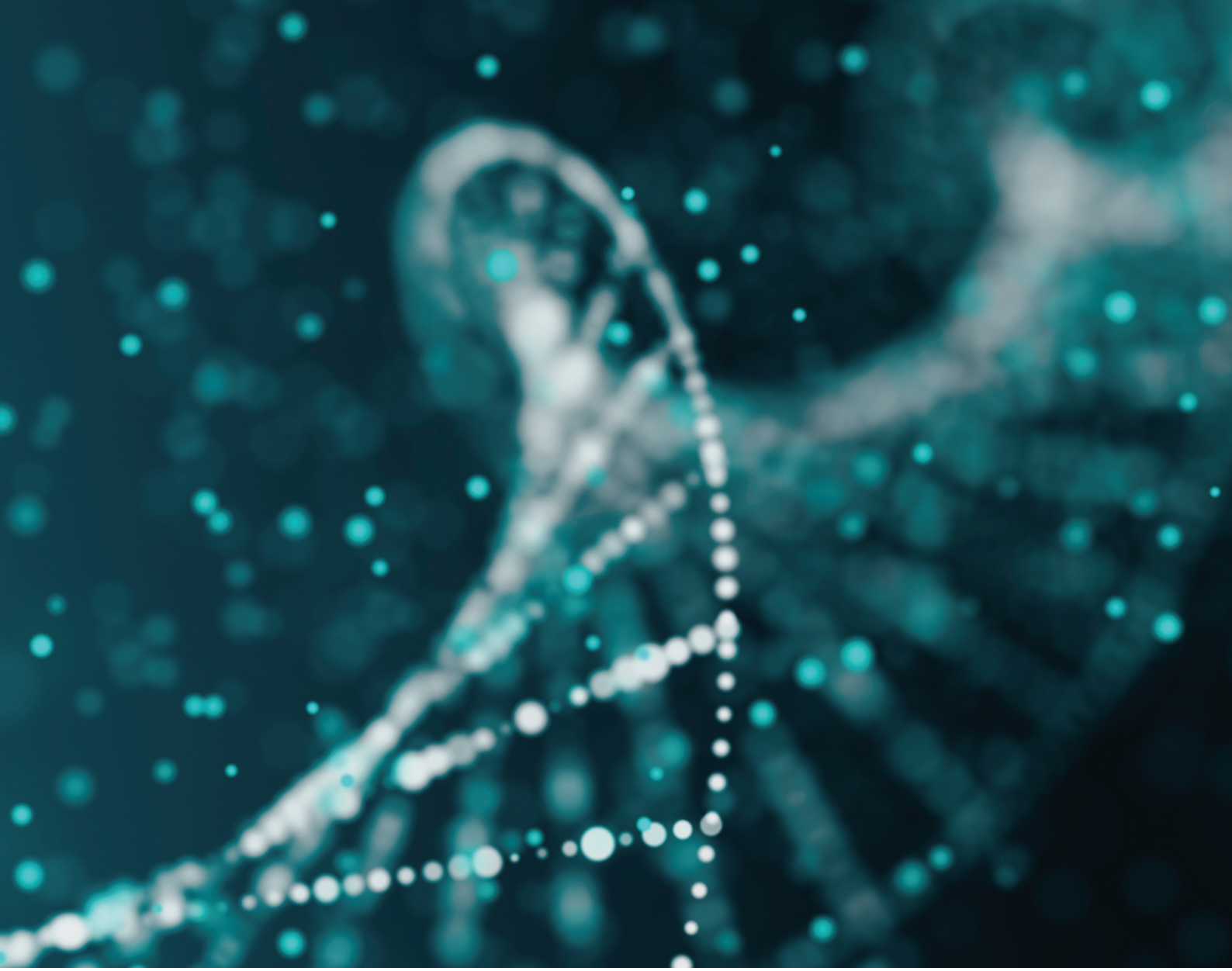


Pharmaceutical Trade Mark Trends



Contents

Healthcare in a metaverse: are you ready?

What is a metaverse?

A metaverse is a virtual world where animated avatars of our physical selves can interact with other people. It offers a combination of technologies including virtual reality, augmented reality and video where users are immersed within a digital universe.

The metaverse ecosystem is a work in progress, so there is no consensus definition. This ecosystem is developing through the continuing, convergent evolution of communications and computing technology, cultural trends in digital interaction and content creation and consumption, and digital commerce.

Hype versus reality

CLAIMS

Metaverse is Virtual Reality

Many iterations right now are experiences on mobile phones and computers. VR headset adoption is still relatively low and in its early stages. Consumer-grade VR will need a few more years. Rather, expect a blend of 'access points into' 3D rendered virtual environments.

Metaverse is Decentralized

Decentralization is not a pre-requisite. In fact, the big players in the space are very centralized organizations.

Metaverse is Web 3

The Web 3 trend is wholly independent of the metaverse trend. The movement to Web 3 however is a point of converging trends with the metaverse.

Metaverse is a Single place

Interoperability will be a big ticket problem to solve and will take a long time. Expect a 'walled garden' approach with many metaverses created by very different companies with different goals.

Why and how is the healthcare industry investing in the metaverse?

The pandemic acted as a catalyst for acceleration of the metaverse, as increased remote working, studying and the need for remote healthcare provision have increased consumer acceptance of online interactions and created demand for those interactions to be more 'life-like'. At the same time, rapidly developing technology and infrastructure is creating the opportunity to perform more activities virtually - for example, real-time remote surgery, which relies on sophisticated robotics and fast and reliable connectivity.

Opportunities for the healthcare industry to move into new virtual worlds include:

Diagnosis and consultation - the pandemic has fundamentally shifted the place of telemedicine within healthcare provision: 95% of healthcare facilities are now able to provide remote treatment to patients (compared to 43% pre-2020). Telemedicine consultations mean patients are no longer limited to being treated by particular clinicians due to their physical location, and VR opens up a wider range of consultations that were previously difficult or impossible to deliver remotely.

Treatment - from remotely assisted or performed surgery to use of virtual reality to deliver immersive hypnotherapy and reduce pain and discomfort, or exposure therapy for phobias. Virtual engagement can also be used to support treatment administration, symptom trackers and clinical trial adherence programs.

Prevention, wellness and fitness - metaverse technologies will allow new opportunities to engage, educate, incentivise and track wellness and fitness programs. Gamification – the use of game mechanics in non-game environments – offers new ways to connect healthcare providers and patients. Its use in healthcare scenarios is largely restricted to wellness and fitness apps at present, for instance AR is used to deliver smarter workouts with guidance from virtual instructors.

Consumer healthcare and marketing - including enhanced patient communities, creation of virtual storefronts and virtual marketing campaigns.

What are the key trade mark issues?

The exploration of this new realm may not necessarily be smooth sailing. New challenges may arise in relation to data protection and cybersecurity. Familiar considerations like compliance with regulatory regimes or IP protection may give rise to complexities that are otherwise not apparent at first glance.

Some of the key issues to consider from a trade mark perspective are:

- **Holistic trade mark protection:** are existing registrations sufficient to protect your brand in a metaverse? If new filings are required, in what class(es) and how should the specification be drafted? How will you support use for the new filings? Case law and registry practice is still developing and the approach will vary across jurisdictions, although the current consensus is that new filings are recommended for key markets and brands. Rights clearance may also require a new approach: as many brands shift into the virtual world, your clearance strategy may need to change to cover new classes.
- **IP enforcement:** the growing virtual world presents both new and familiar challenges. The risk of infringement taking place in a virtual environment creates variations on issues around jurisdiction, applicable law, identification of infringers, liability of platform providers, exhaustion of rights and effective enforcement strategies. Where companies in the healthcare industry create their own virtual environments, they will be faced with a host of unfamiliar challenges around user-generated content and intermediary liability, rights clearance and content moderation.
- **Commercial terms:** it is essential to establish licenses and terms of use which balance the companies interest to protect the brand and its goodwill but yet ensure users are not put off from participating.
- **Copyright issues:** ownership and enforcement of copyright in a metaverse raises many challenging questions. Is copyright infringed if someone tokenizes a digital work that they did not create? What damages would be payable by the creator or seller of a copyright-infringing NFT? Who owns the copyright if an avatar creates a work in the metaverse? As with trade mark issues, the answers to these questions are still developing.

The opportunity for healthcare companies to capitalise on the metaverse is advancing. Preparation, as ever, remains crucial.

Parallel imports: trends and developments

Parallel trade - taking genuine goods placed on the market in one jurisdiction and selling them in another - continues to generate disputes between IP owners and parallel importers. Below we highlight some recent developments and common trends.

- **When is repackaging necessary for market access?** In the EU, repackaging is permitted where rules or practices in the Member State of importation prevent the marketing of the product in question in the original packaging, but not where the repackaging is exclusively for a commercial advantage. The boundaries of this requirement continue to be tested in the courts. The latest cases referred to the CJEU (C-253/20 & C-254-20) relate to the repackaging of authorised generic product with the originator trade mark. In the Advocate General's opinion, it is for the person marketing a generic drug to convince consumers to use it as an alternative to the originator drug. Any attempt to achieve this by replacing the trade mark is a search for commercial advantage and not covered by exhaustion principles. Judgment by the CJEU is awaited as a further indication of the breadth of the necessity condition for repackaging. We also continue to see important verdicts on repackaging from the national courts. For example, the Polish Supreme Court recently ruled in favour of the trade mark holder in a repackaging dispute, holding that a parallel importer cannot freely adopt the trademark used in the country of importation unless it can present solid arguments supporting the necessity of rebranding, other than just the need to secure a better market position in the country of importation.
- **When can repackaging alter the quality of the product?** China adopts international exhaustion: once the trade mark owner has put goods bearing the trade mark onto the market anywhere in the world, its trade mark rights are generally exhausted. Exhaustion is, however, subject to the trade mark affixed to the product not being altered. In 2021, Shanghai Pudont New Area Court established that the doctrine of exhaustion is subject to a further restriction in relation to repackaging ((2021) Hu Min Zhong 596 - Klüber). The repackaging in question was not done under the trade mark owners' product quality control, and so there was possible impairment of the quality of the product. Since the

repackaged containers altered the quality and design features in the product, damage had been caused to the trade mark functions of maintaining quality and reputation. This indicates a relatively broad scope to argue that damage to goods/reputation has been caused in China, although this will depend on the facts of the relevant case.

- **Impact of the Falsified Medicines Directive (FMD).** The FMD requires certain medicines to include a unique identifier and tamper evident features on the pack. This creates new issues and unanswered questions for parallel importers and IP owners: does the FMD allow the parallel importer to unseal the package and then apply a new tamperevident feature? If so, does the replacement tamper evident feature need to be technically identical to the original? Can the parallel importer argue that full reboxing is necessary because removal and replacement of the tamper evident feature on the existing packaging would leave visible traces,and potentially generate resistance to the product? How should the uniqueidentifier be applied? Can national authorities require full repackaging of all parallel imported products which incorporate safety features under the FMD? We await rulings from the CJEU and national courts to determine how the established legal principles relating to packaging will be applied to products incorporating the new features required by the FMD.

- **UK position on exhaustion.** Following the UK's exit from the EU, the UK adopted "UK+", or EEA exhaustion: once goods are placed on the market in the UK or anywhere in the EEA, trade mark (and other IP) rights are exhausted. In 2021 the UK IPO consulted on what exhaustion regime should be implemented in the longer term, but in early 2022 announced it was not able to make a decision and would retain the current UK+ model. The IPO stated: "Unfortunately, there is not enough data available to understand the economic impact of any of the alternatives to the current UK+ regime. As a result, it has not been possible to make a decision based on the criteria originally intended. However, the government remains committed to exploring the opportunities which might come from a change to the regime. Further development of the policy framework needs to happen before reconsidering the evidence and making a decision on the future exhaustion of IP rights regime." There appears to be appetite to review the position again and agree a more permanent solution, so brand owners should keep a careful

eye on developments. A tighter position seems unlikely under the current government, but in an environment of political uncertainty the future is difficult to predict.

- **Parallel imports into Russia.** Earlier this year, the Russian Ministry of Industry and Trade partially legalized parallel imports, setting a list of products and product categories for which parallel imports into Russia are allowed. There are currently no pharmaceutical products on the list, although some medical devices are included. The general position of the state is that in the absence of a shortage of a drug, parallel imports will not be permitted. In addition, as in other jurisdictions, regulatory rules (for example relating to packaging) hinder the parallel import of medicines. However, the partial legalization of parallel imports has weakened the practical effectiveness of customs controls and increased the risk of illegal parallel imports. In light of the risk of harm to patients and the reputational risk to the brand holder, IP owners may wish to adjust their local customs measures.

Parallel trade and competition rules

Pharma companies need to be aware of competition rules when trying to control cross-border sales by a reseller. This is especially the case in Europe where, except in relation to certain carefully defined circumstances [Footnote], it is illegal for a supplier to prevent a reseller from selling outside of its allocated territory (to customers located in other territories in the EU/EEA). A restriction on resellers in the EU/EEA not to sell outside the EU/EEA will not normally violate EU competition law, but may violate the competition rules of the affected countries outside the EU/EEA (in particular Switzerland and the UK). An agreement to restrict the ability of resellers outside the EU/EEA from selling into the EU/EEA may in theory raise competition issues, but a trademark owner may be able to rely on its trademark rights to stop import into the EEA. Additional rules apply to companies with market power (typically a market share exceeding 40%). Other countries/regions (for example the Eurasian Economic Union, Egypt, Japan) may take a similarly strict approach to cross-border restrictions/bans on exports into their territories.

Ask us about

Developing the optimum brand protection and enforcement strategy for pharmaceutical products is complex and requires an expert understanding of the legal issues, regulatory environment and practical challenges.

Our team of trade mark practitioners would be happy to talk to you about any of the issues raised above, or some of the other current challenges facing pharmaceutical brands:

- **Trade mark filing strategy for healthtech products**
- **Indirect confusion and comparative advertising in the healthcare context**
- **US Trademark Modernization Act**
- **Liability of online marketplaces for TM infringement**

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